Annals of Health Law

Volume 29 Issue 1 *Winter 2020*

Article 6

2020

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Katherine Drabiak *Disentangling Dicta: Prince v. Massachusetts, Police Power and Childhood Vaccine Policy*, 29 Annals Health L. 173 (2020). Available at: https://lawecommons.luc.edu/annals/vol29/iss1/6

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Disentangling Dicta: Prince v. Massachusetts, Police Power and Childhood Vaccine Policy

Katherine Drabiak*

INTRODUCTION

According to the Centers for Disease Control and Prevention (CDC), from January 1 to August 29, 2019, 1,234 individual cases of measles have been confirmed in 31 states.¹ Although the CDC declared measles eliminated in 2000,² cases still occur every year, with most cases imported into the United States by international travelers.³ Public health scientists maintain that vaccine mandates tied to school attendance are crucial to achieving widespread vaccination because they create herd immunity at the population level and reduce the risk of any individual contracting the disease.⁴ Some health professionals and legislators assert outbreaks could be prevented by reducing or eliminating non-medical exemptions for school attendance or by expanding mandates to all children,⁵ and several state legislatures are debating bills to remove non-medical exemptions tied to childcare and education.⁶

As healthcare providers, public health officials and legislators respond, it is critical to consider both the power—and the limits—of potential solutions.⁷

 ⁵ See Erwin Chemerinsky & Michele Goodwin, Compulsory Vaccination Laws are Constitutional, 110 Nw. U. L. REV. 589, 593-95 (2016) (stating compulsory vaccination laws are constitutional and should extend to all children, only allowing for medical exemptions).
 ⁶ See generally Neal D. Goldstein et al., Trends and Characteristics of Proposed and Enacted State Legislation on Childhood Vaccination Exemption, 2011-2017, 109 AM. J. PUB. HEALTH 102, 103-04 (2019) (discussing the trends of state proposed legislation to

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¹ Measles Cases and Outbreaks, CTRS. FOR DISEASE CONTROL & PREVENTION,

https://www.cdc.gov/measles/cases-outbreaks.html (last visited Sept. 3, 2019).

² Measles History, CTRS. FOR DISEASE CONTROL & PREVENTION,

https://www.cdc.gov/measles/about/history.html (last visited Feb. 5, 2018).

³ Measles Cases and Outbreaks, supra note 1.

⁴ Eileen Wang et al., Nonmedical Exemptions from School Immunization Requirements: A Systematic Review, 104 AM, J. PUB. HEALTH e62, e62 (2014).

remove exemptions to existing vaccination laws or make exceptions more difficult to obtain).

⁷ See generally Wendy K. Mariner et al., Jacobson v. Commonwealth of Massachusetts: *It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581, 582 (2005) (explaining the societal and government structural changes that have occurred since *Jacobson* was decided in 1905).

While policy solutions may offer non-compulsory means designed to increase vaccination rates among under-vaccinated populations, areas of interconnected legal doctrine and public health ethics support the proposition that state laws should not eliminate conscientious objection. Part I of this article explores the role of non-medical exemptions, reasons for parental vaccine hesitancy, and nuances involved in parental decision-making. In Part II, this article builds upon legal scholar Wendy Mariner and colleagues' observation that courts following Jacobson v. Massachusetts "expanded, superseded, or even ignored" portions of Jacobson's limitations on police power, and analyzes the impact of how subsequent courts distorted precedent by applying dicta in Prince v. Massachusetts as binding law. Part III traces the development of jurisprudence in the areas of substantive due process, informed consent, a child's right to an education, and parental decisionmaking, providing analysis of how current legislation that removes nonmedical exemptions (NMEs) may exceed the permissible scope of the state's police power based on Constitutional and jurisprudential limits. Part IV complements the evolution of vaccine law with a discussion of public health ethics and policy solutions that prioritize accountability, transparency, and trust.

Finally, this article suggests that coercive approaches would fracture public trust and supports a model that integrates public health experts Daniel Salmon and Andrew Siegel's proposal for preserving conscientious objection.

I. FRAMING NON-MEDICAL EXEMPTIONS AND VACCINE HESITANCY

While most parents comply with their state law vaccine schedule for their children, a small minority of parents opt for NMEs.⁸ This section describes both statistics behind parents choosing NMEs and explores research on reasons why parents express hesitancy towards vaccinating their children.

A. Vaccines as a Public Good.

CDC classifies vaccines as one of the top ten public health achievements,⁹ and the vast majority of parents across the U.S. as a whole comply with the state law mandated schedule of vaccines for their children.¹⁰ Vaccines, like any other FDA-approved product, such as a prescription drug or medical

⁸ See Wang et al., *supra* note 4, at e64 (stating that state-level NME rates in 2012-2013 were 1.9 percent).

⁹ Ram Koppaka, *Ten Great Public Health Achievements* — United States, 2001-2010, 60 MORBIDITY & MORTALITY WKLY. REP. 605, 619 (2011).

¹⁰ See Wang et al., *supra* note 4 at e81 (finding overall that vaccine coverage in the U.S. remains high, with pockets of a higher prevalence of NMEs and geographic clusters of NMEs that have developed over time).

device, carry a set of risks and benefits.¹¹ Unlike other medical interventions that a patient takes in response to a disease or condition, physicians provide vaccines to healthy persons.¹² Accordingly, standards for safety should be higher, and public tolerance for adverse risks is substantially lower that other medical interventions.¹³

Several legislators and public health professionals assert that removing NMEs constitutes a necessary step toward increasing vaccination rates and to eliminate measles outbreaks.¹⁴ In the midst of crisis, public health professionals and legislators have a duty to rapidly and effectively respond, which requires sifting through alarm and rhetoric.¹⁵ Media, legal scholars, and politicians cite an astounding 337 percent increase in NMEs in small geographic areas,¹⁶ asserting parental decision-making is based on "unfounded safety concerns",¹⁷ and "no scientific evidence exists to suggest vaccines cause life threatening or disabling diseases."¹⁸ Both of these claims warrant further examination.

B. Nuances in Parental Decision-making.

This characterization incites divisiveness by dismissing nuances of parental behavior, medical decision-making, and value-based risk assessment. Although several states have witnessed NMEs doubling, the median absolute rate of parents seeking NMEs for their children in kindergarten is 2.2 percent.¹⁹ In 2017-2018, the median coverage for

 12 Id. at 48.

¹³ Id.

¹⁶ Love v. State Dep't of Educ., 240 Cal. Rptr. 3d 861, 866 (Cal. Ct. App. 2018).

¹⁷ Julia Belluz, *Measles is Back Because States Give Parents Too Many Ways to Avoid Vaccines*, Vox (Feb. 22, 2019, 12:32 PM), https://www.vox.com/science-and-

health/2019/2/16/18223764/measles-outbreak-2019-vaccines-anti-vax.

¹¹ See CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 47 (13th ed. 2017) [hereinafter PREVENTION, EPIDEMIOLOGY AND PREVENTION] (stating that while vaccines are among the most significant public health successes of all time, no pharmaceutical product is completely safe or completely effective).

¹⁴ Wang et al., *supra* note 4, at e62.

¹⁵ Matthew K. Wynia, *Ethics and Public Health Emergencies: Encouraging Responsibility*, 7 AM. J. BIOETHICS 1, 1 (2007); *see also* Jim Rossi, *State Executive Lawmaking in Crisis*, 56 DUKE L. J. 237, 237 (2006) (stating that state and local authority in addition to federal authority have a duty to treat patients in the midst of an epidemic).

¹⁸ See Letter from Adam B. Schiff, Member of Congress, U.S. House of Representatives, to Mark Zuckerberg, Chairman & Chief Executive Officer Facebook Inc. (Feb. 14, 2019), https://schiff.house.gov/imo/media/doc/Vaccine%20Letter_Zuckerberg.pdf (writing as a Member of Congress concerned about the medically inaccurate information being shared on social media platforms).

¹⁹ See JENELLE MELLERSON ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, 67 MORBIDITY & MORTALITY WKLY. REP., VACCINATION COVERAGE FOR SELECTED VACCINES AND EXEMPTION RATES AMONG CHILDREN IN KINDERGARTEN — UNITED STATES, 2017–18 SCHOOL YEAR 1115 (2018) (analyzing state vaccine mandates and the high numbers of

kindergarten children who received their MMR vaccine was 94.3-99.4 percent and CDC states vaccination coverage for kindergarteners remains high.²⁰ According to public health scholar Daniel Salmon and colleagues, 36 percent of parents worry that vaccines may be unsafe and 17 percent of parents express concern that vaccines are not sufficiently tested.²¹

Research suggests vaccine hesitancy represents a crisis in public confidence and research shows that parents describe specific concerns, such as the potential for adverse reactions, individual vaccine necessity, safety, and increased risk of chronic disease, immune system dysfunction, or developmental injury.²² Communications professor Melissa Carrion highlights further issues stemming from healthcare provider confidence in the vaccine administration schedule and lack of communication with concerned parents, such as unwillingness of healthcare providers to acknowledge parental concerns, address conflicting risk information (such as manufacturer disclosed risks versus the information on CDC's website), and refusal to follow up when adverse reactions occur.²³ Despite such concerns, most parents (about 98 percent) comply with the state mandated vaccine schedule,²⁴ highlighting the critical role of engagement and trust between healthcare providers and parents.

II. POLICE POWER TO CONTROL OUTBREAKS

This section first traces the evolution of police power articulated in *Jacobson v. Massachusetts* and the original limits set forth by the Court. Second, this section describes how subsequent courts dramatically expanded state police power pertaining to vaccine law and explains the role of legislative deference. Third, this section describes how multiple courts relied on citing *Prince v. Massachusetts* as precedent and provides a critical

sufficiently vaccinated children).

²⁰ Id.

²¹ See Daniel A. Salmon et al., *Vaccine Hesitancy: Causes, Consequences, and a Call to Action*, 33 VACCINE D66, D67 (2015) (citing to a nationally representative study surveying parents of children ages 1-6).

²² See Melissa L. Carrion, An Ounce of Prevention: Identifying Cues to (In)Action for Maternal Vaccine Refusal, 28 QUALITATIVE HEALTH RES. 2183, 2187-88 (2018) (citing adverse reactions to vaccines as a driving reason parents choose not vaccinate their children; see also Salmon, supra note 21, at D67 (reporting parental concerns regarding vaccines include potential adverse reactions, weakened immune system dysfunction, and safety concerns); see also Wang et al., supra note 4, at e64 (reporting common parental concerns regarding vaccines include lack of necessity, safety concerns, immune system dysfunction, chronic conditions, and developmental problems).

 $^{^{23}}$ See Carrion, *supra* note 22, at 2191 (highlighting the role providers have in encouraging parents to have their child vaccinated, and making parents feel informed and sufficiently educated).

²⁴ See Wang et al., *supra* note 4, at e64 (noting that in 2012–2013 NME rates were at 1.9 percent).

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analysis of how this process improperly distorted dicta into the rule of law. The past several decades of vaccine jurisprudence have not only dramatically expanded the scope of police power but have done so by indiscriminately incorporating dicta while simultaneously disregarding pertinent facts in citing authority.

A. Police Power in Jacobson v. Massachusetts

In *Jacobson v. Massachusetts* the Supreme Court did not question the state's police power relating to vaccine mandates because individual liberty is not absolute and the state is justified in protecting the safety of the public.²⁵ The Court did note that the state could not enforce vaccination regulations that are arbitrary or oppressive, such as forcing regulations on individuals who would experience a harmful reaction or death.²⁶ Subsequent courts have disregarded specific limitations, increased the scope of vaccine mandates, and upheld almost all challenges to state laws based on substantial deference to state legislatures.²⁷ Closer examination, however, reveals that numerous cases misapplied dicta in *Prince v. Massachusetts* as binding precedent without acknowledgement or adjudication.²⁸ As a result, subsequent cases afforded little weight to the evolution of substantive due process and informed consent, children's right to an education, and parental liberties.

Jacobson v. Massachusetts occurred at a time when infectious disease was the leading cause of death and universally feared.²⁹ Disease ran rampant from overcrowded housing conditions, inadequate sanitation, and impure drinking water.³⁰ In 1905, *Jacobson* upheld a state law delegating power to local health officials mandating that adults receive one smallpox vaccine in the midst of an epidemic or pay a fine (about \$130 today).³¹ Under the concept of police power, states have a duty to enact laws that promote the health, safety, and welfare of its residents.³² *Jacobson's* factual background constituted narrow circumstances: one vaccine for the entire adult population

²⁵ Mariner et al., *supra* note 7, at 582.

²⁶ Id. at 583.

²⁷See generally Mariner et al., *supra* note 7, at 583–84 (explaining that the Court did not question whether legislation was oppressive and arbitrary in *Zucht v. King* (1922), which prohibited attendance in public and private schools without a certificate of vaccination, how the Court justified sterilization of "feeble minded" individuals in *Buck v. Bell* (1927), and gave legislatures broad deference in defining a threat to public health). ²⁸ See infra note 47.

²⁹ Mariner et al., *supra* note 7, at 582.

³⁰ Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y, L., & ETHICS 39, 42 (2013). ³¹ Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11, 39 (1905); *see also* Katherine Drabiak, *During measles outbreaks, fines and public bans are legal, but there are limits*, PBS (Apr. 12, 2019, 11:43 AM), https://www.pbs.org/newshour/health/during-measles-outbreaks-fines-and-public-bans-are-legal-but-there-are-limits.

³² Jacobson, 197 U.S. at 25.

in the context of a contagious deadly epidemic.³³ The Court warned that exercise of police power may not be arbitrary, unreasonable, or go so far beyond what is required for the safety of the public and may not violate rights secured by the Constitution.³⁴

According to public health law expert Lawrence Gostin's interpretation of *Jacobson*, a valid exercise of police power requires several factors including: assessing the necessity of the intervention, using reasonable means, proportionality of the law (laws should not overreach nor unduly burden the population), and harm avoidance (that the intervention should not cause harm).³⁵ Balanced against the state's power, the 14th Amendment protects individual liberty encompassing freedom from restraint, thought, belief, and decision-making.³⁶ Public health authorities may offer and encourage vaccines as a method of prevention, but medical professionals, public health authorities, and even courts may not legally compel a person to submit to a vaccine.³⁷

B. Expansion of Police Power and Legislative Deference.

Subsequent court decisions dramatically increased both the scope of vaccine mandates by including children, mandating additional vaccines, removing the requirement for an epidemic, broadening the doctrine of *parens patriae*, and clarifying potential questions relating to vaccine exemptions.³⁸ Courts consistently upheld state laws, finding they served an overriding and compelling public interest to immunize children against "crippling and deadly diseases"³⁹ and "it has long been settled that individual rights may be subordinated to the compelling state interest of protecting society against the spread of disease."⁴⁰

³³ See generally Holland, *supra* note 30, at 46 (explaining the Supreme Court's specific language granting the state police power to impose one vaccine on the entire population, in the context of a deadly epidemic).

³⁴ See Jacobson, 197 U.S. at 28 (stating the court would usurp the functions of another branch of government (such as the legislative) if it judged that the mode adopted to protect the public was arbitrary, and not justified by the necessities of the case).

³⁵ Lawrence Gostin, Jacobson v. Massachusetts *at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 579 (2005).

³⁶ *Due Process of Law*, JUSTIA, https://law.justia.com/constitution/us/amendment-14/04due-process-of-law.html (last visited Nov. 11, 2019).

³⁷ See Mariner et al., *supra* note 7, at 586 (theorizing that a state statute that forces people to be medicated or vaccinated over their refusal would likely be considered unconstitutional under modern jurisprudence); *see also* Wendy Parmet, *Informed Consent and Public Health: Are They Compatible When it Comes to Vaccines*?, 8 J. HEALTH CARE L. & POL'Y 71, 110 (2005) (suggesting that instead of attempting to compel persons to receive

vaccinations, instead encourage physicians to foster a level of trust in patient relationships where recommendations to vaccinate are more likely to be heeded).

³⁸ Holland, *supra* note 33, at 49-50.

³⁹ Brown v. Stone, 378 So. 2d 218, 221 (Miss. 1979).

⁴⁰ See McCarthy v. Boozman, 217 F. Supp. 2d 945, 948 (E.D. Ark. 2002) (explaining the

Zucht v. King examined a state vaccine mandate for children as a condition of school attendance.⁴¹ The Court upheld state officials' power to enact laws relating to vaccine mandates, but did not address the substantive questions about the validity of the ordinance based on whether it was necessary, whether the vaccine in question for smallpox still posed a danger because it was not a disease in circulation, or whether the law was arbitrary or oppressive.⁴² Courts have described children attending school as a "natural class" "more liable to contagion" based on many students interacting in shared close quarters.⁴³ *Zucht* extended *Jacobson's* substantial deference to the legislature over school children, while disregarding *Jacobson's* balancing test articulated by Gostin.

Jacobson's requirement of a current outbreak of a deadly disease permitting a vaccine mandate was overlooked by *Board of Education of Mountain Lakes v. Maas*, which held that the absence of an existing emergency did not warrant denial of the state exercising preventive means through compulsory vaccination.⁴⁴ The court stated that holding otherwise would destroy prevention as a means of combatting disease.⁴⁵ Several courts have similarly concluded states may enact preventive mandates even where the disease does not pose a clear and present danger.⁴⁶

Under the doctrine of *parens patriae*, the state may intervene with measures designed to provide for the health and safety of children, such as mandating school attendance and prohibiting child labor.⁴⁷ In *Prince v*. *Massachusetts*, the Court stated in dicta that *parens patriae* also permits the state to further restrict parental authority: Parents "cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include the liberty to expose the community or child to communicable disease or the latter to ill

constitutionality of immunization requirements).

⁴¹ See Zucht v. King, 260 U.S. 174, 175 (1922) (noting "[o]rdinances of the city of San Antonio, Texas, provide that no child or other person shall attend a public school or other place of education without having first presented a certificate of vaccination").

⁴² Mariner et al., *supra* note 7, at 583–84.

⁴³ French v. Davidson, 77 P. 663, 664 (Cal. 1904); Love v. State Dep't of Educ., 240 Cal. Rptr. 3d 861, 872 (Cal. Ct. App. 2018).

⁴⁴ Board Educ. Mountain Lakes v. Maas, 152 A. 2d 394, 405–09 (N.J. Super. Ct. App. Div. 1959).

⁴⁵ Id. at 409.

⁴⁶ See Boone v. Boozman, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002) (holding "[i]t is well established that the State may enact reasonable regulations to protect the public health and the public safety, and it cannot be questioned that compulsory immunization is a permissible exercise of the State's police power"); see also Davis v. State, 451 A.2d 107, 111–12 (Md. 1982) (stating "[a]lthough we recognize that some courts have taken this approach with respect to similar statutes challenged on Establishment Clause grounds, for us to do so would flatly violate settled principles of statutory construction in this State").
⁴⁷ Prince v. Massachusetts, 321 U.S. 158, 166 (1944).

health or death.³⁴⁸ Numerous cases precipitously adopted these statements of dicta as binding law,⁴⁹ stating it is "well settled" that parental rights are not absolute,⁵⁰ that parental beliefs or religion do not provide exemptions for parents seeking to avoid compulsory vaccination,⁵¹ and one court ruling that offering religious or NMEs goes beyond what the Constitution requires.⁵²

Every state requires compulsory vaccination for childcare and school attendance, and three states have no NME.⁵³ Reliance on dicta set forth in *Prince* has substantially shaped both legislative and judicial interpretation of the power for states to require compulsory vaccination and guided the removal of NMEs in states such as Mississippi⁵⁴ and California.⁵⁵

If, however, states do offer a religious exemption, courts have been clear that health officials and school officials do not have discretion to require the child's parent to identify with an organized religion⁵⁶ or reject the sincerity of the parent's religious beliefs because this violates the Establishment Clause of the First Amendment.⁵⁷ Indeed, *In Re LePage v. Wyoming* held "We do not believe the legislature . . . anticipated or authorized a broad investigation into an individual's belief system in an effort to discern the merit of a request for exemption."⁵⁸

In practice, judicial challenges highlight the difficulty of discerning between parents' religious and philosophical beliefs behind a parent's request for exemption.⁵⁹ This uncertainty prompted state legislatures to implement varied solutions in response to litigation challenges relating to what constitutes parental religious beliefs rather than sincerely held objections based on conscience, philosophy, or other reasoning.⁶⁰

⁵² See Phillips v. City of New York, 775 F.3d 538, 543 (2d Cir. 2015) (writing that California, Mississippi and West Virginia do not have an NME for vaccines).

⁴⁸ *Id.* at 166–67.

 ⁴⁹ Whitlow v. California, 203 F. Supp. 3d 1079, 1084 (S.D. Cal. 2016); Workman v. Mingo County Schs., 667 F. Supp. 2d 679, 689 (S.D. W. Va. 2011); McCarthy v. Boozman, 212 F. Supp. 2d 945, 948 (W.D. Ark. 2002); Brown v. Stone, 378 So. 2d 218, 222 (Miss. 1979); Bd. of Educ. of Mountain Lakes, 152 A.2d at 407; Davis, 451 A.2d at 112;.

⁵⁰ McCarthy, 212 F. Supp. 2d at 948.

⁵¹ Workman, 667 F. Supp. 2d at 688–89; Davis, 451 A.2d at 112–13.

⁵³ States With Religious And Philosophical Exemptions From School Immunization Requirements, NAT'L CONF. ON ST. LEGISLATURES (June 14, 2019),

http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx. ⁵⁴ *Brown*, 378 So. 2d at 222.

⁵⁵ Love v. State Dep't of Educ., 240 Cal. Rptr. 3d 861, 871 (Cal. Ct. App. 2018).

⁵⁶ McCarthy v. Boozman, 212 F. Supp. 2d 945, 949 (W.D. Ark. 2002); Davis v. State, 451 A.2d 107, 112–13 (Md. 1982).

⁵⁷ In re LePage v. State, 18 P.3d 1177, 1180 (Wyo. 2001).

⁵⁸ Id. at 1181.

⁵⁹ Workman v. Mingo Cty Schs., 667 F. Supp. 2d 679, 689 (S.D. W. Va. 2011); In re LePage v. State, 18 P.3d at 1181.

⁶⁰ Brown v. Stone, 378 So. 2d 218, 223 (Miss. 1979); McCarthy v. Ozark Sch. Dist., 359 F.3d 1029, 1036 (S.D. Ala. 2004).

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Mississippi, for example, decreased parental decision-making by eliminating all NMEs.⁶¹ To compare, Arkansas removed its religious exemption to eliminate confusion over classifying parental beliefs but maintains a broad NME that includes both religious and philosophical objections and enacted additional procedural requirements.⁶²

C. Prince v. Massachusetts: The Impact of Distorting Dicta Into Law

Over a century of jurisprudence has consistently upheld compulsory vaccination laws as they expanded in scope and rejected challenges both to compulsory vaccination laws and the removal of NMEs.⁶³ Problematically, there is scant discussion recognizing *Prince* as dicta,⁶⁴ which raises jurisprudential concerns and leaves open Constitutional questions.⁶⁵ Moreover, the implications of elevating *Prince*'s dicta to binding law are significant for the direction of compulsory vaccine policy, particularly as state legislatures consider removing NMEs because it clarifies forgotten limits on police power.⁶⁶

Prince, despite the Court's comments on the matter of communicable disease and vaccines, addressed a wholly separate matter of the state's police power to uphold child labor laws.⁶⁷ *Prince* upheld the state's power to enforce child labor laws under the doctrine of *parens patriae*, even where the parents claimed this impinged on religious liberty for the child to sell religious booklets and pamphlets in public streets.⁶⁸ *Prince's* holding preventing children from engaging in commercial activity is both factually, and legally, distinct from state vaccine mandates as a condition of school attendance because medical interventions entail a substantial bodily intrusion and physical risks.

Notably, the Court in *Prince* cited to *People v. Pierson* as support for its remarks on vaccination, which also entailed a factually distinct circumstance.⁶⁹ In *Pierson*, the court examined whether a parent who

⁶⁷ Prince v. Massachusetts, 321 U.S. 158, 166 (1944).

68 Id. at 166-67.

⁶¹ Brown, 378 So. 2d at 223.

⁶² McCarthy, 359 F.3d at 1036.

⁶³ Chemerinsky & Goodwin, *supra* note 5, at 604; Kristine Severyn, *Jacobson v*.

Massachusetts: Impact on Informed Consent and Vaccine Policy, 5 J. OF PHARMACY & L. 249, 273 (1995).

⁶⁴ Dorit Rubinstein Reiss, *Litigating Alternative Facts: School Vaccine Mandates and the Courts*, 21 UNIV. OF PENN, J. OF CONST, L. 207, 240 (2018).

⁶⁵ See Ryan S. Killian, Dicta and the Rule of Law, 2013 PEPPERDINE L. REV. 1, 10-12

^{(2013);} Judith M. Stinson, *Why Dicta Becomes Holding and Why It Matters*, 76 BROOKLYN L. REV. 219, 223-25 (2010).

⁶⁶ See generally Stinson, *supra* note 65, at 227 (explaining that some courts defer to a deciding court (i.e. federal courts), granting special consideration to the intent of the court issuing judicial dicta).

⁶⁹ Id. at 167.

believed in Divine Healing could claim a religious defense for refusing to seek medical treatment for a "dangerously ill" child suffering from catarrhal pneumonia who died from complications.⁷⁰ The court held that religion did not constitute a defense to provide the child with the basic necessities of life, such as food, clothing, shelter, and medical attendance when it became reasonable to see that the child's life threatening condition required medical care.⁷¹ Importantly, *Pierson's* holding examined the reasonableness of parental conduct and imposed a duty to seek medical care.⁷² The *Pierson* ruling contained *no comments at all related to vaccination*.⁷³

Accordingly, neither *Pierson* nor *Prince* adjudicated parental duty, police power, or *parens patriae* relating to vaccination.⁷⁴ Despite the inertia of precedent, subsequent legislatures, courts, and health officials must distinguish that the dicta set forth in *Prince* is not, and cannot, serve as rule of law.⁷⁵ Under Article III of the Constitution and Separation of Powers doctrine, courts may only adjudicate actual cases and controversies based on the facts before it.⁷⁶ This promotes accuracy in reaching a correct decision based on the specific facts and circumstances of the case, ensures the adversarial system provides reasoned analysis, and protects the legitimacy of the court's decision-making process.⁷⁷ Subsequent courts cannot make law simply by announcing a rule without adjudication, and court decisions to summarily dismiss attempts to address the topic by asserting the matter has been "foreclosed,"⁷⁸ "firmly settled"⁷⁹ or that "no discussion is required"⁸⁰

III. RECONCILING PROPOSALS TO REMOVE NON-MEDICAL EXEMPTIONS WITH CONSTITUTIONAL PRINCIPLES

Although many legal scholars assert Jacobson and subsequent precedent

⁷⁰ See generally People v. Pierson, 68 N.E. 243, 247 (N.Y. 1903) (concluding that the legislature had the right to punish those who committed acts which were public wrongs, or which were destructive of private rights, in light of the constitutional right to the free exercise of religion).

⁷¹ Id. at 246–47.

⁷² Id.

⁷³ Id.

⁷⁴ See generally Prince v. Massachusetts, 321 U.S. 158 (1944); See generally Pierson, 68 N.E. 243.

⁷⁵ Killian, *supra* note 65, at 10; Pierre Leval, *Judging Under the Constitution: Dicta About Dicta*, 81 N.Y.U. L. REV. 1249, 1274–75, 1282 (2006).

⁷⁶ Killian, *supra* note 65, at 9-10; Stinson, *supra* note 65, at 225–28.

⁷⁷ Killian, *supra* note 65, at 10; Stinson, *supra* note 65, at 225–277.

⁷⁸ Phillips v. City of New York, 775 F.3d 538, 542 (2d Cir. 2015).

⁷⁹ Brown v. Stone, 378 So. 2d 218, 222 (Miss. 1979); Cude v. State, 377 S.W.2d 816, 819

⁽Ark. 1964); Love v. State Dep't of Educ., 240 Cal. Rptr. 3d 861, 868 (Cal. Ct. App. 2018). ⁸⁰ Brown, 378 So. 2d at 222; *Cude*, 377 S.W.2d at 819; *Love*, 240 Cal. Rptr. 3d at 868.

supports both current vaccine mandates and eliminating NMEs,⁸¹ this position minimizes *Jacobson's* balancing test for limitations on police power and overlooks flawed reliance on dicta set forth in *Prince*. Further examination suggests that proposals to remove NMEs could be construed as ultra vires action, exceeding limits of police power because it infringes on substantive due process rights, informed consent, a child's right to an education and private parental decision-making. Although some courts have already rejected these claims, these holdings relied on applying *Prince's* dicta as binding law and disregarded critical developments in the law as described below reflecting unyielding deference to state legislatures.⁸²

A. Substantive Due Process and Police Power in Other Contexts

Substantive due process entails a right to be free from state actions that impinge on individual liberty, restraint, bodily invasion, and freedom of conscience and belief.⁸³ Several state constitutions also address prohibitions against the state impinging on the right of individual conscience.⁸⁴ The law is clear that public health authorities and law enforcement may place restrictions on a person's individual liberty—including religious liberty—in situations where a person's actions pose a direct, immediate, and compelling harm to others, such as using venomous snakes in religious worship⁸⁵ or asserting a nonexistent "right" to use an illegal substance such as marijuana when operating a motor vehicle.⁸⁶ A healthy person choosing to forgo a medical intervention is not comparable to deliberately exposing others to a dangerous animal or choosing to drive under the influence, both of which constitute gravely dangerous actions involving imminent foreseeable harm.

In public health law relating to communicable disease, state power to physically constrain individual rights requires a very specific standard: a person must have a present disease *and* this person's actions must pose a direct threat to others.⁸⁷ For example, health officials may seek a quarantine order or civil commitment to treat a person with active Tuberculosis who continues to frequent highly populated public spaces until the person is no

85 Harden, 216 S.W.2d at 709.

⁸¹ Chemerinsky & Goodwin, supra note 5, at 604.

⁸² Love, 240 Cal. Rptr. 3d at 993–94.

⁸³ Due Process of Law, supra note 36.

⁸⁴ See Harden v. State, 216 S.W.2d 708, 711 (Tenn. 1948) (noting that the Kentucky Constitution in part states that "the civil rights…of no person shall be taken away, or in any wise diminished or enlarged, on account of his belief or disbelief of any religious tenet, dogma or teaching. No human authority shall, in any case whatever, control or interfere with the rights of conscience"); Cude v. State, 377 S.W.2d 816, 818 (Ark. 1964) (stating the Constitution of Arkansas provides: "No human authority can, in any case or manner whatsoever, control or interfere with the right of conscience").

⁸⁶ State v. Hardesty, 214 P.3d 1004, 1005 (Ariz. 2009).

⁸⁷ City of Newark v. J.S., 652 A.2d 265, 270 (N.J. Super Ct. 1993).

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longer contagious.⁸⁸ Even in such a case, health authorities can offer treatment and limit a person's movement to prevent infecting others, but the law does not permit forcibly medicating a competent person against his will.⁸⁹ Based on this requirement, legal precedent does not support viewing a healthy person as a threat to the public, nor would attenuated theoretical concerns permit overriding that persons' right to bodily integrity.

B. Informed Consent

Health law has a strong history of recognizing bodily integrity as a constitutionally protected liberty wherein adults can choose whether to accept or refuse a proposed medical intervention, which creates substantial tensions when considering vaccine mandates and the removal of NMEs.⁹⁰ Vaccines, like any other FDA approved product such as a prescription drug or medical device, carry a set of risks and benefits.⁹¹ These calculations vary depending on the vaccine, its efficacy, its safety, potential side effects, the severity of the illness the vaccine aims to protect against, and the individual to whom it is administered.⁹² Vaccines are classified as "unavoidably unsafe" products in the law, which means even when FDA approves them as safe and effective, and they are manufactured and designed correctly, they still pose risk of injury and death to some people.⁹³

Health law jurisprudence recognizing the requirement and value of informed consent has evolved significantly since the time of *Jacobson.*⁹⁴ Indeed, as health law expert George Annas has articulated: "the patient is the one who experiences the invasion and lives with its consequences. There is no obligation to accept any medical treatment, and it is remarkable that anyone ever considered it acceptable practice to treat a person without that person's informed consent."⁹⁵ Similarly, despite the American Medical Association's Statement calling to remove NMEs for vaccination, it also acknowledges the rights of patients to accept or refuse any medical treatment.⁹⁶

⁸⁸ Id. at 268.

⁸⁹ Mariner et al., *supra* note 7, at 586 "Constitutional limits include protection against unjustified bodily intrusions, such as forcible vaccination of individuals at risk for adverse reactions, and physical restraints and unreasonable penalties for refusal").

⁹⁰ See, e.g., Schloendorff v. Soc'y of N. Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (stating "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body").

⁹¹ PREVENTION, EPIDEMIOLOGY AND PREVENTION, *supra* note 11.

⁹² PREVENTION, EPIDEMIOLOGY AND PREVENTION, *supra* note 11.

⁹³ Bruesewitz v. Wyeth, 562 U.S. 223, 225, 243 (2011).

 ⁹⁴ See Severyn, *supra* note 63, at 249 (discussing the continued impact of *Jacobson v. Massachusetts* on the practice of medical informed consent and U.S. vaccination policy).
 ⁹⁵ See id. at 253 (quoting George Annas).

⁹⁶ Id.

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Both the legal doctrine of informed consent and ethicist Tom Beauchamp's framework of medical ethics principles illustrate that informed consent constitutes more than acquiescence (cursory agreement to vaccinations based on provider recommendation and legal mandates) but requires disclosure, comprehension, voluntariness, competence, and consent.⁹⁷ Providing accurate and balanced information relating to risks, benefits, and alternatives supports patient autonomy and dignity, in addition to promoting trust in the health professions.⁹⁸ These principles support the proposition that policy solutions may maximize non-compulsory means to increase vaccination rates among parents who seek access to vaccines for their children, but that implementing coercive strategies through conscientious objection disregards the development of informed consent.

As part of informed consent, the law must have a system to recognize claims that occur as a result of the medical intervention, even if such claims are rare, and provide compensation to injured parties.⁹⁹ Under the National Childhood Vaccine Injury Act, the National Vaccine Injury Compensation Program has original jurisdiction over all claims involving childhood vaccine injury from federally recommended vaccines.¹⁰⁰ *Bruesewitz v. Wyeth* held that the National Childhood Vaccine Injury Act eliminated manufacturer liability for unavoidable adverse side effects of vaccines and preempted most civil claims.¹⁰¹ Prior to *Bruesewitz*, however, litigation raised significant— and still potentially unresolved—procedural issues relating to disclosure, voluntariness, and actual consent that arise in the context of population-based vaccination campaigns that would pose potentially irreconcilable difficulties for states that remove NMEs.¹⁰²

1. Allison v. Merck: Adequate Disclosure and Voluntariness

In Allison v. Merck, Allison alleged that Merck's MMR vaccine caused her 17-month-old son "to contract encephalitis and suffer from consequent blindness, deafness, mental retardation, and spastic

⁹⁷ Severyn, *supra* note 63, at 252–53.

⁹⁸ See Severyn, *supra* note 63, at 255 (explaining that contemporary reports of medication errors and medical malpractice illustrate the fallacy of medical paternalism, and emphasize the importance of patient autonomy as well as the right to refuse medical care).

⁹⁹ Parmet, *supra* note 37, at 89–92.

¹⁰⁰ Parmet, *supra* note 37, at 77.

¹⁰¹ Bruesewitz v. Wyeth, 562 U.S. 223, 243 (2011).

¹⁰² See Davis v. Wyeth Laboratories Inc., 399 F.2d 121, 131 (9th Cir. 1968) (illustrating patient information must accurately disclose the small chance of potential risks because they impact individual decision-making); see also Mazur v. Merck, 964 F.2d 1348, 1352 (3d Cir. 1992) (raising issues regarding disclosure of sufficient information to make informed decisions and addressing specific considerations for consent in the context of mass vaccination); see also Allison v. Merck, 878 P.2d 948, 951–52 (Nev. 1994) (discussing adequate disclosure and voluntariness).

contractures."103 The court examined the discrepancy of information provided on the manufacturer's insert disclosing risks and adverse reactions compared to CDCs parent handout.¹⁰⁴ Specifically, the MMR package insert listed each of the child's debilitating medical conditions as potential adverse reactions to the vaccine, but the parent handout from CDC equivocated potential reactions and stated, "experts are not sure" in addition to "there might be a very remote possibility — a chance in a million — that takers of the vaccine may have a more serious reaction, such as encephalitis."¹⁰⁵ The court noted that the parent handout from the CDC did not warn of possible risks of blindness, deafness, and permanent brain damage.¹⁰⁶ The court further concluded that a jury could find that the CDC's handout was "slanted and insufficient"¹⁰⁷ based on testimony from a CDC physician to the fact that CDC had a policy of preparing the parent information sheets to avoid overwarning to prevent discouraging the use of vaccines.¹⁰⁸ According to the court, "at no time was Ms. Allison ever made aware that the vaccine might result in her son becoming an invalid."109

The court in *Allison v. Merck* opined that it appeared that Allison did not receive a fair warning and that a jury could find that the warning was inadequate based on its disclosures.¹¹⁰ Despite public health officials' goal to encourage vaccination, public health law expert Wendy Parmet has noted that if health professionals make a determination of significant population level benefit, this creates an incentive to promote vaccination even at the risk of limiting disclosures pertaining to contraindications or downplaying risks.¹¹¹

Allison v. Merck highlights the unresolved tension of how vaccination mandates undermine the voluntariness of parental consent on behalf of their children. Parents may seek vaccination on an involuntary basis if the state requires vaccination compliance for entry to childcare and school facilities, and this lack of choice becomes particularly acute in states without NMEs.¹¹² As pharmacy scholar Kristine Severyn has pointed out, if one cannot refuse, then this nullifies consent.¹¹³ While some scholars assure the public that this coercion does not rise to draconian force against parents such as incarceration for failure to comply, this mistakes the fundamental role of public health as

- ¹⁰³ Allison, 878 P.2d at 951–52.
- ¹⁰⁴ Id. at 957.
- ¹⁰⁵ Id.

¹¹⁰ *Id.* at 957, 961.

¹¹¹ Parmet, *supra* note 37, at 108.

¹⁰⁶ Id. at 957–58

¹⁰⁷ *Id.* at 957.

¹⁰⁸ *Id.* at 958.

¹⁰⁹ *Id.* at 957–58.

¹¹² Parmet, *supra* note 37, at 102.

¹¹³ Severyn, *supra* note 63, at 255.

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a mechanism for education, persuasion, and facilitating the delivery of agreed upon health services.¹¹⁴ Parmet aptly concludes that conditioning childcare and school attendance on compliance does not constitute much of a choice, a conclusion also shared by the court in *Allison v. Merck*.¹¹⁵

2. Davis v. Wyeth: Squaring Population with Individualized Decisionmaking

Davis v. Wyeth illustrates that while vaccine campaigns may promote a population level strategy designed to protect the public, patient information must accurately disclose the small chance of potential risks because they impact individual decision-making. ¹¹⁶ Despite the case addressing a population-wide campaign including both children and adults,¹¹⁷ the court's holding bears important considerations for balancing population goals versus individual decision-making that is relevant for children's mandates.

Davis was a 39-year old man who received the polio vaccine as part of a mass vaccination campaign, subsequently developed poliomyelitis from the vaccine, and became paralyzed from the waist down.¹¹⁸ The court examined whether Wyeth satisfied its duty to warn of risks of the polio vaccine by omitting any mention of the small risk of contracting polio and developing paralysis.¹¹⁹ At the time, Wyeth's marketing materials, the U.S. Surgeon General's public statement and media represented the vaccine as "completely safe for all" without any mention of possible risks.¹²⁰ The court held that population-based statistics that demonstrate exceedingly small risk do not minimize the duty of the manufacturer or the learned intermediary to warn of those risks, particularly where risks are gravely serious, disabling, or could result in death.¹²¹ The court stated that Davis' "risk of contracting the disease without immunization was about as great (or small) as his risk of contracting it from the vaccine."¹²² "Under these circumstances we cannot agree with appellee that the choice to take the vaccine was clear."¹²³ The court stated that decisions to incur risk not only depend on individual judgment, but also that patients making individual decisions are less likely to accept risk for preventing a disease versus treating a disease.¹²⁴

¹¹⁴ Reiss, *supra* note 64, at 252–253.

¹¹⁵ Parmet, *supra* note 37, at 102; Allison v. Merck, 878 P.2d 948, 961 (Nev. 1994).

¹¹⁶ Davis v. Wyeth Laboratories Inc., 399 F.2d 121, 131 (1968).

¹¹⁷ Id. at 124.

¹¹⁸ Id. at 122.

¹¹⁹ Id. at 129.

¹²⁰ Id. at 125.

¹²¹ Id. at 129–30.

¹²² Id. at 130.

¹²³ Id. at 131.

¹²⁴ Id. at 130.

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3. Mazur v. Merck: Mass Vaccination Campaigns, Individualized Assessment, and Actual Consent

Mazur v. Merck raised similar issues relating to the disclosure of sufficient information to make an informed decision and addressed specific considerations for consent in the context of mass vaccination.¹²⁵ In *Mazur v. Merck*, Mazur alleged that the MMR II vaccine caused her previously healthy 13-year-old daughter Lisa Marie to contract Subacute Sclerosing Panencephalitis (SSPE), a rare form of chronic progressive brain inflammation caused by measles virus.¹²⁶ During a mass vaccination campaign at school, Mazur informed the school that Lisa Marie was already vaccinated, did not consent to revaccination, and did not sign the permission slip.¹²⁷ The school wide vaccination program relied on providing parents the CDC handout on the MMR II vaccine, collecting parental permission slips, and the school nurse administering vaccinations in an assembly line fashion in the school cafeteria.¹²⁸ Despite Mazur's decision to decline, the school nurse mistakenly administered the MMR II vaccine to Lisa Marie.¹²⁹

While mass vaccination campaigns may be an expedient method for achieving high rates of vaccine compliance, the facts in *Mazur* illustrated the importance of accurate parent handouts when the vaccine manufacturer delegates its duty to warn to the CDC. In most other contexts, the healthcare provider acts as the learned intermediary and must use his or her independent judgment of the vaccine's risks and benefits, knowledge of the patient's medical history, and current condition to discern whether administration of the vaccine is appropriate.¹³⁰ Vaccine mandates, particularly without NMEs, are in conflict with the healthcare provider's duty to independently assess each individual patient.¹³¹ In *Mazur*, the court found the school nurse did not engage in independent medical decision-making and was not even aware that SSPE could arise as an adverse reaction from the vaccine, but merely administered the vaccine as part of the mass immunization program without consent.¹³²

4. Vaccine Litigation Highlights Procedural Considerations for Informed Consent

Integrating the holding in Jacobson with the development of informed

¹²⁸ Id.

¹²⁵ Mazur v. Merck, 964 F.2d 1348, 1352 (3d Cir. 1992).

¹²⁶ Mazur v. Merck, 767 F. Supp. 697, 698 (E.D. Pa. 1991).

¹²⁷ Mazur, 964 F.2d at 1351.

¹²⁹ *Id.* at 1352.

¹³⁰ Id. at 1356.

¹³¹ Parmet, *supra* note 37, at 96.

¹³² Mazur, 964 F.2d at 1359.

consent and selected cases of vaccine litigation demonstrates a significant tension in vaccine mandates or public immunization campaigns and the conflicts inherent in removing NMEs. Even in the context of mandated vaccines, the current standard in health law suggests that parents should receive accurate disclosures of the benefits, risks, and alternatives for each vaccine and the healthcare provider should work with parents to make an individualized assessment of whether the child in his independent medical judgment should receive the vaccine.¹³³ Under the framework of public health ethics, physician and L.A. County Health Department official Alvin El Amin and colleagues clarify that even as a public health measure, vaccination should be of benefit to the individual patient in question.¹³⁴

Mandates using persuasion may be permissible, but removing NMEs would negate crucial elements of voluntariness, actual consent, and individualized patient assessment. As Parmet has summarized: "despite firm legal bases for the general principle that states can require children to be vaccinated prior to school, existing law does not support a total abnegation of either individualized choice or individualized decision-making."¹³⁵ Prioritizing population level goals by implementing a strategy that minimizes or discards critical developments in informed consent law forces a precedent that could be applied not only to other population such as healthcare workers but other sectors of the general population.¹³⁶ Furthermore, deferring to respected scientific consensus as a means to justify forced medical interventions in the name of individual benefit and the public good has historically resulted in some of the most egregious Constitutional and human rights atrocities in the United States, such as mass forcible sterilization during the eugenics movement.¹³⁷

C. Children's Right To An Education

1. State Authority to Enact School Related Regulations

Pierce v. Society of Sisters held that parents have a right to direct their child's education, including where their child receives an education, and stands for the proposition that children have a right to receive an education.¹³⁸

¹³³ Id. at 1358, 1367.

¹³⁴ Alvin Nelson El Amin et al., *Ethical Issues Concerning Vaccination Requirements*, 34 PUB. HEALTH REV. 1, 3 (2012).

¹³⁵ Parmet, *supra* note 37, at 81.

¹³⁶ Andrew C. Miller & David W. Ross, Mandated Influenza Vaccines and Health Care Workers' Autonomy, 12 VIRTUAL MENTOR: AM. MED. Ass'N J. ETHICS 706, 706–710 (2010); George J. Annas. Don't Force Medical Pros to Get H1N1 Vaccine, NEWSDAY (Oct. 3, 2009, 5:56 PM), https://www.newsday.com/opinion/opinion-don-t-force-medical-pros-to-geth11-vaccine-1.1496620.

 ¹³⁷ Buck v. Bell, 274 U.S. 200, 207 (1927); Mariner et al., *supra* note 7, at 584.
 ¹³⁸ Pierce v. Soc'y of Sisters, 268 U.S. 510, 534 (1925).

Multiple Supreme Court cases have held that access to public education provides "a pivotal role in maintaining the fabric of society,"¹³⁹ is instrumental in preparing children to be productive members of society,¹⁴⁰ and states must make education equally available to all children.¹⁴¹

Health law scholar Dorit Rubinstein Reiss maintains neither compulsory vaccination laws nor removing NMEs violates a child's right to an education, but rather constitutes an extension of school regulations already in place. Reiss asserts schools already constitute a highly regulated space designed to promote the health and safety of the students, particularly based on sharing close quarters. Both parents and schools have a duty to keep children safe while in school, which includes enacting measures to protect students against the spread of communicable disease. Reiss argues California's strategy of removing NMEs constitutes an important and necessary decision because less restrictive means would not meet the goal of complete vaccination, stating "limiting parents' liberty is supported by both the child's interest to be free from disease — an interest the state can legitimately protect — and the public health.

Pierce recognizes that states may enact reasonable rules to regulate, inspect, and examine schools; but held that these regulations must be balanced with Constitutional rights.¹⁴² Certainly, school districts have a duty to enact disciplinary policies to ensure a safe and secure school environment for all children. Policies may prohibit types of conduct, such as assault, possession of dangerous weapons, controlled substances, or intoxicating beverages on school premises.¹⁴³ In some circumstances, students may forfeit their right to a public education if their *behavior and conduct* poses safety concerns and endangers other students (e.g. suspending or expelling students who brought weapons to school, were in possession of controlled substances, or assaulted other students).¹⁴⁴

But what if the child has a medical condition and his actions negatively affect other students by disrupting classroom learning and school functioning? Federal special education law has already addressed the related question of whether schools may require students to take certain types of

¹³⁹ Plyler v. Doe, 457 U.S. 202, 221 (1982).

¹⁴⁰ Wisconsin v. Yoder, 406 U.S. 205 (1972).

¹⁴¹ Brown v. Board of Education, 374 U.S. 483, 495 (1954).

¹⁴² *Pierce*, 268 U.S. at 534.

¹⁴³ See e.g. Doe v. Superintendent of Schools of Worcester, 653 N.E.2d 1088, 1098 (Mass. 1995). (Holding that schools have a duty to provide education in a secure and safe environment. Schools may enact disciplinary policies relating to possession of weapons, controlled substances, and intoxicating beverages; and enact policies penalizing assault. If student actions violate these rules and place other students at risk of harm, student misbehavior may constitute grounds for removal from the school).

¹⁴⁴ Id. at 133.

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medication to receive education services.¹⁴⁵ Even in circumstances where a child has a diagnosed condition, such as ADHD and where the child is aggressive, disruptive, and causes disorder to the classroom, the state or school cannot mandate that parents medicate their child with a Controlled Substance to receive educational services.¹⁴⁶ At least one federal circuit and the U.S. Department of Education have stated this principle more broadly to mean that schools cannot condition any child's education upon a parent's decision to "medicate" the child.¹⁴⁷

Of course, there are factual differences between mandating a Controlled Substance for a child with a current condition such as ADHD as a means to mitigate classroom disruption and mandating children who attend school must receive certain vaccinations designed to reduce the risk of contracting communicable disease in the future. However, the proposition from special education law suggests even if health professionals believe that the medical intervention will benefit both the individual child and the greater student body by preventing disorder impacting the rest of the student body, these factors do not outweigh the parents' ability to make the medical decision whether to accept or decline the medical intervention.

Litigation challenging the removal of NMEs in California on the basis that it infringes on a child's right to receive an education have been unsuccessful. In one of several cases, *Love v. State Department of Education*, parents asserted that California's law conditions the right to attend school on giving up other fundamental rights, including the right to forgo recommended medical interventions, the right to bodily integrity, and the right of parents to engage in decision-making on behalf of their children.¹⁴⁸ The court rejected the plaintiffs' arguments, citing to *French v. Davidson* which held that school constitutes an appropriate place for compulsory vaccination based on

¹⁴⁷ Valerie, 771 F. Supp. at 490.

¹⁴⁵ Individuals with Disabilities Education Act, 20 U.S.C. §§ 1400, 1401; 20 U.S.C. § 1412(a)(25); 34 C.F.R. §§ 300.17, 300.174.

¹⁴⁶ In a clarification memorandum, Acting Deputy Assistant Secretary, Department of Education William Knudsen specified the scope of § 300.174: "Educational services...cannot be conditioned upon a parent's decision to medicate his or her child." Knudsen clarified the law applies to all children, not just children with a disability. Letter from William Knudsen, Acting Deputy Assistant Secretary, Department of Education to U.S. Senator James Inhofe, Mandatory Medication Under the IDEA (Oct. 27, 2007), https://sites.ed.gov/idea/idea-files/policy-letter-october-22-2007-to-u-s-senator-james-minhofe/. See also Valerie J. v. Derry Cooperative Sch. Dist., 771 F. Supp. 483, 490 (D.N.H. 1991) Casey J. was a child receiving public education, had a diagnosis of ADHD, and the court found Casey J. was a disruptive influence to his teachers, classmates and others. Casey J.'s parents initially consented to placing him on Ritalin, but be developed side effects such as "lack of self-worth, insomnia, touchiness, and stomach aches." Casey J.'s parents objected to his Individual Education Plan based on a requirement that he must continue submitting to taking Ritalin to receive educational benefits. The Court held Casey J.'s right to a free appropriate public education could not be premised on the condition that he be medicated without his parent's consent.

¹⁴⁸ Love v. State Dep't of Educ., 240 Cal. Rptr. 3d 861, 872 (Cal. Ct. App. 2018).

children sharing close quarters that could facilitate the spread of communicable disease.¹⁴⁹

Both Love and Davidson reasoned that deference to the legislature requires upholding the state compulsory vaccination laws tied to education because vaccination constitutes a reasonable means of preventing communicable disease.¹⁵⁰ French v. Davidson occurred in 1904 prior to any of the seminal cases that set forth contemporary standards for substantive due process and bodily integrity, informed consent, recognizing the rights of parents to make decisions on behalf of their children, narrow circumstances when the state may intervene, and recognizing a child's right to education as an important right.¹⁵¹ Remarkably, the court in *Love* not only adopted the presumption of legislative deference upholding the state's exercise of police power, but did so without according weight to the robust doctrine of competing rights.¹⁵² Quoting French v. Davidson, the court in Love stated "[The legislation] in no way interferes with the right of the child to attend school, provided the child complies with the provisions . . . When we have determined the act is within the police power of the state, nothing further need be said."¹⁵³ Though state laws designed to promote the health and safety of the public falls within the police power, such laws are not insulated from further examination, nor can they exceed the scope of legal authority defined by unduly impinging on other Constitutional rights.¹⁵⁴

Moreover, the court in *Love* further deferred to the California state legislature's goal of 100 percent compliance as a means to "total immunization" as a reasonable goal.¹⁵⁵ Accepting that 100 percent compliance constitutes a reasonable goal forecloses the option of less restrictive alternatives because as *Love* opined, permitting *any* NMEs would undermine attaining such outcome.¹⁵⁶ The amount of outbreaks that repeatedly occur in both fully vaccinated persons and in highly vaccinated populations should raise important questions as to whether a numeric metric for compliance in fact constitutes a reasonable goal and an objective so compelling as to warrant overriding competing rights. Finally, there is no

¹⁵⁵ Love, 240 Cal. Rptr. 3d at 864.

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¹⁴⁹ Id.

¹⁵⁰ *Id.* at 990, 991; French v. Davidson, 143 Cal. 658, 661-62 (Cal. 1904).

¹⁵¹ Pierce v. Soc'y of Sisters, 268 U.S. 510, 535 (1925); *French*, 143 Cal. 658; *Love*, 240 Cal. Rptr. 3d 861.

¹⁵² See generally Love, 240 Cal. Rptr. 3d at 861 (adopting the presumption of legislative deference and the state's use of police power without discussing the right to bodily integrity, the right to turn down medical treatment, or a parent's right to engage in decision-making for his or her child).

¹⁵³ *Id.* at 872-73.

¹⁵⁴ Jorge E. Galva et al., *Public Health Strategy and the Police Powers of the State*, 120 PUB. HEALTH REP. 20, 20 (2005).

¹⁵⁶ Id. at 870.

question that the best interest of children requires the state to step in with reasonable regulation to prevent the spread of contagious disease.¹⁵⁷ Vaccination constitutes one method aimed at disease prevention. To protect children, the state may also use its expertise to recommend or order isolation, quarantine, exclusion of unvaccinated children during an active outbreak at the school while honoring sincerely held NMEs.¹⁵⁸

Consider issues such as teenage pregnancy, use of deadly tobacco products such as e-cigarettes, drug abuse, and binge drinking.¹⁵⁹ It would be reasonable for schools to enact measures that address discipline or health behaviors, such as disseminating reproductive care information, prohibiting the use of tobacco products on school grounds, and security measures to limit the flow of controlled substances and alcohol onto school grounds.

However, the principles used by legislatures to prevent disease and promote population health in the context of restricting vaccine exemptions extends the state's power much further. Plaintiffs in *Love* correctly framed the issue: state laws that remove NMEs set the precedent that protecting public health empowers the state to not only regulate conduct and behavior but requires certain students to undergo medical interventions as a condition for school attendance.¹⁶⁰

D. Parental Decision-Making For Children

In *Pierce v. Society of Sisters*, the Court held parents have care, custody, and control over their children to direct their child's upbringing and education.¹⁶¹ *Pierce* held certain core decisions rest with the parents because the "child is not the mere creature of the state," and represented the proposition that certain private decisions of family life are beyond the reach of state intervention and parental decision-making constitutes a fundamental right.¹⁶² In most cases, this standard includes respecting parents' ability to make medical decisions to consent or forgo recommended medical interventions for children, operating by the presumption that parents generally act in the best interest of their children.¹⁶³

Parenting decisions are not absolute, and the state acting under parens

Thorny Questions Over Control, The Conversation (Sept. 24, 2019),

¹⁵⁷ Id. at 871.

 ¹⁵⁸ See People ex rel. Hill v. Bd. of Educ., 195 N.W. 95, 98 (Mich. 1923) (stating that the board could exclude unvaccinated children from school during a smallpox outbreak).
 ¹⁵⁹ Katherine Drabiak, *California Law to Restrict Medical Vaccine Exemptions Raises*

https://theconversation.com/california-law-to-restrict-medical-vaccine-exemptions-raisesthorny-questions-over-control-123563.

¹⁶⁰ See generally Love, 240 Cal. Rep. 3d 861.

¹⁶¹ Pierce v. Soc'y of Sisters, 268 U.S. 510, 534–35 (1925).

¹⁶² *Id.* at 535.

¹⁶³ Parham v. J.R., 442 U.S. 584, 603 (1979); see also In re LePage v. State, 18 P.3d 1177, 1181 (Wyo. 2001).

patriae has a duty to intervene in circumstances where the child suffers harm, exploitation, and neglect.¹⁶⁴ Some legal scholars assert vaccine mandates should be extended to all children and legislatures should eliminate all NMEs because the state has a compelling interest in protecting all children from communicable disease, that vaccines are essential to save children's lives, stop needless suffering, and prevent children from dying.¹⁶⁵

While the state does have an interest in protecting children from communicable disease, vaccination campaigns constitute one factor of many impacting the rates of communicable disease and mortality. Mortality rates for communicable disease in developing nations where children may experience malnutrition and lack of access to medical care are vastly different than mortality rates in developed countries such as the U.S. ¹⁶⁶ Moreover, U.S. Public Health Service data demonstrates steep decreases in mortality from communicable diseases decades prior to the introduction of specific vaccines, ¹⁶⁷ highlighting how multiple successful advances in public health such as sanitation, clean water, and nutrition have dramatically impacted communicable disease incidence and mortality.¹⁶⁸

Invoking *parens patriae* and state intervention to override parental medical decision-making requires specific factors above the state's intention to provide a positive intervention for the child. Cases that uphold state intervention to protect a child by compelling medical treatment generally require that: (1) the child has an illness; (2) the illness is severe and life threatening; and (3) the benefits of the proposed intervention far outweigh the risks.¹⁶⁹ In these cases, the state has a high burden to demonstrate that parental decision-making runs contrary to the child's best interest.¹⁷⁰ Perhaps most critically, such decisions require satisfying each of the three factors, including *the child must currently be suffering from a serious life threatening illness*. Some courts permit states to petition to intervene in cases where the child has an ongoing substantial medical condition, but even then will assess the nature of the child's condition and would likely not be permitted to order

¹⁶⁴ Chemerinksy & Goodwin, supra note 5, at 613-14.

¹⁶⁵ Chemerinksy & Goodwin, *supra* note 5, at 599–600, 614.

¹⁶⁶ See Amy L. Rice et al, *Malnutrition as an Underlying Cause of Childhood Deaths Associated with Infectious Diseases in Developing Countries*, 78 BULL. WORLD HEALTH ORG. 1207, 1208 (2000) (stating that poor health associated with infectious diseases is especially high in developing countries); *see also* PHILIP STEVENS, DISEASES OF POVERTY AND THE 10/90 GAP 5 (2004) (showing in Table 1, that infectious diseases cause a higher mortality rate in low income countries).

¹⁶⁷ ROBERT D. GROVE & ALICE M. HETZEL, U.S. DEP'T. HEALTH, EDUC., WELFARE, VITAL STATISTICS RATES IN THE UNITED STATES 1940–1960 84–85 (1968).

¹⁶⁸ Ursula Schlipköter & Antoine Flahault, *Communicable Diseases: Achievements and Challenges for Public Health*, 32 PUB. HEALTH REV. 90, 108 (2010).

¹⁶⁹ Lee Black, *Limiting Parents' Rights in Medical Decision Making*, 8 AM. MED. Ass'N J. ETHICS 676, 679 (2006).

¹⁷⁰ *Id*. at 676.

treatments that are risky, invasive, or toxic, demonstrating recognition that medical interventions constitute a bodily invasion.¹⁷¹

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Accordingly, there is no basis to extend decisions to override parental medical decision-making in circumstances where the child is not presently sick and does not have a life threatening existing medical condition.¹⁷² Moreover, as both courts and medical ethicists recognize, the risk benefit calculation differs significantly for treating a present illness versus preventing theoretical illness.¹⁷³ To be sure, states do have a duty and a right to intervene when parents do not act according to child's best interest.¹⁷⁴ Medical ethics recognizes the acceptability – and necessity – of intervening in certain cases, such as to order medically necessary blood transfusions for dying children even if it runs contrary to the parents' faith, or requiring parents to seek medical care for children who are dying of a life threatening condition, such as in *Pierson*.¹⁷⁵

However, even if courts substantially modify the current standard and include the prevention of life threatening illness, some vaccines still may not meet that standard.¹⁷⁶ For example, when measles was historically more prevalent, physicians and scientists did not refer to measles as a life threatening condition, but rather described it as a "self-limiting infection of short duration, moderate severity, and low fatality."¹⁷⁷ Certain vaccines may also target diseases to which most children would not be exposed (Hepatitis B),¹⁷⁸ or diseases for which alternate methods of prevention exist (HPV).¹⁷⁹

¹⁷¹ Id. at 677.

 $^{^{172}}$ See *id.* at 679 (stating that cases that have upheld state intervention had to meet the three factors of (1) a child with an illness; (2) the illness is severe and life threatening; and (3) the benefits of the proposed intervention far outweigh the risks).

¹⁷³ See Miller ex rel. Miller v. HCA, Inc., 118 S.W.3d 758, 767 (Tex. 2003) (holding that emergent circumstances prevent a physician from committing a legal wrong when operating on a minor without consent); Committee on Pediatric Emergency Medicine and Committee on Bioethics, *Policy Statement – Consent for Emergency Medical Services for Children and Adolescents*, 128 AM. ACAD. PEDIATRICS 427, 430 (2011) (stating that the emergency medical professional does not have the right to treat a minor for medical conditions that are not serious or life-threatening) [hereinafter Committee On Pediatric Emergency Medicine Policy Statement].

¹⁷⁴ Black, *supra* note 169, at 675–76.

 ¹⁷⁵ People v. Pierson, 68 N.E. 243 (N.Y. 1903); Jehovah's Witnesses of Wash. v. King Cnty.
 Hosp., 278 F. Supp. 488, 495 (W.D. Wash. 1967); Committee on Pediatric Emergency
 Medicine Policy Statement, *supra* note 173.

¹⁷⁶ Langmuir et al. *infra* note 177.

¹⁷⁷ Alan D. Langmuir et al., *The Importance of Measles as a Health Problem*, 52 AM. J. PUB. HEALTH 1, 1 (1962).

¹⁷⁸ See generally Holland, *supra* note 30, at 76 (stating "The rationale to vaccinate the whole population of infants and young children in order to avoid later incidence of the disease among the adult population was unproven...The public health rationale for the hepatitis B vaccination of newborns, infants, and young children is weak).

¹⁷⁹ See Preventing HPV-Associated Cancer, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Aug. 22, 2018), https://www.cdc.gov/cancer/hpv/basic_info/prevention.htm (listing multiple prevention measures for HPV).

Finally, some vaccines such as varicella are designed to prevent a "generally mild and self-limited" infection and while they decrease a young child's risk of contracting varicella,¹⁸⁰ they also increase risk of contracting a more severe case as an adolescent or adult with risk of complications and increase the risk of experiencing shingles as an adult.¹⁸¹ At the international level, scientists and health officials do not merely disagree whether the varicella vaccination should be required, but whether it should even be recommended.¹⁸²

Such considerations – What is the severity of the disease? Is it life threatening? What are the chances the child will encounter the disease? What alternatives to prevention or treatment exist? What is the balance of benefit versus risks? – constitute critical questions to not only understand how each vaccine mandate fits within Gostin's four criteria for appropriate exercise of police power, but also whether overriding parental decision-making by removing NMEs would withstand legal scrutiny if a court engaged in examining these criteria.

1. Misapplication of Precedent and the Loss of Parental Rights

In exceedingly rare cases, courts have disregarded clear standards for overriding parental decision-making, ordering parents who decline vaccination to either consent and or face charges of child neglect and possibly child removal.¹⁸³ Recently, several physicians and ethicists argued the parental decision to forgo vaccination itself constitutes child neglect because parents are refusing evidence-based and safe preventive care, stating physicians have a duty to report the parent to the appropriate child welfare agency.¹⁸⁴ This recommendation not only disregards clear standards in medical ethics conflating treatment and prevention, but it also relies on inaccurate application of legal precedent and threatens trust in the medical profession.

In one case, In the Matter of Christine M., the parents sought medical treatment for their child with a fever and declined their physician's

 $^{^{180}}$ Ctrs. for Disease Control & Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases 355 (13th Ed. 2015).

¹⁸¹ Id.

¹⁸² See generally Chickenpox Vaccination FAQs., NAT'L HEALTH SERV. (last reviewed Jan.23, 2019), https://www.nhs.uk/conditions/vaccinations/chickenpox-vaccine-questions-answers/ (stating the "[c]hickenpox vaccination is not part of the NHS childhood vaccination program" because "[t]heres a worry that introducing the chickenpox vaccination for all children could increase the risk of chickenpox and shingles in adults).

¹⁸³ Efthimios Parasidis & Douglas Opel, *Parental Refusal of Childhood Vaccines and Medical Neglect Laws*, 107 AM. J. PUB. HEALTH 68, 71 (2017).

¹⁸⁴ Frank A. Chervenak et al., *Professional Responsibility and Early Childhood Vaccination*, 169 J. PEDIATRICS 305, 308 (2016).

recommendation for vaccination during the treatment encounter.¹⁸⁵ The treating facility reported the parents to child protective services to investigate child neglect on the basis of the parents' decision to forgo vaccination.¹⁸⁶ The court found the parents were "capable and loving" but examined the father's decision to forgo the MMR vaccine for his child based on concerns relating to side effects and risks.¹⁸⁷ This decision alone to decline a recommendation for a preventive measure, according to the court, constituted a violation of the child neglect statute.¹⁸⁸

Problematically, however, the court relied on a factually dissimilar case, *In the Matter of Hofbauer*, which involved parents who rejected conventional medical treatment for their child with Hodgkins disease.¹⁸⁹ Comparable to the well-settled standard in medical ethics, *In the Matter of Hofbauer* examined: (1) the seriousness of the child's condition; (2) the possibility of a cure; (3) risks associated with treatment; and (4) whether parents sought alternate treatment.¹⁹⁰ The *Christine M.* court modified the *Hofbauer* standard without explanation, eliminating the need for a current life threatening illness and added the language "prevention" into the second prong to address whether the MMR vaccine would prevent the disease, substantially distorting the elements historically required to override parental decision-making to support its finding that the parents violated the child neglect statute.¹⁹¹

In another case, *Cude v. State*, the parents objected to vaccination for religious reasons, but wanted their children to attend school.¹⁹² The state did not recognize the parents' religious objections, so the children were not permitted to attend school.¹⁹³ The court in *Cude* offered circular logic in its holding: the parents would not permit vaccination, so their children could not attend school; thus the parents' actions violated the compulsory school attendance laws constituting child neglect.¹⁹⁴ *Cude* held it was in the best interest of the children to order the state to remove the children from their

¹⁸⁸ Id.

¹⁹⁰ Id.

¹⁹² Cude v. State, 377 S.W.2d 816, 817 (1964).

¹⁹³ Id.

¹⁹⁴ Id.

¹⁸⁵ In the Matter of Christine M., 595 N.Y.S.2d 606, 607 (N.Y. Fam. Ct. 1992).

¹⁸⁶ Id. at 609.

¹⁸⁷ Id. at 618.

¹⁸⁹ In the Matter of Hofbauer, 393 N.E.2d 1009 (N.Y. 1979).

¹⁹¹ *Id.*; *see* In the Matter of Christine M., 595 N.Y.S.2d at 613 (citing *Matter of Hofbauer* when stating "In determining whether a parent has provided a child with adequate medical care courts generally consider, inter alia, the seriousness of the child's condition and the possibility of a cure (or prevention), the risk associated with the recommended treatment, and whether, if the parents have sought alternative treatment, such treatment is recommended by a physician and not one totally rejected by all reasonable medical authority").

parents on this basis alone.¹⁹⁵

Similar to *Christine M.*, the court in *Cude* relied on factually distinct precedent as well as dicta set forth in *Prince*.¹⁹⁶ *Cude* reasoned that overriding the parents' religious objection was permissible because the state has a duty to intervene when religious practices overlap and transgress on other members of society.¹⁹⁷ The court cited to cases that rejected a religious right to perform human sacrifice or when parents refuse a life-saving blood transfusion for a dying child.¹⁹⁸ It is unclear how reliance on such cases provides support for *Cude* 's holding. Performing human sacrifice already constitutes an existing crime, and it strains logic of how this action is comparable to a healthy person declining an unwanted medical intervention. In very specific circumstances, the court may indeed intervene to protect the life of a child and order a medical intervention, but *Cude* did not provide analysis as to why it eliminated the most important requirement for intervention: that the child presently has a grave disabling or life threatening condition.¹⁹⁹

The impact of conflating this distinction becomes particularly critical when public health officials respond to an outbreak and must distinguish with precision whether they are offering vaccines as a matter of prevention, intervening to offer life-saving treatment for a child with an existing illness, or forcibly ordering vaccination for healthy children despite parental objection.²⁰⁰ Independent of health officials and healthcare providers positive intentions, neither legal precedent nor medical ethics justifies forced interventions for healthy children.

The court's reasoning in *Christine M.* and *Cude* dramatically expands police power and *parens patriae* to scrutinize parental decision-making even when children are healthy and safe, which is contrary to the purpose of child welfare statutes authorizing state intervention.²⁰¹ Unless a child is currently suffering from a serious or life-threatening medical condition, there is no legal authority for initiating state intervention.²⁰² Moreover, this level of judicial interference sets a precedent for intrusive inquiries into parenting decisions for prevention and could result in expanded actions designed to

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¹⁹⁵ Id. at 821.

¹⁹⁶ Id. at 819.

¹⁹⁷ Id. at 818-19.

¹⁹⁸ Id. at 819.

¹⁹⁹ Black, *supra* note 169, at 679.

²⁰⁰ See generally Anders Kelto, Why A Court Once Ordered Kids Vaccinated Against Their Parents' Will, WUSF HEALTH NEWS FL. (Feb. 19, 2015).

²⁰¹ See In the Matter of Christine M., 595 N.Y.S.2d 606, 613 (holding that to decline a recommendation for a preventive measure, according to the court, constituted a violation of the child neglect statute); *see Cude*, 377 S.W.2d at 817 (holding that the state may intervene to protect the life of a child and order a medical intervention).

²⁰² Black, *supra* note 169, at 679.

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compel parents to accept medical interventions they assess their child does not need.

Writing for the dissent in *Cude*, Justice Johnson offered a scathing warning:

[T]he precedent set here that permits the taking of children at all is the vice that opens a Pandora's box which may haunt the court for years to come...one of the foreseeable specters is the unfettered interference by the State Welfare Department in areas where it has no legal standing whatsoever.²⁰³

Shifting this balance of power to the state runs contrary to the limits set forth in *Pierce* recognizing the fundamental rights of parents to make decisions affecting their children and to decline medical interventions except in specific circumstances. Cases such as *Christine M*. and *Cude* that overrode parental decision-making, charged the parents with child neglect, and or forcibly removed the child from the parents not only improperly applied the limits of legal precedent but appear to be in deep conflict with core public health values.

IV. APPLYING PUBLIC HEALTH ETHICS

As a matter of law, proposals to remove NMEs disregard specific limits on the police power articulated in *Jacobson*, misapply dicta set forth in *Prince*, and dismiss the evolution of key legal doctrines. This section considers the related policy implications pertaining to vaccine mandates and describes the importance of solutions that incorporate principles of public health ethics.

First, this section will describe the principle of accountability, why current research provides an incomplete risk assessment relating to vaccine safety, and explain how the current injury compensation creates disincentives for product improvement. Second, this section will explore the principle of transparency, describe how current data shows that outbreaks still occur in highly vaccinated populations for multiple diseases, and why removing NMEs is not sufficient to prevent future disease outbreaks. Finally, this section will address the importance of trust in public health ethics and propose a solution that maximizes noncompulsory strategies to offer vaccination to parents who agree while respecting the small percent of parents who may decline.

²⁰³ Cude v. State, 377 S.W.2d 816, 821-22 (Ark. 1964).

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A. Accountability

1. Incomplete Risk Assessment

While the CDC states that benefits far outweigh the risks of recommended vaccines, vaccines,²⁰⁴ like other recommended medical interventions, can result in adverse events ranging from mild, to severe, and ultimately life-threatening.²⁰⁵ Accountability to the public and justice require accurate and well-functioning regulatory and legal systems to understand these risks and compensate persons appropriately for their injuries.²⁰⁶

In 1986, Congress passed the National Childhood Vaccine Injury Act as a mechanism to grant broad legal immunity to vaccine manufacturers who were facing multiple lawsuits over alleged injuries arising from vaccines, stabilize the vaccine market, and create a compensation mechanism for resolving vaccine injury claims paid from a consumer excise tax fund.²⁰⁷ The Health Resources and Services Administration (HRSA) recognizes a covered list of injuries arising from individual vaccines, including life threatening and disabling conditions such as chronic arthritis, Guillan Barre Syndrome, vaccine strain polio, encephalopathy, and death.²⁰⁸ HRSA states in the majority of cases vaccines cause no side effects and the U.S. has the safest, most effective vaccine supply in history.²⁰⁹

Several studies have attempted to capture data on rate and severity of adverse events from vaccination.²¹⁰ These studies include admissions data for adverse vaccine reactions resulting in emergency department visits and passive reporting data from the Vaccine Adverse Events Reporting System.²¹¹

In one study, pharmacist Nadine Shehab and colleagues tracked emergency department admissions arising from adverse drug reactions by

²⁰⁴ PREVENTION, EPIDEMIOLOGY AND PREVENTION, *supra* note 11, at 50.

²⁰⁵ Molly Mort et al., World Health Organization, Vaccine Safety Basics – Learning Manual 71–73 (2013).

²⁰⁶ El Amin et al., *supra* note 134, at 3; Parmet, *supra* note 37, at 108.

²⁰⁷ *H.R.* 5546 – *National Childhood Vaccine Injury Act of 1986*, CONGRESS.GOV, https://www.congress.gov/bill/99th-congress/house-bill/5546 (last visited Oct. 19, 2019); *What You Need To Know About the National Injury Vaccine Compensation Program*, HEALTH RESOURCES & SERV. ADMIN. 3, 13 (2016).

²⁰⁸ Vaccine Injury Table, HEALTH RESOURCES & SERV. ADMIN.,

https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf (last visited Oct. 19, 2019).

²⁰⁹ What You Need To Know About the National Injury Vaccine Compensation Program, supra note 207, at 3.

 ²¹⁰ Sandra Chavez et al., Safety of Varicella Vaccine after Licensure in the United States: Experience from Reports to the Vaccine Adverse Event Reporting System, 1995–2005, 197
 J. INFECTIOUS DISEASES \$170, \$170 (2008); see Nadine Shehab et al., US Emergency Department Visits for Outpatient Adverse Drug Events, 316 JAMA 2115, 2115 (2016).
 ²¹¹ Id.

drug class and age group.²¹² Based on nationally representative surveillance data, Shehab and colleagues found each year there are 5133 cases of children under five years of age who are admitted to the emergency department from an adverse drug reaction.²¹³ In this group of children under five, an adverse reaction to a vaccine amounts to 19.5 percent of cases, which means in one year approximately 455 children under five suffered an adverse reaction to vaccination that resulted in emergency admission.²¹⁴ Limitations of Shehab and colleagues' study leave open questions such as how many reactions occur but do not result in emergency department admission, and the status of health outcomes for children who are admitted from an adverse reaction.²¹⁵

Patients who do experience an adverse reaction (whether or not they seek emergency care) may report this reaction to the Vaccine Adverse Events Reporting System, a passive voluntary reporting system.²¹⁶ Using data compiled in the Vaccine Adverse Events Reporting System, medical epidemiologist Sandra Chavez and colleagues examined reports of adverse reactions to one vaccine – the varicella vaccine – over a ten year period following licensure.²¹⁷ Chavez and colleagues found 25,306 adverse events reported from varicella from 1995-2005, or 52.7 adverse events per 100,000 vaccines given.²¹⁸ Five percent of reported adverse reactions were classified as serious, including conditions such as convulsions, pneumonia, vaccine strain meningitis, and death.²¹⁹ Based on this data, on the population level serious adverse events appear rare.

However, in a report commissioned by the Agency for Healthcare Research and Quality, Harvard Pilgrim Healthcare found the vast majority of adverse events – only one percent of all events – are ever reported, leading it to conclude underreporting slows and precludes identifying vaccines that may be posing an unacceptable risk of adverse events that endangers public health.²²⁰ Insufficient reporting of adverse effects also means we simply do not have sufficient information to assess how rarely, or how often, certain adverse effects occur.

²¹⁸ Id.

²¹² Shehab et al., *supra* note 210, at 2115.

²¹³ *Id.* at 2117 (citing Table 1).

²¹⁴ *Id.* at 2122 (citing Table 4).

²¹⁵ Id. at 2124.

²¹⁶ Vaccine Adverse Event Reporting System, U.S. DEP'T HEALTH & HUM. SERVS., https://vaers.hhs.gov/ (last visited Nov. 11, 2019).

²¹⁷ Chavez et al., *supra* note 210 at S170.

²¹⁹ Id. at S172–73 (citing Table 1 and Table 2).

²²⁰ ROSS LAZARUS ET AL., ELECTRONIC SUPPORT OF PUBLIC HEALTH-VACCINE ADVERSE EVENT REPORTING SYSTEM 6 (2010); see also Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153, 2223 (2017) (citing Robert T. Chen et al., *The Vaccine Adverse Event Reporting System (VAERS)*, 12 VACCINE 542, 548 (1994) (outlining inability to find causal relationships between vaccine and adverse event as greatest limitation of VAERS)).

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Lack of reporting further impairs assessing the merit of scientists' competing claims addressing what types of adverse events may or may not be caused by vaccination. Some scientists allege a link between certain vaccines and the development of chronic health conditions,²²¹ including central nervous system disorders;²²² autoimmune responses²²³ such as lupus,²²⁴ type 1 diabetes,²²⁵ arthritis;²²⁶ pervasive developmental disorders;²²⁷ neurological disorders;²²⁸ febrile seizures;²²⁹ and allergies/asthma.²³⁰ Conversely, there is a body of research that denies that these adverse

²²¹ See generally VACCINES AND AUTOIMMUNITY (Yehuda Shoenfeld et al. eds., Wiley-Blackwell 2015) (explaining the connection between vaccines and the development of autoimmune disorders).

 ²²² Yann Mikaeloff et al., Hepatitis B Vaccine and the Risk of CNS Inflammatory Demyelination in Childhood, 72 NEUROLOGY 873, 877-78 (2009); Claude Vital et al., Postvaccinal Inflammatory Neuropathy: Peripheral Nerve Biopsy in 3 Cases, 7 J.
 PERIPHERAL NERVOUS SYS. 163, 166 (2002); Manuel Martínez-Lavín et al., HPV vaccination syndrome. A questionnaire-based study, 34 CLINICAL RHEUMATOLOGY 1981, 1982 (2015).
 ²²³ See generally VACCINES AND AUTOIMMUNITY, supra note 221; Vijendra K. Singh & Ryan L. Jensen, Elevated Levels of Measles Antibodies in Children with Autism, 28 PEDIATRIC NEUROLOGY 292, 293 (2003).

²²⁴ Bing Wang et al., *Vaccinations and Risk of Systemic Lupus Erythematosus and Rheumatoid Arthritis: A Systematic Review and Meta-Analysis*, 16 AUTOIMMUNITY REVS. 756, 757 (2017).

²²⁵ John Barthelow Classen & David Classen, Clustering of Cases of Type 1 Diabetes Mellitus Occurring 2-4 Years After Vaccination is Consistent with Clustering After Infections and Progression to Type I Diabetes Mellitus in Autoantibody Positive Individuals, 16 J. PEDIATRIC ENDOCRINOLOGY & METABOLISM 495, 508 (2003); John Barthelow Classen & David Classen, Clustering of Cases of Insulin Dependent Diabetes (IDDM) Occurring Three Years After Hemophilus Influenza B (HiB) Immunization Support Causal Relationship Between Immunization and IDDM, 35 AUTOIMMUNITY 247, 252 (2002); but see Anders Hvvid et al., Childhood Vaccination and Type 1 Diabetes, 350 NEW ENG. J. MED. 1398, 1403 (2004) (finding that "[t]he development of type 1 diabetes in genetically pre-disposed children (defined as who had siblings with type 1 diabetes) was not significantly association with vaccination")..

²²⁶ Monica Fisher et al., Adverse Events Associated with Hepatitis B Vaccine in U.S. Children Less Than Six Years of Age, 1993 and 1994, 11 ANNALS OF EPIDEMIOLOGY 13, 16 (2001).

²²⁷ Jose Dorea, Low-Dose Thimerosal in Pediatric Vaccines: Adverse Effects in Perspective, 152 ENVIRONMENTAL RES. 280, 280–93 (2017); Carolyn Gallagher & Melody Goodman, Hepatitis B Vaccination of Male Neonates and Autism Diagnosis, NHIS 1997-2002, 73 J. TOXICOLOGY & ENVTL HEALTH 1665, 1665–677 (2010).

²²⁸ Nancy Agmon-Levin et al., *Transverse Myelitis and Vaccines: A Multi-Analysis*, 18 LUPUS 1198, 1198-1204 (2009); Anthony R. Mawson et al., *Pilot Comparative Study on the Health of Vaccinated and Unvaccinated 6- to- 12- Year Old U.S. Children*, 3 J. TRANSLATIONAL SCI. 1, 1–12 (2017) (citing Sienkiewicz D. et al., Neurologic Adverse

Events Following Vaccination, 2 Prog Health Sci. 129, 129-141).

²²⁹ See Peter Collignon et al., *Ramifications of Adverse Events in Children in Australia*, 340 BRIT. MED. J. 1262, 1262 (2010) (discussing alleged connection between vaccines and febrile seizures).

²³⁰ See MAWSON ET AL., *supra* note 228, at 4-12; *see also* Trudy Kemp et al., *Is Infant Immunization a Risk Factor for Childhood Asthma or Allergy*?, 8 EPIDEMIOLOGY 678, 678-80 (1997).

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outcomes are associated with vaccination.²³¹ Thus, the question is not whether vaccines can and do result in serious adverse reactions, but rather how often adverse events occur, what constitutes acceptable risk, and whether certain types of adverse outcomes and chronic disease can be attributed to vaccines.²³²

2. Barriers to Ongoing Product Assessment and Lack of Incentive for Improvement

Accountability also includes reviewing evidence behind safety, efficacy, and commitment to the ongoing process of assessing benefits and risks to ensure the vaccine supply is the safest and most effective as possible. This should include investigating whistleblower allegations of clinical trial fraud by a manufacturer,²³³ CDC whistleblower claims of data manipulation,²³⁴ and allegations by a scientific expert recruited by the Department of Justice that the Department of Justice manipulated his testimony to downplay risk and undermine causality between vaccines and neurological injury.²³⁵ As ethicists Gregory Kaebnick and Michael Gusmano assert, "the public has legitimate interests in asking challenging, even distrusting, questions about

²³¹ Vaccine Myths Debunked, PUB. HEALTH, www.publichealth.org/public-

awareness/understanding-vaccines/vaccine-myths-debunked/ (last visited Nov. 11, 2019); Common Vaccine Safety Concerns, CTRS. DISEASE CONTROL & PREVENTION,

www.cdc.gov/vaccinesafety/concerns/index.html (last reviewed Nov. 11, 2019).

²³² See generally Gregory E. Kaebnick & Michael Gusmano, Forget About "Because Science", SLATE (April 15, 2019), https://slate.com/technology/2019/04/vaccination-valuesscience-based-policy.html?fbclid=IwAR3IUxLpcq9fYYEAMhSTLSvYBQsqu8N-HOe7pM9RrujNX4VY04h3Jd_u0Kc ("Values are not ignored in the vaccine debate; claims about parents' rights and harms to children are common. But too often, the pro-vaccination discourse fails to recognize or thoroughly explore the role they play in the discussion, and in parents' minds.").

²³³ Amended Complaint for Plaintiff at 44, U.S. ex rel. Krahling v. Merck & Co., Inc, 44 F. Supp. 3d 581 (E.D. Penn. 2014) (No. 10-4374), 2012 WL 2945082 (claiming that Merck & Co. falsified test data in a clinical trial to show that the mumps vaccine had an efficacy rate of ninety-five percent in order to maintain their monopoly over vaccine sales in the United States); James T. Mulder, *Syracuse University Mumps Outbreak: Whistleblowers Say Vaccine is Flawed*, SYRACUSE: HEALTH NEWS (Nov. 14, 2017),

www.syracuse.com/health/2017/11/su_mumps_outbreak_whistleblowers_say_vaccine_ineff ective.html (last updated Jan. 4, 2019).

²³⁴ See generally Kevin Barry, Vaccine Whistleblower: Exposing Autism Research Fraud at the CDC (Skyhorse Publishing, 2015).

²³⁵ See Committee on Government Reform, The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices 13 (2000),

https://www.congress.gov/congressional-report/106th-congress/house-report/977/1 (describing criticism of Department of Justice practices to increase the adversarial nature of proceedings, attempts to impeach witnesses, replace unfavorable witnesses, and use "abrasive, tenacious, and obstreperous litigation tactics" that are "inappropriate" in a non-

adversarial compensation program); Sharyl Atkisson, *How A Pro-Vaccine Doctor Reopened Debate About Link To Autism*, THE HILL (Jan. 13, 2019),

https://thehill.com/opinion/healthcare/425061-how-a-pro-vaccine-doctor-reopened-debate-about-link-to-autism.

who's in control of the scientific enterprise."²³⁶ According to statements from Congressional representatives including Dan Burton, Bill Posey, and former representative Dave Wheldon, lobbyists have forcefully thwarted attempts to bring these issues to the floor of Congress for full public discussion.²³⁷ Precluding investigation or launching ad hominem attacks for posing questions relating to safety, efficacy, and risk not only undermines both public health interests but ignores the reasons behind diminishing public trust.²³⁸

Finally, legal scholar Effhimios Parasidis observed the current structure of passive monitoring and shielding manufacturers from liability not only poses obstacles to assessing risk, but may impede product improvement.²³⁹ Private resolution of claims means that information normally gleaned from products liability litigation involving allegations of injury from medical interventions does not exist in the same degree in the public domain, rendering it difficult to assess patterns of alleged injuries, examine causal evidence, or use the litigation as a tool to improve vaccine safety and efficacy.²⁴⁰ Dissenting in *Bruesewitz*, Justices Sotomayor and Ginsberg opined manufacturers have no incentive to create safer or more effective products because the current liability system "leaves a regulatory vacuum in which no one ensures vaccine manufacturers adequately account of scientific or technological advancements when designing or distributing their products."²⁴¹

B. Transparency: Removing NMEs Will Not Prevent Outbreaks

Even if public health authorities and legislatures expand vaccine mandates or eliminate NMEs, policy discussions should be transparent that these steps are not likely to prevent all future disease occurrence or outbreaks. Presenting the removal of NMEs as a sufficient solution misleadingly simplifies vital facts behind why outbreaks occur. Research suggests communicable disease outbreaks occur both from failure to vaccinate and vaccine failure.²⁴² Scientists define vaccine failure as either primary vaccine failure, wherein between two and ten percent of persons do not develop antibodies to the vaccine that confer immune protection, and waning

²³⁶ KAEBNICK & GUSMANO, *supra* note 232.

²³⁷ Full Measure Staff, *The Vaccination Debate*, FULL MEASURE NEWS (Jan. 6, 2019), http://fullmeasure.news/news/cover-story/the-vaccination-debate; *Rep. Bill Posey Calling for an Investigation of the CDC's MMR Research Fraud*, C-SPAN (July 29, 2015), www.c-span.org/video/?c4546421/rep-bill-posey-calling-investigation-cdcs-mmr-reasearch-fraud.
²³⁸ Parasidis, *supra* note 220, at 2164-65.

²³⁹ Id. at 2165.

²⁴⁰ Bruesewitz v. Wyeth, 562 U.S. 223, 249 (2011).

²⁴¹ Id. at 250.

²⁴² See Gregory A. Poland & Robert M. Jacobson, *The Re-Emergence of Measles in Developed Countries: Time to Develop the Next-Generation Measles Vaccine?*, 30 VACCINE 103, 103 (2012).

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immunity, defined as decreasing effectiveness over time.²⁴³ Both case reports and research demonstrate outbreaks of communicable diseases including measles, mumps, and pertussis still occur in populations with high vaccination rates and in persons who have been fully vaccinated.²⁴⁴

In a review in the Journal of the American Medical Association, physician Varun Phadke and colleagues reviewed published summaries and outbreak reports for disease occurrence and vaccination status for measles and pertussis from 2000-2015.²⁴⁵ Phadke and colleagues found in 1416 measles cases 56.8 percent of persons had no history of measles vaccination, translating to 43.2 percent of persons who were partially or fully vaccinated yet still contracted measles.²⁴⁶ For 10,609 cases of pertussis, 55 to 76 percent of persons who contracted pertussis were fully vaccinated.²⁴⁷ Recently, a 2019 outbreak of thirty students who contracted pertussis at Harvard-Westlake school in the Los Angeles area were all vaccinated, school officials affirmed the community has rate rates of vaccination, and the outbreak could not be attributed to lack of vaccination.²⁴⁸ In 2015-2016, CDC investigated an outbreak of mumps with 317 diagnosed cases, finding 89 percent of persons were fully vaccinated against mumps, four percent were partially vaccinated against mumps, and only two percent were not vaccinated against mumps.²⁴⁹ In addition to people who contract the disease despite being fully

²⁴⁷ Id. at 1154.

²⁴³ Tracy L. Gustafson et al., *Measles Outbreak in Fully Immunized Secondary-School Population*, 316 New Eng. J. Med. 771, 773–74 (1987).

²⁴⁴ See Eva Avramovich et al., Measles Outbreak in a Highly Vaccinated Population – Israel, July–August 2017, 67 MORBIDITY & MORTALITY WKLY. REP. 1186, 1186–88 (2018) (discussing two outbreaks in highly vaccinated areas of Israel); see also Hae Jie Kang et al., An Increasing, Potentially Measles Susceptible Population Over Time After Vaccination in Korea, 35 VACCINE 4126, 4126–32 (2017) (discussing that outbreaks occur in highly vaccinated populations); see also Varun K. Phadke et al., Association Between Vaccine Refusal and Vaccine Preventable Diseases in the United States: A Review of Measles and Pertussis, 315 JAMA 1149, 1149–58 (2016) (discussing studies that have identified instances of measles and pertussis outbreak in fully vaccinated populations); ; see also Jennifer Rosen et al., Outbreak of Measles Among Persons With Prior Evidence of Immunity, New York City, 2011, 58 CLINICAL INFECTIOUS DISEASES 1205, 1205-10 (2014) (stating that an individual who was twice vaccinated for measles contracted measles); Soumya Karlamangla, 30 Harvard-Westlake Students Diagnosed With Whooping Cough Amid Wider Outbreak, L.A. TIMES (Feb. 27, 2019),

https://www.latimes.com/local/california/la-me-ln-whooping-cough-harvard-20190226story.html (reporting that Harvard-Westlake typically has high vaccination rates among its students as over the past several years roughly 98% of 7th graders had all of their shots). ²⁴⁵ Phadke et al., *supra* note 244, at 1149.

²⁴⁶ Id.

²⁴⁸ Karlamanga, *supra* note 244; Chris Mills Rodrigo, *Officials Deny Lack of Vaccinations Caused Whooping Cough Outbreak in Los Angeles*, THE HILL (Feb. 29, 2019), https://thehill.com/homenews/state-watch/431848-officials-deny-lack-of-vaccinations-caused-whooping-cough-outbreak-in.

²⁴⁹ Justin P. Albertson et al., Mumps Outbreak at a University and Recommendation for a Third Dose of Measles-Mumps-Rubella Vaccine — Illinois, 2015–2016, 65(29) MORBIDITY & MORTALITY WKLY. REP. 731, 731–34 (2016).

vaccinated, fully vaccinated persons can transmit and spread the disease creating an outbreak,²⁵⁰ and outbreaks can occur in persons with detectable antibodies who scientists previously hypothesized would be immune.²⁵¹

While increasing vaccination coverage or reducing NMEs could potentially decrease outbreaks, it would likely not eliminate outbreaks as long as people continue to travel globally because the CDC estimates 90 percent of outbreaks originate from foreign travel.²⁵² Some public health models suggest that drops in overall vaccination coverage as a result of parents choosing NMEs produce dramatic impact on disease incidence and outbreaks.²⁵³ It should also be noted these projections constitute theoretical models that do not account for multiple real world complexities such as vaccine failure, waning efficacy, transmission by vaccinated persons, or employing effective alternative interventions such as isolation, guarantine, or school closure. Health professionals and legislators state that parents' opting for vaccine exemptions has increased communicable disease outbreaks.²⁵⁴ Evidence behind these assertions is mixed: according to public health scholars Y. Tony Yang and Victoria Debold, compelling evidence of a causal relationship between increased use of NME's and certain diseases has not been established.²⁵⁵ In a study published in the American Journal of Public Health, Yang and Debold did not find an association between NMEs restrictiveness, vaccine uptake, and disease incidence rates for hepatitis B, HIB, measles, or mumps.²⁵⁶

Each of these nuances should be both clearly communicated in public discussion and should raise the question of whether numeric goals such as 100 percent vaccination for school children constitutes the correct metric for measuring successful vaccine policy.

C. Prioritizing Public Trust: Retaining NMEs

Mariner and colleagues maintain the public is more likely to trust health officials that uphold and protect their personal liberty, asserting that public

²⁵⁰ Avramovich et al., *supra* note 244; Rosen et al., *supra* note 244.

²⁵¹ Rosen et al., *supra* note 244, at 1207.

²⁵² NAT'L CTR. FOR IMMUNIZATION & RESPIRATORY DISEASES, *What Would Happen If We Stopped Vaccinations?*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed June 29, 2018), www.cdc.gov/vaccines/vac-gen/whatifstop.htm.

 $^{^{253}\} FRED\ Measles\ Simulator,$ Pub. Health Dynamics Laboratory,

https://fred.publichealth.pitt.edu/measles (last visited Nov. 11, 2019). ²⁵⁴ Jacqueline K. Olive et al., *The State of the Antivaccine Movement In The United States: A*

Focused Examination Of Nonmedical Exemptions In States And Counties, 15 PLOS MED. 1, 1-10 (2018).

²⁵⁵ Y. Tony Yang & Vicky Debold, A Longitudinal Analysis of the Effect of Nonmedical Exemption Law and Vaccine Uptake on Vaccine Targeted Disease Rates, 104 AM. J. PUB. HEALTH 371, 371 (2014).

²⁵⁶ Id.

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health policy should prioritize communication and persuasion rather than force.²⁵⁷ Recognizing limits on police power and drawing on the difficulties in ascertaining whether parental dissent arises from religious or philosophical beliefs, public health scholars Daniel Salmon and Andrew Siegel propose a model for conscientious objection to respect sincerely held beliefs.²⁵⁸ Salmon and Siegel's policy model permitting a conscientiously held religious or philosophical NMEs²⁵⁹ falls within appropriate parameters for state police power to recommend and facilitate the delivery of medical interventions to further public health objectives but accounts for both legal constraints and prioritizing public trust.

Public health ethics requires maximizing noncompulsory strategies and permitting conscientious objections, which do not necessarily impede health officials' desired outcome.²⁶⁰ Research suggests that even states with NMEs can obtain high rates of vaccine compliance, especially in states that maximize noncompulsory procedural strategies.²⁶¹ These procedural requirements may address issues such as under vaccination as a matter of convenience, employ patient reminders, remediate administrative support for accuracy in vaccine recordkeeping, and formalize procedures for parents who hold sincere objections.²⁶² Public health scholar Jennifer Rota and colleagues suggests the decision of whether states offer NMEs may be less important than the state's procedural requirements, but preserving a method for parents who wish to conscientiously object preserves critical principles of public health ethics.²⁶³ As Parmet has noted, high rates of vaccination tied to school mandates occurs not because of coercive threats, but because of social norms, routines that integrate discussion of vaccines, and trust between patients and medical providers.²⁶⁴ Finally, if high numbers of persons are opting out,

²⁵⁷ Mariner et al., *supra* note 7, at 588.

²⁵⁸ Daniel A. Salmon & Andrew W. Siegel, *Religious and Philosophical Exemptions and Vaccination Requirements: Lessons Learned from Conscientious Objectors to Conscription*, 116 PUB. HEALTH REPS. 289, 289-91 (2001).

²⁵⁹ Id.

²⁶⁰ El Amin et al., *supra* note 134, at 5-6; Douglas Opel & Douglas Diekema, *Finding the Proper Balance Between Freedom and Justice: Why We Should Not Eliminate Personal Belief Exemptions to Vaccine Mandates*, 37 J. HEALTH POL., POL'Y & LAW 141, 141-57 (2012); Douglas Diekema, *Personal Belief Exemptions from School Vaccination Requirements*, 35 ANN. REV. PUBLIC HEALTH 275, 275-92 (2014).

²⁶¹ Nina R. Blank et al., *Exempting Schoolchildren from Immunizations: States with Few Barriers Had Highest Rates of Nonmedical Exemptions*, 32 HEALTH AFF. 1282, 1282-90 (2013); Jennifer S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645, 645-48 (2001).

²⁶² See, e.g. C. Lee Ventola, *Immunization in the United States: Recommendations, Barriers and Measures to Improve Compliance*, 41 PHARMACY & THERAPEUTICS 426, 426 (2016) (stating that examples of provider-based unvaccination interventions are the use of patient counseling, practice alerts and electronic medical records).

 ²⁶³ ROTA ET AL., *supra* note 261, at 647; *see* EL AMIN ET AL., *supra* note 134, at 16.
 ²⁶⁴ Parmet, *supra* note 37, at 104; University of Waterloo, *Social Norms Strongly Influence Vaccination Decisions, The Spread of Disease*, SCI. DAILY (Feb. 14, 2014),

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public health scholars suggest this not only signals a problem of public confidence but should prompt assessment of current mandates, how to improve administration of noncompulsory strategies, and how to address disease risk balanced against concerns of vaccine safety and efficacy.²⁶⁵

CONCLUSION

As health officials, legal scholars, and legislatures consider leveraging vaccine mandates and removing NMEs as a solution to prevent future outbreaks, it is crucial to recall the original limitations set forth in *Jacobson* and the Court's recognition that police power may not unduly impinge upon Constitutional rights. In absolute deference to the legislature, recent courts have omitted consideration for these competing rights relating to substantive due process, informed consent, children's right to an education, and parental decision-making, with numerous cases improperly citing to – and even incorrectly expanding – dicta set forth in *Prince*. Neither *Prince* nor *Pierson* addressed vaccination as part of its holding but instead *Pierson* and subsequent cases have addressed parental duty and the appropriateness of state intervention to seek life-saving medical care for a dying child. Despite numerous courts adopting dicta as holding, *Prince's* remarks on vaccination and the appropriateness of *parens patriae* cannot stand as force of law.

Current jurisprudence in health law and medical ethics explicitly precludes forcing medical interventions without consent or using coercion to obtain consent, even in circumstances where health officials and medical professionals assert such intervention provides public benefit. Close analysis of health law and medical ethics also specifies the state may only intervene on behalf of children in specific cases conditioned upon factual circumstances where the child has a life-threatening medical condition. Though schools may enact reasonable regulations to promote the health and safety of their students, legislative deference alone should not insulate the law from further examination. Further, legislatures should not condition a child's right to an education upon surrendering competing fundamental rights. Courts and public health officials that override parental decisionmaking by force to compel vaccinations or remove children from their parents exceed the scope of their authority because there is no legal basis for the state intervention-particularly to order a medical intervention against parent's discretion-for children who are currently healthy and safe in their parent's care.

Dismissing the parameters of legal boundaries, or justifying unnecessary force not only undermines fundamental liberties, but fuels parental and community distrust of health officials and sets back the ultimate goals of

www.sciencedaily.com/releases/2014/02/140214111211.htm.

²⁶⁵ Diekema, *supra* note 260, at 289; El Amin et al., *supra* note 134.

protecting the public. Responding to communicable disease outbreaks and enacting preventive measures through vaccine mandates requires reframing an adversarial narrative and permitting discussion of critical questions relating to safety, efficacy, product improvement, and reducing risks. Healthcare providers, public health officials and legislators should recognize the differences between parental beliefs and actions; acknowledge the existence of risks along with barriers to risk assessment; and maintain transparency that even compulsory force would still be insufficient to prevent future outbreaks based on patterns of importation, vaccine failure, and waning immunity. Finally, policy solutions may maximize noncompulsory means to increase vaccination rates among under-vaccinated population while including NMEs to respect sincerely held conscientious objection.