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Floridians' Right to Choose or Refuse Vaccinations

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Cover Page Footnote

Professor Tolan teaches at WMU-Cooley Law School from the campus in Riverview, Florida. The remarks in this article reflect his own views and opinions and not necessarily those of WMU-Cooley Law School. Prior to his work at Cooley, Professor Tolan taught at Barry Law School and at the United States Air Force Academy. He has extensive experience in environmental law including toxic torts, remediation of past toxins under various federal statutes, natural resource damages, green buildings, and earth jurisprudence—putting the planet first as a life-saving force to protect humanity and all of nature. He has recently refocused his research agenda on protecting the most vulnerable members of our society—children and the unborn—from the hazards of human interference with God's plan. The author thanks Professor Brendan Berry, Dean James McGrath and my teaching assistant, Jeanneth Miranda, for their staunch support and assistance in the writing and publication process. I dedicate the article to my wife and Registered Nurse of 35 years, Tonya Leigh Tolan, without whose passion this article would not have come to fruition.

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*Patrick E. Tolan, Jr.**

ABSTRACT

Every state must strike the right balance between an individual's freedom to make medical choices and the state's role in protecting the public health and the welfare of its people. Florida, by and through its Constitution, has afforded heightened protections for individual self-determination over medical treatment decisions and evaluates infringement of these private medical rights with strict scrutiny. This article is about legal rights for adults to obtain or refuse vaccines and for parents to decide the timing or administration of any vaccine or group of vaccines proposed for their school-aged, preschool, newborn, or unborn children.

I argue that States have an obligation to their people to strive for herd immunity from contagious viruses. However, I urge using voluntary measures to encourage vaccination when such measures can be protective of public health. I also argue that the protections of the Florida Constitution regarding individual liberties and privacy could be emulated by other states to elevate state actions involving forced medical procedures

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from the rational basis test to a heightened level of scrutiny (strict scrutiny).

In short, this article is about freedom to choose what medical treatments are put into your body or your children's bodies. In the face of potential new vaccine mandates, understanding the scope of a person's freedom to choose whether to take one or more COVID-19 vaccines, or any vaccine, is important both as a matter of individual liberty and privacy, and as an important public health concern.

Introduction	3
Background: Herd Immunity and the Vaccine Controversy	6
A. Achieving Herd Immunity	6
B. Vaccine Hesitancy as an Impediment to Herd Immunity	8
C. Exclusions to Vaccine Mandates May or May Not Hamper Herd Immunity.....	10
D. Recent Narrowing of Exemptions from Public School Immunization Requirements.....	11
E. Historic Resistance to Vaccines—The Jacobson Case	12
F. Anti-Vaccine Movements Began in Response to the Earliest Vaccines	15
G. Anti-Vaccine Concerns Persist	24
1. Vaccines Contain Dangerous Ingredients.	25
2. Conflicts of Interest With Vaccine Manufacturers.....	31
3. Escalating Vaccine Exposure for Children	34
4. No Valid Control Group for Vaccine Studies	36
The Right to Refuse Medical Treatment in Florida	37
Tension Between Individual Rights and State Protection of Public Welfare	43
A. Continued Viability and Applicability of Jacobson.....	43
1. Florida's Current Situation	45
2. Florida Constitutional Limits on Vaccine Mandates	48

3. Some Vaccines, Including the EUA Vaccines, Do Not Serve a Compelling State Interest	49
4. Narrow Tailoring: Vaccine Mandates Must Exempt the Medically Vulnerable to Survive Strict Scrutiny	53
5. Other States	55
6. Federal Preemption	58
B. A Post-Jacobson Restraint on Vaccine Mandates.....	59
C. Is the Supposed Tension Between Individual Autonomy and Public Health a False Tension Concerning Vaccine Mandates?	61
Conclusion.....	64
Epilogue	65

INTRODUCTION

In the face of potential vaccine mandates,¹ understanding the scope of a person's freedom to choose whether to take one or more SARS-CoV-2 (*Covid* or *COVID-19*) vaccines,² or any vaccine, is important both as a matter of individual liberty and privacy, and as an important public health concern. The purpose of this article is not to advocate for or against vaccines or to showcase the concerns about the latest vaccines that have been fast-tracked to the public to deal with the current pandemic. Plenty of those articles have already been written.³ Instead, this article is about

¹ Donna Rosato, *You Could Be Required to Get Vaccinated Against COVID-19*, CONSUMER REPS., <https://www.consumerreports.org/covid-19/you-could-be-required-to-get-vaccinated-against-covid-19-a1878931538/>, (last updated Apr. 01, 2021).

² SARS Cov-2 is the proper medical name for "COVID-19." *Basics of Covid 19*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html>, (last updated Nov. 4, 2021).

³ See Dennis Thompson, *Anti-Vaxxers Wage Campaigns Against COVID-19 Shots*, HEALTHDAY REP. (Jan. 29, 2021), <https://www.webmd.com/vaccines/covid-19-vaccine/news/20210129/anti-vaxxers-mounting-internet-campaigns-against-covid-19-shots>; Paul Vieira & Kim Mackrael, *Canada Urges Halt in Use of AstraZeneca COVID-19 Vaccine in People Under 55: Health Officials Revise Guidance Based on Reports of*

legal rights for adults to obtain or refuse vaccines and for parents to decide the timing or administration of any vaccine or group of vaccines proposed for their school-aged, preschool, newborn, or unborn children. In short, this article is about freedom—your right to choose what medical treatments are put into your body or your children's bodies.

Part II puts both sides of the vaccine controversy in context. It explains the concept of “herd immunity” as a justification for vaccine mandates (universal or at least widespread vaccinations). For over 100 years, the federal precedent has clearly allowed vaccine mandates; but the seminal Supreme Court decision, *Jacobson v. Massachusetts*, also makes it abundantly clear that the authority to mandate vaccines resides in the states.⁴ Part II explores the *Jacobson* case and the resistance to vaccine mandates that it spawned.⁵ This part also considers the federalization of many aspects of the vaccine program including transfer of the principle adjudication of vaccine cases to a federal Vaccine Court as a matter of first resort, federal efforts to enhance the United States' preparedness for pandemics through a more robust Strategic National Stockpile, and federal development of vaccines as pandemic countermeasures. It also explores more recent opposition of many groups who are concerned about the safety and efficacy of modern vaccines so that readers can appreciate the magnitude of the divide between public health officials and "anti-vaxxers."⁶

Blood-clotting Side Effects in Europe, THE WALL ST. J., https://www.wsj.com/articles/canada-to-recommend-halt-in-use-of-astrazeneca-covid-19-vaccine-in-people-under-55-11617046072?mod=business_lead_pos6 (last updated Mar. 29, 2021, 6:01 PM); Holly Elliot, *Mutations Could Render Current COVID Vaccines Ineffective in a Year or Less*, *Epidemiologists Warn*, CNBC: HEALTH & SCI., https://www.cnbc.com/2021/03/30/mutations-could-make-current-covid-vaccines-ineffective-soon-survey.html?__source=sharebar|linkedin&par=sharebar (last updated Mar. 30, 2021, 6:46 AM); Frank Jordans, *Germany to Restrict AstraZeneca Use in Under-60s Over Clots*, ASSOCIATED PRESS (Mar. 30, 2021), <https://abcnews.go.com/Health/wireStory/german-state-suspends-astrazeneca-vaccine-60s-76766477>.

⁴*Jacobson v. Massachusetts*, 197 U.S. 11, 24-5 (1905).

⁵Nicholas Mosvick, *On This Day, The Supreme Court Rules on Vaccines and Public Health*, NAT'L CONF. CTR.: CONST. DAILY (Feb. 20, 2021), <https://constitutioncenter.org/blog/on-this-day-the-supreme-court-rules-on-vaccines-and-public-health>.

⁶For the sake of convenience, I refer to the opponents of mandatory vaccination collectively as "anti-vaxxers" even though some are not opposed to all or even most vaccines.

Florida law will be examined in detail in Part III as Florida provides its citizens the clearest protection of individual freedom to decide whether to be vaccinated. Effective July 1, 2021, the State guarantees every citizen freedom of access to business and education regardless of Covid vaccination status. In addition, by and through its Constitution, Florida has guaranteed heightened protections for individual privacy, including self-determination over medical treatment. These broad protections have been evident in several areas, including the notorious *Schindler v. Schiavo* right to die cases.⁷ Florida also has a legislated "Patient Bill of Rights" that entitles patients to informed consent before making a medical decision.⁸ Part III of this Article highlights important Florida-specific protections regarding individual liberties and privacy that could be emulated by other states.

One way to protect individuals is to elevate state actions involving forced medical procedures from the rational basis test to a heightened level of scrutiny (strict scrutiny). Indeed, recent Florida legislation imposes strict scrutiny on local decisions to restrict individual liberties in the face of an emergency.⁹ Ultimately, whether the strict scrutiny test applies, or the rational basis test is used, often determines the outcome.¹⁰ For example, in *Jacobson*, the court essentially applied the rational basis test to find that the Massachusetts vaccine statute was rationally related to protecting the public health of the commonwealth, and Mr. Jacobson's liberty to be free from vaccination reasonably gave way to the needs of the public at large.¹¹

Part IV examines the erosion of individual liberty and privacy when states use the rational basis test to justify government intrusion into

⁷ Despite her parent's protests, extensive litigation spanning several years in both state and federal courtrooms, and an eleventh hour stay by Governor Jeb Bush of the withdrawal of life support, Terri Schiavo's husband (and guardian) was ultimately allowed to terminate her artificial life support based on his testimony that it reflected her wishes. *Schindler v. Schiavo*, 780 So.2d 176, 176-80 (Fla. Dist. Ct. App. 2001). See *Terri Schiavo: Timeline*, TERRI SCHIAVO, <https://terrischiavo.org/story/timeline/> (last visited Feb. 10, 2021); see also, ABC News, *Terri Schiavo Timeline*, ABC NEWS (Jan. 6, 2006, 8:13 AM), <https://abcnews.go.com/Health/Schiavo/story?id=531632&page=1>.

⁸ FLA. STAT. § 381.026(b) (2020).

⁹ FLA. STAT. § 252.38(4)(b) (2021).

¹⁰ See e.g., *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 227 (1995) ("Finally, we wish to dispel the notion that strict scrutiny is 'strict in theory, but fatal in fact.'"); see also *Moxie Owl, Inc. v. Cuomo*, 527 F. Supp. 3d 196, 201 (N.D.N.Y. 2021).

¹¹ *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905).

historically private decisions. It looks at the tension between an individual's freedom to make medical choices and the state's role in protecting public health and the welfare of its people with due consideration of those who may be most vulnerable to vaccines. The cases in New York and California highlight how legislative changes in those states curtail the autonomy of the individual under the rational basis test, limiting both religious freedom and failing to protect children and other vulnerable populations' legitimate medical concerns.

As these and other states are taking away religious exemptions and denying medical exemptions from vaccine mandates of school-aged children, it is important to understand the dynamics of constitutional and other protections for parents with medically vulnerable children or significant religious concerns.¹² Other states, by legislation or constitutional amendment of their state constitutions, could impose strict scrutiny or at least intermediate scrutiny to keep the government from overriding individual freedoms every time the state declares an emergency.

BACKGROUND: HERD IMMUNITY AND THE VACCINE CONTROVERSY

A. Achieving Herd Immunity

"The importance of extensive vaccination should not be understated—the efficacy of vaccination relies on the theory of 'herd immunity.'"¹³ According to the World Health Organization (hereafter "*WHO*"), "'Herd immunity', also known as 'population immunity', is the indirect protection from an infectious disease that happens when a population is immune either through vaccination or immunity developed through previous infection."¹⁴ The percentages required for herd immunity of a population either previously exposed to a disease or vaccinated against a disease varies based on the disease itself (frequently ranging from 80-95% of the concerned population being protected).¹⁵ At this point, it doesn't mean that it is scientifically impossible for anyone to contract the

¹² See *infra* notes 35-39 and accompanying text.

¹³ *Nikolao v. Lyons*, 875 F.3d 310, 316 (6th Cir. 2017) (citations omitted) (denying violations of Establishment and Free Exercise Clauses of the 1st Amendment when a vaccine waiver was granted to a Michigan mother based on her religious beliefs).

¹⁴ World Health Org., *Coronavirus Disease (COVID-19): Herd Immunity, Lockdowns and COVID-19*, WORLD HEALTH ORG., <https://www.who.int/news-room/questions-and-answers/item/herd-immunity-lockdowns-and-covid-19> (last updated Dec. 31, 2020).

¹⁵ *Id.*

disease; instead, it means that the occasional incidence of the disease does not pose a threat to the public at large because most of the population is immune.¹⁶ The flip side is that lacking population immunity, an isolated case can more easily be spread to others, potentially leading to an epidemic or pandemic outbreak of the disease.

It is unclear what percentage of individuals will be required for population immunity to Covid.¹⁷ "While people infected with the SARS-CoV-2 virus develop antibodies and immunity, we do not yet know how long it lasts."¹⁸ It was conservatively estimated that "a range of 60–75% immune individuals would be necessary to halt the forward transmission of the virus and community spread of the virus."¹⁹ More recently, Dr. Anthony Fauci estimated up to 90% of the populace would need to have been exposed to or vaccinated for COVID-19.²⁰ Of course, with COVID-19 vaccines only recently approved, the length of protection from these vaccines is also uncertain, especially as new strains of the virus are being detected. This uncertainty will only be resolved as information about the disease, and immunity provided by the vaccines further unfolds.

¹⁶ Compare with smallpox eradication (no continuing natural threat of the disease at all). Smallpox is the only infectious disease claimed to be eradicated/eliminated. World Health Org., *Smallpox*, WORLD HEALTH ORG., https://www.who.int/health-topics/smallpox#tab=tab_1 (last visited Feb. 11, 2022). WHO declares smallpox eradication is "the most notable and profound public health success in history." *Id.* The CDC points out: "Thanks to the success of vaccination, the last natural outbreak of smallpox in the United States occurred in 1949. . . and no cases of naturally occurring smallpox have happened since." *Smallpox*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/smallpox/index.html#:~:text=Thanks%20to%20the%20success%20of,occurring%20smallpox%20have%20happened%20since> (last updated July 12, 2017).

¹⁷ *Coronavirus Disease (COVID-19): Herd Immunity, Lockdowns and COVID-19*, WORLD HEALTH ORGANIZATION (Dec. 31, 2020), https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/herd-immunity-lockdowns-and-covid-19?gclid=Cj0KCQiApL2QBhC8ARIsAGMm-KF-DmA7NPPaIqwmvsPqVqmv43eY3O25O2n08u2V6eMIPis-85_eLAEaArn9EALw_wcB

¹⁸ *Id.*

¹⁹ Malik Sallam, *COVID-19 Vaccine Hesitancy Worldwide: A Concise Systematic Review of Vaccine Acceptance Rates*, 9(2) MDPI: VACCINES 160, Discussion at 4 (Feb. 16, 2021).

²⁰ Justine Coleman, *Rubio Criticizes Fauci for Raising herd immunity estimate to 90 percent*, THE HILL (Dec. 28, 2020, 12:52 PM), <https://thehill.com/homenews/senate/531829-rubio-slams-fauci-for-raising-his-herd-immunity-estimate-to-up-to-90-percent>.

The U.S. Food and Drug Administration (hereafter “FDA”) reviews the results of new vaccines in lengthy clinical trials before it approves or licenses a vaccine.²¹ Typically, the full approval process takes many years to complete and involves pre-clinical trials in animals.²² However, in circumstances where there is an urgent need for a vaccine, the FDA has an additional tool for more expedient review; this tool is called an Emergency Use Authorization (hereafter “EUA”).²³ Emergency review is not as thorough as a typical vaccine approval because it is done more quickly based on comparatively little clinical data.²⁴ Of course, a more thorough study would take longer and preclude the ability to get any emergency vaccine solution quickly to market. This language from the FDA explains the differences in approval processes:

The EUA process is different than FDA approval, clearance, or licensing because the EUA standard may permit authorization based on significantly less data than would be required for approval, clearance, or licensing by the FDA. This enables the FDA to authorize the emergency use of medical products that meet the criteria within weeks rather than months to years.²⁵

B. Vaccine Hesitancy as an Impediment to Herd Immunity

An important challenge to herd immunity for COVID-19 is related to the hesitancy of many people, including some health care workers, to get the new COVID-19 vaccines. Some people consider them experimental due to the rush to get them authorized for emergency use. Reluctance to be vaccinated is known as “vaccine hesitancy.” In a “systematic search of the [thirty-one English language] peer-reviewed

²¹ *COVID-19 Frequently Asked Questions*, FDA, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions> (last visited Feb. 11, 2022).

²² FDA, *Vaccines Development - 101*, FDA, <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101> (last visited Feb. 11, 2021).

²³ See e.g., FDA: Ctr. for Biologics Evaluation & Rsch., *Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry*, FDA (May 25, 2021) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

²⁴ FDA, *COVID-19 Frequently Asked Questions*, FDA <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions> (last visited Feb. 11, 2022).

²⁵ *Id.*

publications indexed in PubMed [as of] 25 December 2020," vaccine acceptance rates varied from a high of 97% in Ecuador to a low of 23.6% in Kuwait.²⁶ For the United States, vaccine acceptance estimates were just shy of 57% for adults in the general public.²⁷ "Only eight surveys among healthcare workers (doctors and nurses) were found, with vaccine acceptance rates ranging from 27.7% in the Democratic Republic of the Congo to 78.1% in Israel."²⁸ Although this study occurred soon after the first vaccines were available, the hesitancy of health professionals to be vaccinated showcases some medical concerns beyond the ordinary vaccine approval and production process. This should not be surprising given the accelerated development of COVID-19 vaccines and the abbreviated EUA procedures used to push the vaccines to market as soon as possible. Consumer Reports explained that most of the 27% of people who responded to their March 2021 survey cited safety concerns as the reason they are "not too likely" or "not at all likely" to get the COVID-19 vaccine.²⁹

If vaccine hesitancy stifles voluntary inoculations, there will likely be pressure to encourage higher voluntary participation and mandates for certain groups to be vaccinated. The longstanding tool used to induce vaccine compliance is school vaccination mandates. Since 1922, the U.S. Supreme Court has approved state vaccination requirements as a prerequisite for school attendance.³⁰

²⁶ Sallam, *supra* note 19.

²⁷ *Id.*; *KFF COVID-19 Vaccine Monitor: An ongoing research project tracking the public's attitudes and experiences with COVID-19 vaccinations*, KFF, https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/?utm_source=web&utm_medium=trending&utm_campaign=COVID-19-vaccine-monitor (last visited Feb. 11, 2022) (as of early March, 61% in U.S. had or want vaccine as soon as possible; the rate for healthcare workers mirrors the general populace with 17% who say they definitely will not get the vaccine or will get it only if required for their job).

²⁸ Sallam, *supra* note 19. (The United States was not mentioned.)

²⁹ Rosato, *supra* note 1. The Kaiser Foundation notes that Republicans are more likely to respond "Definitely Not" to the vaccine and only about half of all Republicans have been vaccinated so far compared to almost 80% of Democrats. *KFF COVID-19 Vaccine Monitor*, *supra* note 27 (Nevertheless, freedom to choose whether to be vaccinated is not a political issue so much as it is a legal issue).

³⁰ *Zucht v. King*, 260 U.S. 174, 176 (1922). Although such a mandate may be a square peg in a round hole concerning COVID-19 vaccines since the SARS-CoV-2 virus seems to have such little impact on youth. Ritwik Ghosh, Mahua J.

C. Exclusions to Vaccine Mandates May or May Not Hamper Herd Immunity

Where people can easily opt out of vaccine mandates, it might appear that exemptions and exclusions compromise or impede herd immunity. However, when a proven vaccine is available, most people will likely choose to get the vaccine rather than suffer the illness. In the face of more uncertainty, on the other hand, an exemption for the medically vulnerable, as well as religious and conscientious objectors, should not compromise herd immunity as many who do not choose the vaccine will likely develop natural immunity after contracting the disease. There should be greater buy in to vaccines and lower vaccine hesitancy as those choosing the vaccine appreciate that the medically vulnerable are protected from the vaccines. Since the exempt population will still face the epidemic threat, many will develop natural immunity from having the infections, which is vital to overall societal immunity. Remember, herd immunity has two chief components—vaccine immunity and natural immunity from those who have had the disease. This natural immunity is at least as protective against the virus as vaccine immunity. There is also a new "super-immunity" to COVID resulting from those who had Covid and at least one dose of the vaccines.³¹

Historically, most states recognized a couple of standard exclusions from the mandate to have a child fully vaccinated to be admitted to school.³² The two principal exemptions are given for medical reasons (high-risk patients) and due to religious objections.³³ Some states, like Florida, construe the religious exemption broadly. A parent or guardian is entitled to have the child declared exempt from immunization requirements if he or she "objects in writing that the administration of

Dubey, Subhankar Chatterjee, Souvik Dubey, Impact of COVID-19 on children: special focus on the psychosocial aspect, *Minerva Pediatrica* 2020 June;72(3):226-35 at 226-227, available at <https://www.minervamedica.it/en/journals/minerva-pediatrics/article.php?cod=R15Y2020N03A0226>.

³¹ Dr. Paul Carson, *COVID Delta Variant and Immunity/ Fr. James Kubicki, Life and Feast of St. Peter Claver*, RELEVANT RADIO (Sept. 9, 2021), <https://relevantradio.com/2021/09/dr-paul-carson-covid-delta-variant-and-immunity-fr-james-kubicki-life-and-feast-of-st-peter-claver/>.

³² Note, *Toward A Twenty-First-Century Jacobson v. Massachusetts*, 121 HARV. L. REV. 1820, 1825 (2008).

³³ *Id.* See also, *States with Religious and Philosophical Exemptions From School Immunization Requirements*, NAT'L CONF. OF STATE LEGISLATURES (Jan. 10, 2022) <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> (explaining that 45 states currently have religious exemptions and 15 have philosophical exemptions).

immunizing agents conflicts with his or her religious tenets and practices."³⁴ Fifteen states also explicitly allow an exemption for conscientious objectors based on philosophical concerns.³⁵

D. Recent Narrowing of Exemptions from Public School Immunization Requirements

In the past few years, the exceptions allowed for unvaccinated children to attend schools have been significantly narrowed. In 2015, California eliminated the right to refuse vaccines for religious reasons.³⁶ In 2019, Maine and New York followed suit, narrowing their waiver authority for compulsory school vaccines to documented medical vulnerabilities to the vaccines.³⁷ Notably, during a time when a measles outbreak was thought to be due to a lack of herd immunity in schools, New York responded by clamping down on exemptions.³⁸ In two cases decided in 2021, Federal District courts in New York dismissed cases where parents had letters from their children's doctors explaining and justifying the medical exemption to vaccination based on the safety of the child, but the treating physicians were overruled by the school board doctor who had never seen the children as patients.³⁹

Concerned parents who cannot qualify under state law for a vaccine waiver for their children face the chilling prospect of having to homeschool their child or children. As next discussed, in the past, states have also used even more draconian vaccine mandates to achieve population immunity—including criminalizing a refusal to be vaccinated.

³⁴ FLA. STAT. §1003.22(5)(a); *see also* *Dep't of Health v. Curry*, 722 So. 2d 874 (Fla. Dist. Ct. App. 1998). Department may not inquire "into the bona fides of the parent's or guardian's objection." *Id.* at 877-78.

³⁵ *States with Religious and Philosophical Exemptions*, *supra* note 33.

³⁶ Michael Martinez & Amanda Watts, *California Governor Signs Vaccine Bill that Bans Personal, Religious Exemptions*, CNN (June 30, 2015), <https://www.cnn.com/2015/06/30/health/california-vaccine-bill/index.html>.

³⁷ *States with Religious and Philosophical Exemptions*, *supra* note 33.

³⁸ *Doe v. Zucker*, 520 F. Supp. 3d 217, 230 (N.D.N.Y. 2021). (explaining tightening of New York vaccine exemption rules for school enrollment). *See also* *W.D. v. Rockland Cty.*, 521 F. Supp. 3d 358, 398 (S.D.N.Y. 2021) ("[N]o parent or guardian of a minor or infant under the age of 18, shall cause, allow, permit, or suffer a minor or infant under their supervision, to enter any place of public assembly in Rockland County, if that minor or infant is not vaccinated against measles for any reason other than being serologically immune to measles as documented by a physician, or prevented from receiving a measles vaccination for a medical reason documented by a physician, or because the infant is under the age of 6 months.").

³⁹ *Doe*, 520 F. Supp. 3d at 233; *W.D.*, 521 F. Supp. 3d at 374-75.

E. Historic Resistance to Vaccines—The Jacobson Case

There has been a long history of opposition to vaccines.⁴⁰ Even in the face of smallpox there was resistance to universal vaccination.⁴¹ *Jacobson* was one such case.

A father in Massachusetts was concerned about the safety of the smallpox vaccine and refused vaccination for himself and his son, fearing adverse reactions.⁴² While state law allowed children with medical concerns to opt out of the vaccine (sparing his son), it imposed a fine of five dollars on adults who refused to be vaccinated.⁴³ *Jacobson* faced criminal charges when he refused the vaccine and refused to pay the fine. He argued that the right to liberty in the Constitution and its Preamble protected him (through the Fourteenth Amendment) from this oppressive requirement. According to the court:

[*Jacobson*] insists that his liberty is invaded when the state subjects him to fine or imprisonment for neglecting or refusing to submit to vaccination; that a compulsory vaccination law is unreasonable, arbitrary, and oppressive, and, therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best; and that the execution of such a law against one who objects to vaccination, no matter for what reason, is nothing short of an assault upon his person.⁴⁴

The *Jacobson* court, however, felt that the individual's liberty interest was subordinate to the collective good of the commonwealth.⁴⁵ In our constitutional scheme, people surrender certain freedoms to the state in order to enjoy the benefits of protection of the common government.⁴⁶ *Jacobson* relied principally on previous decisions related to quarantines to restrict the spread of dangerous disease as grounds for superseding an individual's liberty for the sake of the public welfare. However, the justification for the constraint on liberty also rested in part upon the need

⁴⁰ Kim Tolley, *School Vaccination Wars: The Rise of Anti-Science in the American Anti-Vaccination Societies, 1879–1929*, 59 HIST. OF EDU. Q. 161-94 (2019).

⁴¹ *Id.* See also SUZANNE HUMPHRIES & ROMAN BYSTRIANYK, DISSOLVING ILLUSIONS: DISEASE, VACCINES, AND THE FORGOTTEN HISTORY, 80-82, 102-05 (2015) (more deaths from smallpox in the 20 years after compulsory vaccinations than the previous 20 years).

⁴² *Jacobson v. Massachusetts*, 197 U.S. 11, 13 (1905).

⁴³ *Id.* at 12.

⁴⁴ *Id.* at 26.

⁴⁵ *Id.* at 29.

⁴⁶ *Id.* at 27.

to make other sacrifices for the public good, such as compulsory service in the armed forces:

The liberty secured by the 14th Amendment, this court has said, consists, in part, in the right of a person 'to live and work where he will' (citations omitted); and yet he may be compelled, by force if need be, against his will and without regard to his personal wishes or his pecuniary interests, or even his religious or political convictions, to take his place in the ranks of the army of his country, and risk the chance of being shot down in its defense. It is not, therefore, true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the state, for the purpose of protecting the public collectively against such danger.⁴⁷

This is an important part of the decision because quarantines (while restricting liberty) do not invade an individual's body—an unwanted touching—for any unvaccinated person not wanting the shot. As argued by Jacobson, this unwanted touching amounts to an assault and battery upon an individual and an undesired intrusion into one's very self.⁴⁸ Tort laws and criminal laws otherwise prevent or deter such unwanted touching, so the justification in the *Jacobson* court's language above regarding compulsory military service allowed the court to intrude further into one's liberty rights than precedent supported from the quarantine cases alone.⁴⁹ Also, to the extent that vaccines might be harmful, compulsory military service creates the archetypal example of the government putting

⁴⁷ *Id.* 29-30.

⁴⁸ *Id.* at 26.

⁴⁹ Of course, there was no constitutional authority at that time protecting one's privacy to decide matters related to one's body as emerged in *Roe v. Wade* and the abortion cases sixty-five years later. *Roe v. Wade*, 410 U.S. 113 (1973), *modified*, *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). For other cases elucidating the federal constitutional right to privacy, *see Id.*; *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Cruzan v. Missouri Dept. of Health*, 497 U.S. 261 (1990) (no federal constitutional right to die). Although consideration of the federal right to privacy is beyond the scope of this article, it can't be said that *Jacobson* would necessarily be decided the same way today. *See generally*, *Jacobson*, 197 U.S. 11. The reasoning in *Cruzan*, deferring to the State in striking the balance between protecting life and protecting the patient's Fourteenth Amendment rights suggests that the states will continue to have a controlling say in the liberty and privacy of their people. *Cruzan*, 497 U.S. 261, 280; *Infra see* Part 2 where Florida's right to privacy is explained.

someone in harm's way—they may have to be shot in a much more deadly way than with a needle.

Perhaps this explains in part the refusal of the courts in *Jacobson* to even consider the evidence on the risks of vaccines.⁵⁰ The trial court rejected Jacobson's offer of proof from members of the medical profession that were prepared to testify that vaccination was of no value in preventing the spread of smallpox and that vaccinations cause other diseases to the body.⁵¹ In *Jacobson*, the court explained:

What everybody knows the court must know, and therefore the state court judicially knew, as this court knows, that an opposite theory accords with the common belief, and is maintained by high medical authority. We must assume that, when the statute in question was passed, the legislature of Massachusetts was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. It was not compelled to

⁵⁰ *Jacobson*, 197 U.S. at 34.

The following excerpt is quoted at length from *Jacobson* as it espouses the same view as many who are currently opposed to vaccination mandates:

The defendant offered to prove that vaccination “quite often” caused serious and permanent injury to the health of the person vaccinated; that the operation “occasionally” resulted in death; that it was “impossible” to tell “in any particular case” what the results of vaccination would be, or whether it would injure the health or result in death; that “quite often” one’s blood is in a certain condition of impurity when it is not prudent or safe to vaccinate him; that there is no practical test by which to determine “with any degree of certainty” whether one’s blood is in such condition of impurity as to render vaccination necessarily unsafe or dangerous; that vaccine matter is “quite often” impure and dangerous to be used, but whether impure or not cannot be ascertained by any known practical test; that the defendant refused to submit to vaccination for the reason that he had, “when a child,” been caused great and extreme suffering for a long period by a disease produced by vaccination; and that he had witnessed a similar result of vaccination, not only in the case of his son, but in the cases of others.

Id. at 36.

⁵¹ *Id.*; see also HUMPHRIES & BYSTRIANYK, *supra* note 41, at 80-81 (graphs showing spikes in smallpox deaths in 1871-1872 (16 years after Smallpox vaccine mandates were enacted in Massachusetts) and again in 1901).

commit a matter involving the public health and safety to the final decision of a court or jury.⁵²

While we do not decide, and cannot decide, that vaccination is a preventive of smallpox, we take judicial notice of the fact that this is the common belief of the people of the state, and, with this fact as a foundation, we hold that the statute in question is a health law, enacted in a reasonable and proper exercise of the police power.⁵³

F. Anti-Vaccine Movements Began in Response to the Earliest Vaccines

After *Jacobson*, the movement against vaccines escalated and the Anti-Vaccination League of America (hereafter “AVLA”) was founded.⁵⁴ The AVLA espoused the principle that:

[H]ealth is nature’s greatest safeguard against disease and that therefore no State has the right to demand of anyone the impairment of his or her health [and AVLA aimed] to abolish oppressive medical laws and counteract the growing tendency to enlarge the scope of state medicine at the expense of the freedom of the individual.⁵⁵

The League warned about what it believed to be the dangers of vaccination and allowing the intrusion of government and science into private life.⁵⁶ Notably, the initial board members of the AVLA included at least four doctors.⁵⁷

Although some opposition to vaccines continued into the 1920s, in 1922, the U.S. Supreme Court decided that states have the authority to bar unvaccinated students from attending school in the interest of public safety.⁵⁸ This *Hobson's choice* likely motivated many parents to allow their children to be vaccinated. In addition, “by the early 1930s, concerns over the safety of vaccines had waned, as the public widely accepted

⁵² *Jacobson*, 197 U.S. at 35.

⁵³ *Id.*

⁵⁴ Tolley, *supra* note 40. Tolley notes that earlier organizations with similar names existed before the *Jacobson* case—dating back to the late 1800s. *Id.* (Explaining the Anti Vaccine Society of America, for example, was established in New York in 1885.)

⁵⁵ Mosvick, *supra* note 5.

⁵⁶ Tolley, *supra* note 40.

⁵⁷ *Id.*

⁵⁸ *Zucht v. King*, 260 U.S. 174, 176-77 (1922).

physicians' recommendations about the efficacy of vaccines."⁵⁹ Eventually, all fifty states had compulsory vaccination laws for schoolchildren.⁶⁰ Widespread public acceptance and compliance with the school vaccine requirements continued for several decades.⁶¹

There was no comprehensive federal program to immunize America's children until 1962 with the passage of the *Vaccine Act*.⁶² After the Vaccine Act was passed, the federal government took an ever-increasing role in advocating for vaccinations and, with the exception of smallpox, adding vaccines to the Center for Disease Control (hereafter "CDC") schedule of child vaccines.

The CDC develops recommended vaccine schedules based on input from the Advisory Committee on Immunization Practices (hereafter "ACIP").⁶³ The ACIP is made up of public health experts. By 1995, vaccines to prevent nine childhood illnesses were routinely administered.⁶⁴ Many of the vaccines protected against multiple illnesses, such as Measles, Mumps, and Rubella (hereafter "MMR"); manufacturers created products that could be given in one shot instead of multiple separate shots.⁶⁵ The ACIP generally encourages the use of such combination vaccines to

⁵⁹ Note, *supra* note 32; *see also*, *Jacobson v. Massachusetts*, 197 U.S. 11, 23-24 (1905) ("[F]or nearly a century most of the members of the medical profession have regarded vaccination, repeated after intervals, as a preventive of smallpox; that, while they have recognized the possibility of injury to an individual from carelessness in the performance of it, or even in a conceivable case without carelessness, they generally have considered the risk of such an injury too small to be seriously weighed as against the benefits coming from the discreet and proper use of the preventive; and that not only the medical profession and the people generally have for a long time entertained these opinions, but legislatures and courts have acted upon them with general unanimity.").

⁶⁰ Note, *supra* note 32.

⁶¹ *Id.* at 1825-26.

⁶² *Id.*; Alan R. Hinman et al., *Vaccine-Preventable Diseases, Immunizations, and MMWR--1961-2011*, CDC (Oct. 7, 2011), <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a9.htm> [The Vaccine Act (Section 317 of the Public Health Service Act) was designed to "achieve as quickly as possible the protection of the population, especially of all preschool children...through intensive immunization activity over a limited period of time . . ."].

⁶³ Advisory Committee on Immunization Practices (ACIP), *General Committee-Related Information*, CDC <https://www.cdc.gov/vaccines/acip/committee/index.html>. (last visited Feb. 11, 2022).

⁶⁴ The Coll. of Physicians of Phila.: The Hist. of Vaccines, *The Development of the Immunization Schedule*, <https://www.historyofvaccines.org/content/articles/development-immunization-schedule> (last updated Nov. 10, 2021).

⁶⁵ *Id.*

reduce the number of injections patients received and to improve overall vaccine coverage rates.⁶⁶

Through the 1970s and early 1980s, people became increasingly concerned about vaccine safety and numerous lawsuits were brought against vaccine manufacturers by people who believed they had been injured by the diphtheria, pertussis, and tetanus (“DPT”) vaccine.⁶⁷ As a result of damages awarded to the victims and the prospect of future liability, some vaccine manufacturers halted production and others dramatically increased prices to account for potential future liability.⁶⁸ “A vaccine shortage resulted, and public health officials became concerned about the return of epidemic disease.”⁶⁹

Congress responded to the above cost and liability concerns in 1986, with the *National Childhood Vaccine Injury Act* (hereafter “*the Act*”).⁷⁰ The Act took effect on October 1, 1988, and basically allowed manufacturers to avoid liability for any vaccine-related injuries or illnesses so long as the manufacturer adequately warned the patients about

⁶⁶ Sara Oliver & Kelly Moore, *Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus influenzae Type b Conjugate, and Hepatitis B Vaccine, and Guidance for Use in Infants*, CDC (Feb. 7, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm> (approving a new combination vaccine addressing six illnesses in one shot).

⁶⁷ *Vaccine Safety, Overview, History, and How the Safety Process Works*, CDC <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html> (last visited Feb. 11, 2022).

⁶⁸ *Id.* (A 1993 report published in the *Journal of the American Medical Association* favored a causal connection between several maladies, such as a causal relation between diphtheria and tetanus toxoids and Guillain-Barré syndrome and brachial neuritis, and found a causal connection had been established between measles vaccine and death from measles vaccine, between measles-mumps-rubella vaccine and thrombocytopenia and anaphylaxis, between oral polio vaccine and poliomyelitis and death from polio vaccine, and between hepatitis B vaccine and anaphylaxis; the report found the evidence did not favor a causal connection between the vaccines and several other injuries, that there was insufficient evidence to accept or reject a causal relation to thirty-three vaccine-related adverse events, and that there was no evidence of causation related to five vaccine-related adverse events.); see also KR Stratton et. al., *Adverse Events Associated with Childhood Vaccines Other Than Pertussis and Rubella: Summary of a Report from the Institute of Medicine*, 271 *JAMA* 1602–05, (1994).

⁶⁹ *Vaccine Safety, Overview, History, and How the Safety Process Works*, *supra* note 67.

⁷⁰ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10 to 300aa-34).

the potential side effects of the vaccine.⁷¹ In exchange, the Act allowed the U.S. government to make payments for cases approved through a new, special, Vaccine Court.⁷²

The vaccine claim process was supposed to be faster and cheaper for the victims than litigation, and the Act capped liability at \$250,000 for pain and suffering or death.⁷³ Plaintiffs were precluded from suing vaccine manufacturers until the vaccine claims process had been completed.⁷⁴ Under the Act, the government was directed to come up with a table of compensable injuries.⁷⁵ Sometimes these injuries are called "unavoidable" injuries because some small percentage of the vaccinated public will be allergic to the vaccine or suffer some other infrequent but predictable response. Identified injuries occurring within the time periods specified in the Vaccine Injury Table are called "Table Injuries," and these injuries require no showing that the vaccine caused the adverse effect:

[A] petitioner must prove either:

⁷¹ See 42 U.S.C.A. §§ 300aa-22(b) (West 2021). "No vaccine manufacturer shall be liable . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings . . . a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title." *Id.* at 300aa-22(b)(1)-(2); see also *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

⁷² UNITED STATES COURT OF FEDERAL CLAIMS, VACCINE CLAIMS/OFFICE OF SPECIAL MASTERS, <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Mar. 25, 2022) ("It establishes the Vaccine Program as a no-fault compensation program whereby petitions for monetary compensation may be brought by or on behalf of persons allegedly suffering injury or death as a result of the administration of certain compulsory childhood vaccines.")

⁷³ *Id.* "Congress intended that the Vaccine Program provide individuals a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation." *Id.* In conjunction, 42 U.S.C. §300aa-15 establishes the compensation limits. 42 U.S.C.A. §300aa-15 (West 1993). These damages are in addition to compensation for lost wages and medical expenses. 42 U.S.C.A. §300aa-15(a)(1) (West 2021).

⁷⁴ 42 U.S.C.A. § 300aa-11(2)(A) (West 2021). The largest vaccine injury award was \$101 million in a Vaccine Court case for a table injury. MCTLAW, *\$101 Million Award for Encephalopathy from MMR Vaccine*, <https://www.mctlaw.com/101-million-dollar-vaccine-injury-mmr/> (last visited Feb. 11, 2022).

⁷⁵ 42 U.S.C.A. § 300aa-14 (West 2021); 42 C.F.R. § 100.3 (2017) (Vaccine injury table).

(1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table— corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative,

(2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”)

[citations omitted].⁷⁶

On the other hand, when an injury is not listed on the table, plaintiffs bear the burden of proving that the vaccine *actually* caused their injury or illness.⁷⁷

By the turn of the 21st century, concerns about a link between immunizations and autism began to rise precipitously. This 2004 University of Michigan Law Journal excerpt explains the phenomenon:

Antivaccination sentiment is growing fast in the United States, in large part due to the controversial and hotly disputed link between immunizations and autism. The internet worsens fears regarding vaccination safety, as at least a dozen websites publish alarming information about the risks of vaccines. Increasing numbers of parents are refusing immunizations for their children and seeking legally sanctioned exemptions instead, apparently fearing vaccines more than the underlying diseases that they protect against. A variety of factors are at play: religious and philosophical beliefs, freedom and individualism, misinformation about risk, and overperception of risk.⁷⁸

Since the CDC and industry have always disavowed any link between immunizations and autism, autism is not considered a "Table Injury," meaning claimants alleging autism injuries from vaccine exposure need to prove actual causation.⁷⁹ Of course, *causation* and *correlation* are two different things. A parent's testimony and a child's medical records can show a *correlation* between the timing of the vaccine and their children's manifestation of illness. Indeed, in a pool of only one child with one illness coincident with the child receiving a vaccination, the

⁷⁶ 42 U.S.C.A. §§ 300aa-11(a), (c)(1)(C)(i)-(ii) (West 2021).

⁷⁷ 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii) (West 2021).

⁷⁸ Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 353 (2004).

⁷⁹ *Science Summary: CDC Studies on Thimerosal in Vaccines*, CDC, <https://www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf> (last visited Feb. 11, 2022) (listing nine CDC studies from 2003-2009 where no link between autism and thimerosal was found).

correlation is 100%. As a result of this strong correlation, many parents will never be convinced that their child's illness was not caused by the vaccine.

Nevertheless, even a 100% correlation alone cannot prove causation. In the Omnibus Autism Proceedings before the Vaccine Court, the court was considering literally thousands of cases where parents were alleging autism was caused by one or more vaccines or excipients.⁸⁰ The Office of Special Masters for the Vaccine Court has a summary of the test cases and general causation theories advanced by the Petitioners' Steering Committee created to help in managing the process.⁸¹

At the risk of oversimplification, three theories were initially advanced by the Petitioners Steering Committee to prove causation: (1) the MMR vaccine alone causes autism; (2) MMR vaccine in conjunction with thimerosal (from other vaccines) causes autism; and (3) thimerosal alone causes autism.⁸² The first theory was eventually dropped since three test cases concerning the second theory were going forward, and the second theory subsumed the first in these test cases.⁸³

In refuting the link between autism and vaccines, the CDC looks at epidemiological data comparing reactions and non-reactions of numerous

⁸⁰ *Cedillo v. Sec'y of Health & Hum. Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. 2009); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328 (Fed. Cir. 2010); *see also* Lauren L. Haertlein, *Immunizing Against Bad Science: The Vaccine Court and the Autism Test Cases*, 75 L. & CONTEMP. PROBS. 211, 219 (2012). (More than 5,000 cases will be impacted by the *Cedillo* decision).

⁸¹ *For Background Use Only, The Autism Proceedings*. U.S. CT. OF FED. CLAIMS (2010), https://www.usfc.uscourts.gov/sites/default/files/vaccine_files/autism_background.2010.pdf; *See Autism Decisions and Background Information*, U.S. CT. OF FED. CLAIMS, <https://www.usfc.uscourts.gov/autism-decisions-and-background-information> (last visited Feb. 11, 2022) (audio recordings of each case).

⁸² *For Background Use Only, supra* note 81. [For a more detailed discussion of the opposition to thimerosal and certain vaccines; *see infra* Subpart (C)(1) below (the DTP vaccine at the time contained thimerosal and parents may have likely had their children vaccinated against both MMR and DTP).]

⁸³ More detailed examination of the legal issues in these cases and the science involved has been addressed in earlier law review articles (both before and after the omnibus autism cases were finally decided) and is beyond the scope of this paper. *See e.g.* Helia Hull, *Induced Autism: The Legal and Ethical Implications of Inoculating Vaccine Manufacturers from Liability*, 73 CAPITAL UNIV. L. REV., 1, 34-36 (2005); Haertlein, *supra* note 80 at 219; Mary S. Holland et. al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENV'T L. REV., 480, 482 (2011).

children in response to the vaccines and excipients as evidence undermining causation.⁸⁴ If a million children received the vaccine, and only one child developed an illness after the vaccine, the odds that the vaccine caused the illness would only be one in a million (1×10^{-6}).

In a vaccine injury case, causation is especially difficult to prove for several reasons. First, the vaccine manufacturers are in control of most of the data from which causation might be established (the clinical trials and any follow-up monitoring they undertake). Some opposed to mandatory vaccinations note that industry is both selective and misleading concerning their actual scientific findings since data can be hidden and the reports shared with the government can be manipulated.⁸⁵ Second, toxins are ubiquitous in our society, making it difficult or impossible to determine which toxic exposure(s) resulted in injury.⁸⁶ Americans are exposed daily to many different chemicals—pesticides, herbicides, preservatives, color and flavor enhancers, artificial sweeteners, chlorides and fluorides, microplastics, water and air pollutants. For example, glyphosate is now thought to cause cancer and perhaps other disorders and glyphosate is found in most of the food Americans eat.⁸⁷ Third, cumulative effects from multiple vaccines, including multiple doses spread over time, may make it impossible to show which vaccine or shot in a vaccine series triggered a disorder. Finally, latent effects are all but impossible to prove because a compensable vaccine injury must be proximate in time to receiving the vaccination.⁸⁸

⁸⁴ See e.g., *Science Summary*, *supra* note 79.

⁸⁵ See e.g. Brian Hooker et. al., *Methodological Issues and Evidence of Malfeasance in Research Purporting to Show Thimerosal in Vaccines Is Safe*, 2014 BIOMED RES INT. 1, 2-3 (2014).

⁸⁶ See generally, GERALD W. BOSTON & M. STUART MADDEN, LAW OF ENVIRONMENTAL AND TOXIC TORTS: CASES, MATERIALS, AND PROBLEMS, 4-16 (West Group, 2nd ed. 2001) (discussing difficulty in proving toxic tort causation).

⁸⁷ Beth Sissons, *Can Weed Killers Containing Glyphosate Cause Cancer?*, MedicalNewsToday (Sep. 20, 2021), <https://www.medicalnewstoday.com/articles/does-roundup-cause-cancer>. See also 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. 1-12 (2017); Alexis Temkin & Olga Naidenko, *Glyphosate Contamination in Food Goes Far Beyond Oat Products*, EWG (Feb. 28, 2019), <https://www.ewg.org/news-insights/news/glyphosate-contamination-food-goes-far-beyond-oat-products>.

⁸⁸ *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1328 (Fed. Cir. 2010) (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

In theory and early practice, the burden of proof on causation was meant to require that plaintiffs merely tip the scales ever so slightly in favor of the claimants because these cases were meant to be quick and easy, even allowing a plaintiff to appear *pro se*.⁸⁹ However, as later cases have shown, the Vaccine Court process has been neither quick nor easy.⁹⁰ This is likely due in large measure to the Federal Circuit Court of Appeals articulation in *Althen v. HHS* of a three-prong test to prove causation for non-table cases. *Althen* requires proof of “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.”⁹¹

As the need for medical proof of causation has risen to prove all three prongs, so has the time and cost to pursue a vaccine case. By the time the Omnibus Autism Cases were litigated, there were numerous experts enlisted by both the government and the plaintiffs, and the reliance on

⁸⁹ See e.g. *Knudsen v. Sec'y of Dep't of Health & Hum. Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (medical certainty was not required to prove causation, only a logical connection between the vaccination and the injury was needed).

⁹⁰ See e.g., *Poling ex rel. Poling v. Sec'y of Health & Hum. Servs.*, No. 02-1466V, 2011 WL 678559 (Fed. Cl. 2011) (case was filed in 2002; decided in favor of Poling in July, 2010; and \$155,000.00 in attorneys' fees and costs were awarded in January, 2011). Poling was a Table Case where DOJ conceded liability without conceding causation (see extract below). *Id.* at *1. A fully litigated trial on causation could be more lengthy and more expensive based on the need for expert witnesses and the fiercely disputed issue of whether the MMR vaccine causes autism. *Id.* at *1. “Respondent conceded that petitioners are entitled to compensation based on a determination that she suffered an injury identified on the Vaccine Injury Table, specifically, a presumptive MMR vaccine-related injury of an encephalopathy. Hannah’s encephalopathy eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela. Based on the persuasive factors supporting petitioner’s vaccine claim and respondent’s election not to challenge petitioner’s claim, the undersigned issued a decision finding that petitioner is entitled to compensation under the Vaccine Program on July 21, 2010, and awarding damages.” *Id.* at *1.

⁹¹ *Althen*, 418 F.3d at 1278-79 (once plaintiffs meet their burden, to avoid damages the government has to show some other more plausible cause for the injury.)

medical evidence to meet the above *Althen* burden resulted in over 3,000 pages of transcripts and 500 pages of briefs in the *Cedillo* case alone.⁹²

By 2007, there had been 4,800 cases brought in Vaccine Court alleging autism injuries from the MMR vaccine and/or from thimerosal (an ingredient then widely used in vaccines).⁹³ Proponents of the safety of the MMR vaccine and thimerosal suggested the court was clogged with these cases because of the reliance on misguided information from some scientists.⁹⁴ By 2010, the Vaccine Court had consolidated and resolved all of the autism cases concluding that plaintiffs had failed to meet their burden of proof to demonstrate causation.⁹⁵

Meanwhile, at the end of 2005, the government created an even greater immunity shield for vaccine manufacturers operating under EUAs.⁹⁶ In an emergency, because they are required to bring vaccines to production before they are approved by the FDA, the vaccine manufacturers opportunity to fully validate the safety and effectiveness of their vaccines is necessarily curtailed so that vaccines can get to market quickly enough to meet the public health crisis. As a result, in such a situation (as we now face for COVID-19), “*the plaintiff shall have the burden of proving by clear and convincing evidence . . . willful misconduct caused death or serious physical injury.*”⁹⁷ These EUA vaccines cannot be mandated, but anyone injured by an authorized emergency vaccine has recourse to the Vaccine Court.⁹⁸ With the much higher burden of proof, however (both regarding clear and convincing evidence versus preponderance for an approved vaccine and willful misconduct versus reckless or negligent misconduct), it's not surprising that no reported injury case has ever been decided in favor of a person volunteering to take an EUA vaccine.⁹⁹

⁹² *For Background Use Only, supra* note 81 (Collectively, in the three test cases, 28 experts testified and 939 medical articles were filed.).

⁹³ Paul A. Offit, *Thimerosal, A Cautionary Tale*, 357 N. ENGL. J. MED. 1278, 1279 (2007).

⁹⁴ *Id.*

⁹⁵ *Vaccine Claims/Office of Special Masters*, U.S. CT. OF FED. CLAIMS, <https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Feb. 11, 2022).

⁹⁶ 42 U.S.C.A. § 247d-6d (West 2020) (codified Public Readiness and Emergency Preparedness Act).

⁹⁷ *Id.*

⁹⁸ 42 U.S.C.A. § 247d-6e (West 2020).

⁹⁹ A thorough search by the author of the claims court yielded no results for Emergency Use Authorization vaccine, emergency, or EUA.

The most recent vaccine-related legislation was passed in 2019 under the Trump Administration.¹⁰⁰ The “Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019” specifically updated procedures to help defend America against a pandemic, including shoring up the Strategic National Stockpile.¹⁰¹ Significantly, it allowed for expedited spending in the face of a pandemic emergency to, among other things, “facilitate and accelerate, as applicable advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to the public health emergency or potential public health emergency. . . .”¹⁰² Countermeasures include vaccines.¹⁰³ Section 302 of the new law also expanded the range of emergency medical contracting to include “ancillary medical supplies to assist with the utilization of such countermeasures.”¹⁰⁴

G. *Anti-Vaccine Concerns Persist*

For the sake of convenience, I refer to those concerned about current vaccinations and the CDC vaccine schedule collectively as *anti-vaxxers*, even though not all who are concerned about vaccines are opposed to all or even most vaccines.¹⁰⁵ Many, especially medical practitioners that support the right of parents to choose their own vaccine schedule, are in favor of most vaccines, but question the CDC vaccine schedule and the prudence of purposely introducing so many toxins into young children and

¹⁰⁰ Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub.L. 116-22 Title II, § 926, June 24, 2019 Stat. 1379 (to be codified in scattered sections of 42 U.S.C.).

¹⁰¹ *Id.*

¹⁰² *Id.* at § 206(1)(C) (to be codified at 42 U.S.C. § 247d(2)).

¹⁰³ 42 U.S.C. § 247d(2) (West 2019).

¹⁰⁴ Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub.L. 116-22 Title II, § 302, June 24, 2019 Stat. 1379 (to be codified in scattered sections of 42 U.S.C. § 300hh–10).

¹⁰⁵ Toni Bark & Gregory Glaser, *Best Practices for Physicians Recommending a Medical Exemption to Vaccination, Physicians for Informed Consent*, PHYSICIANS FOR INFORMED CONSENT (2019), <https://physiciansforinformedconsent.org/wp-content/uploads/2020/03/Bark-and-Glaser-Best-Practices-for-Physicians-Writing-a-Medical-Exemption-to-Vaccination.pdf>. (Physicians for Informed Consent advocates that doctors advise patients of vaccine risks and make decisions regarding vaccines or obtaining vaccine exemptions based on the patient's individual circumstances.)

pregnant women—ultrasensitive classes of patients.¹⁰⁶ Others favor most or all vaccines but question the latest vaccines as inherently more unpredictable and intrusive than past vaccines.¹⁰⁷ Those in the naturopathic community continue to oppose mandatory vaccinations for the same reasons raised by the AVLA in the late 1800s and early 1900s. Vaccines introduce known toxins into an otherwise healthy person; the individual and community's resilience against disease is better fostered by being exposed to and overcoming the disease itself than through universal vaccination, and the government is invading an area that should be left to individual choice.¹⁰⁸ These positions are explained more fully below.

1. Vaccines Contain Dangerous Ingredients.

One of the complaints of the AVLA and the petitioner in *Jacobson* was that vaccines inject harmful agents into healthy people. A vocal minority of doctors and scientists then and now continue to disagree with the fundamental premise that vaccines are safe and effective. Perhaps, if the FDA and CDC emphasized that *most vaccines are mostly safe and effective for most people*, the government message would not be so hard to swallow for victims of vaccine injuries. The more than four billion dollars paid by the Vaccine Court to date is tangible evidence that vaccines

¹⁰⁶ See e.g., Cornelia Franz, *Common Sense Pediatrics*, THE FRANZ CTR, <https://www.thefranzcenter.com/common-sense-pediatrics/> (last visited Feb. 12, 2022). Dr. Franz proposes this alternative vaccine schedule to parents who want their children to be able to go to school:

- 12 months DtaP
- 15 months HIB
- 18 months DTaP
- 24 months DTaP or Prevnar (only need one Prevnar after age 2)
- 27 months IPV or Prevnar
- 30 months IPV
- 36 months MMR
- 48 months DTaP booster and IPV booster
- 5 years Whatever was not done at age 4.
- And we recommend the blood test to check for antibody response. The reality is that we need fewer vaccines than are even listed here. . . .

Id.

¹⁰⁷ Bark & Glaser, *supra* note 105.

¹⁰⁸ Tolley, *supra* note 40; see also HUMPHRIES & BYSTRIANYK, *supra* note 41.

are dangerous to some people as well as a tacit admission that not all vaccine risks can be avoided.¹⁰⁹

One might have thought that the Omnibus Autism Proceedings laid to rest the issue of whether vaccines or thimerosal cause or contribute to the risk of autism. Nothing could be further from the truth. Vocal opponents of mercury additives continue to research the adverse effects of thimerosal. Notably, these opponents include Robert F. Kennedy, Jr. (son of Senator and U.S. Attorney General Bobby Kennedy and nephew of President John F. Kennedy), then Chair of the World Mercury Project (which is now the Children's Health Defense Organization, hereafter Children's Health Defense or "*CHD*").

According to Children's Health Defense:

Concerned citizens owe it to themselves and family members to be as educated as possible when it comes to these toxicants, many of which are contained in vaccines. Even very low-level exposures can induce symptoms identical to those of many devastating psychological, neurological and behavior conditions in children and adults injuring the sensory, immune, gastrointestinal and central nervous systems, kidneys and other organs, and interfering with critical cellular pathways. And, it's not just toxins driving the epidemics. According to the latest research, the body's own reaction to a vaccine, i.e., immune activation, is enough to trigger conditions like autism and auto-immunity. Scientists from around the world are sounding alarms and voicing grave concerns about the poor health impact of vaccines and the need for vaccine safety and regulatory oversight.¹¹⁰

The earliest autism cases were noted in the 1930s.¹¹¹ This corresponds to the point in time when mercury was first used in vaccines.¹¹² When parents of children with autism found out that mercury was an ingredient in their child's vaccine, it is no surprise that, in addition

¹⁰⁹ Leah Durant, *VICP Compensation Surpasses \$4 Billion in 2020*, VACCINE ATTORNEY-VACCINE BLOG (Oct. 19, 2020) [https://vaccinelaw.com/lawyer/2020/10/19/Filing-a-Claim/VICP-Compensation-Surpasses-\\$4-Billion-in-2020_bl41040.htm](https://vaccinelaw.com/lawyer/2020/10/19/Filing-a-Claim/VICP-Compensation-Surpasses-$4-Billion-in-2020_bl41040.htm).

¹¹⁰ *Science Library*, CHILDREN'S HEALTH DEF., https://childrenshealthdefense.org/research-database/?itm_term=home (last visited Feb. 12, 2022).

¹¹¹ *Vaccine Safety: Thimerosal*, CDC, <https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html> (last visited Feb 12, 2022).

¹¹² *Science Library*, *supra* note 110.

to alleging the vaccine caused their children's injuries, they also attacked the ingredient thimerosal as a potential cause.¹¹³

Mercury was first used as an “adjuvant,” an ingredient added to vaccines to “enhance the immune reaction to the vaccine.”¹¹⁴ Adjuvants are known toxins chosen for their ability to provoke a response from the body to fight against the disease.¹¹⁵ Mercury (in the form of thimerosal) and aluminum have most frequently been used as adjuvants; aluminum is the prevalent adjuvant currently being used in the U.S.¹¹⁶ Both mercury and aluminum are known as xenobiotic, because they are not naturally found in the body.¹¹⁷ As a result, the body must begin to generate antibodies to oppose this toxic invasion.¹¹⁸ This triggered response is important and intentional to the efficacy of some vaccines that don't produce an immune response by exposure to the active component of the vaccine alone, because a “non-response” by the body to the vaccine means no antibodies would be created; and hence the vaccinated individual would receive no protection from the threat.¹¹⁹

Other vaccine additives are used to “stabilize and prolong the shelf-life of the vaccine (stabilizers) and preserve the vaccine components (preservatives).”¹²⁰ Collectively, these additives are known as

¹¹³ See e.g., *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328 (Fed. Cir. 2010).

¹¹⁴ Ananya Mandal, *Vaccine Excipient*, NEWS MED. LIFE SCI., <https://www.news-medical.net/health/Vaccine-Excipients.aspx> (last updated June 5, 2019).

¹¹⁵ *Vaccine Safety: Adjuvants*, CDC, <https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html> (last visited Feb. 11, 2022). An adjuvant is purposely designed to trigger or enhance an immune response “strong enough to protect the person from the disease he or she is being vaccinated against.” *Id.* Adjuvanted vaccines can cause more adverse reactions than vaccines without adjuvants. *Id.*

¹¹⁶ *Id.*; see also *Excipients in Vaccines Per 0.5 mL Dose*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, INSTITUTE FOR VACCINE SAFETY, <https://www.vaccinesafety.edu/components-Excipients.htm> (last visited Feb. 12, 2022).

¹¹⁷ José G. Dórea, *Exposure to Mercury and Aluminum in Early Life: Developmental Vulnerability as a Modifying Factor in Neurologic and Immunologic Effects*, *Int. J. Environ. Res. Public Health* 2015, 12, 1295-1313 at Abstract, Conclusion; doi:10.3390/ijerph120201295; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4344667/pdf/ijerph-12-01295.pdf>.

¹¹⁸ *Id.* at 1297.

¹¹⁹ *Vaccine Safety: Adjuvants*, *supra* note 115 (FAQ, what is an adjuvant).

¹²⁰ Mandal, *supra* note 114.

excipients.¹²¹ Although no longer used as an adjuvant in the United States, thimerosal is still being used as a preservative.¹²² It is intended to prevent bacteriological contamination where multiple doses of vaccines are produced and stored in the same vial; it is not found (in more than trace amounts) in the individual-dose vaccines.¹²³ The discrete individual-dose vials are sterile until use and then discarded after use, unlike the multiple-dose vials which are used over and over again; they are handled and stored for subsequent uses after the vial has been exposed to the air and to syringes from earlier uses.¹²⁴ When used as an excipient in a vaccine, the resulting vaccine is still roughly 50% by weight thimerosal.¹²⁵

Methyl mercury (which is typically related to consumption of large fish, such as tuna) is highly toxic to infants and children, so it stands to reason that ethyl mercury, or mercury found in other compounds, might also adversely affect the neurological system of a fetus, newborn, or infant child.¹²⁶ Children's Health Defense lists over a dozen peer-reviewed studies relating ethyl mercury (thimerosal) to autism and other neurological impairments.¹²⁷

The CDC has continuously denied any causal connection between thimerosal and autism.¹²⁸ Thimerosal is *ethyl* mercury, and it was used as an adjuvant in the United States prior to 2001.¹²⁹ The CDC asserts that *ethyl* mercury is biologically different than *methyl* mercury and, instead of bioaccumulating, it is quickly eliminated from the body.¹³⁰ In addition, the CDC cites to numerous studies in the United States and abroad that show that vaccines with thimerosal are safe and effective.¹³¹ It is also important to note that in addition to input from the ACIP, the CDC also solicits and receives approval from numerous pediatric and medical organizations before modifying the vaccine schedule.¹³²

¹²¹ *Id.*

¹²² *Vaccine Safety: Thimerosal and Vaccines*, *supra* note 111.

¹²³ *Excipients in Vaccines*, *supra* note 116.

¹²⁴ *Vaccine Safety: Thimerosal and Vaccines*, *supra* note 111.

¹²⁵ *Science Library*, *supra* note 110.

¹²⁶ 42 U.S.C.A. §§ 11001-11050 (West 2001) (mercury is very toxic) (guidance for reporting toxic chemicals: mercury and mercury compounds).

¹²⁷ *Science Library*, *supra* note 110.

¹²⁸ *Vaccine Safety: Thimerosal*, *supra* note 111.

¹²⁹ *See id.*

¹³⁰ *Id.*

¹³¹ *See, e.g., Science Summary*, *supra* note 79.

¹³² *Immunization Schedules: Child & Adolescent Immunization Schedule, Recommended Child and Adolescent Immunization Schedule for Ages 18 Years*

"In July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure."¹³³ In 2012, the WHO banned all mercury compounds in whatever form *except thimerosal*.¹³⁴ The exception for thimerosal was based on its use as a preservative in third world countries that lack refrigerated storage facilities; nevertheless, the quantity by weight of mercury in those exposed to thimerosal remains the same (whether the substance is used as an adjuvant or a stabilizer or a preservative).¹³⁵ At .25 mg per shot, it is 125 times higher than the maximum contaminant level for mercury in drinking water.¹³⁶

Although aluminum has not drawn as much attack as thimerosal, aluminum is thought to contribute to Alzheimer's Disease or neurological symptoms indistinguishable from Alzheimer's Disease.¹³⁷ However, the controversy over whether aluminum *causes* Alzheimer's Disease or not is potentially as contentious and unresolved as the thimerosal allegations discussed already.¹³⁸ The CDC emphasizes that aluminum has safely been used in vaccines for decades.¹³⁹ The Agency for Toxic Substances and Disease Registry (ATSDR) likewise explains that consumption of

or Younger, United States, 2021, CDC <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-hib> (last visited Feb, 12, 2022). The schedule is approved by the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists (ACOG), American College of Nurse-Midwives (ACN), American Academy of Physician Assistants (AAPA), and National Association of Pediatric Nurse Practitioners (NAPNAP)). *Id.*

¹³³ *Vaccine Safety: Thimerosal*, *supra* note 111.

¹³⁴ Rebecca Kessler, *Global Treaty to Curb Mercury—Except When It Comes to Children's Vaccines*, FairWarning.Org., June 27, 2013 available at <https://www.fairwarning.org/2013/06/global-treaty-to-curb-mercury-except-when-it-comes-to-childrens-vaccines/>

¹³⁵ *Id.*

¹³⁶ *National Primary Drinking Water Regulations*, EPA <https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations> (last updated Jan. 26, 2022).

¹³⁷ IOS Press, *Aluminum is intricately associated with the neuropathology of familial Alzheimer's disease*, SCI. DAILY (Apr. 9, 2021), <https://www.sciencedaily.com/releases/2021/04/210409124748.htm>.

¹³⁸ WebMD, *Controversial Alzheimer's Disease Risk Factors*, WEBMD (Jan. 19, 2021), <https://www.webmd.com/alzheimers/guide/controversial-claims-risk-factors>.

¹³⁹ *Vaccine Safety: Adjuvants*, *supra* note 115.

aluminum in small quantities is safe for most people.¹⁴⁰ The ATSDR notes, however, that people with kidney problems and premature children are especially vulnerable to aluminum toxicity and so, these groups should avoid all aluminum exposure.¹⁴¹

Although the FDA could take a more cautious approach and ban thimerosal or aluminum outright in vaccines for pregnant women and newborn children, it is unlikely to do so since some vaccines need the help of an adjuvant to trigger an antigen response, and the FDA still allows limited consumption of methyl mercury from fish by pregnant women despite scientific evidence of its threat.¹⁴² Consumer Reports, on the other hand, advises no consumption of methyl mercury or mercury in any form for this vulnerable group.¹⁴³

The laundry list of other vaccine ingredients such as: formaldehyde, fetal tissue from aborted fetuses, bovine and other animal tissues, and other chemicals also raises alarm bells in the anti-vaxxer community.¹⁴⁴ Dr. Theresa Deisher, founder and lead scientist for the Sound Choice Pharmaceutical Institute asserts that, “[n]ot only are the human fetal contaminated vaccines associated with autistic disorder throughout the world, but also with epidemic childhood leukemia and lymphomas.”¹⁴⁵ She also notes that the FDA failed to analyze the safety of DNA being used in vaccines, and instead capped the amount of fetal DNA allowed in vaccines at ten nanograms—a level that independent labs demonstrate has been vastly exceeded in practice.¹⁴⁶ Many people who are aware of the use of aborted fetuses, oppose vaccines containing these tissues on ethical and

¹⁴⁰ U.S. DEP’T OF HEALTH & HUM. SERV., PUB. HEALTH SERV., AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, *Toxicological Profile for Aluminum* (2008), at 1,5 <https://www.atsdr.cdc.gov/ToxProfiles/tp22.pdf>.

¹⁴¹ *Id.* at 5.

¹⁴² FDA, U.S. Dep’t of Health & Hum. Serv., *FDA and EPA issue final fish consumption advice*, FDA (Jan. 18, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537362.htm>.

¹⁴³ *Too much tuna, too much mercury: Consumer Reports says the country needs stricter guidelines*, CONSUMER REP. (Apr. 30, 2015), <https://www.consumerreports.org/cro/magazine/2015/06/too-much-tuna-too-much-mercury/index.htm>.

¹⁴⁴ *Safety Concerns*, SOUND CHOICE PHARM. INST., <https://soundchoice.org/vaccines/safety-concerns/> (last visited Feb. 12, 2022) (“It is well understood scientifically that primitive human DNA fragments when injected into a person could 1) activate the immune system and potentially trigger and autoimmune reaction in genetically susceptible people and 2) insert into the genome of blood forming stem cells causing mutations.”).

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

religious grounds. But most people are simply unaware that some vaccines contain these components.¹⁴⁷

Even if a vaccine with some of these additives is totally safe, mishandling and contamination in production and distribution could lead to adverse events.¹⁴⁸ In March of 2021, the New York Times (hereafter “NYT”) reported one such mishap when a subcontractor of Johnson & Johnson mixed their vaccine with the AstraZeneca vaccine being processed at the same plant:

Vaccine production is a notoriously fickle science, and errors are often expected to occur and ruin batches. But Emergent’s mistake went undiscovered for days until Johnson & Johnson’s quality control checks uncovered it, according to people familiar with the situation. By then, up to 15 million doses had been contaminated. . . .¹⁴⁹

So why would the government continue to use Emergent Biosciences for the strategic national stockpile vaccines? Additional concerns about this manufacturer’s “too friendly” and “too influential” relations with politicians are discussed next.

2. Conflicts of Interest With Vaccine Manufacturers

Earlier in 2021, investigative journalists with the NYT exposed a pattern of incestuous relationships between current and former Emergent employees and consultants and government officials responsible for purchasing Emergent Bioscience’s vaccines.¹⁵⁰ Anti-vaxxers note that numerous vaccine manufacturers have revolving doors with their

¹⁴⁷ *Id.*; *Vaccines*, SOUND CHOICE PHARM. INST., <https://soundchoice.org/vaccines/> (last visited Feb 12, 2022) (opposing use of aborted fetus induced to be born alive so the fetal lung tissue and organs could be harvested alive to host a new vaccine cell line).

¹⁴⁸ See HUMPHRIES & BYSTRIANYK, *supra* note 41, at 102-05 (contaminated vaccines from cows used for both vaccine production and eating resulted in epidemics of foot and mouth disease in New England in 1870, 1880, 1884, and 1902 causing many to believe that the vaccines contaminated with diseased bovine materials were promoting disease in vaccinated children).

¹⁴⁹ Sharon LaFraniere & Noah Weiland, *Johnson & Johnson’s Vaccine is Delayed By a U.S. Factory Mix Up*, N.Y. TIMES (May 12, 2021), <https://www.nytimes.com/2021/03/31/world/johnson-and-johnson-vaccine-mixup.html> (Federal officials attributed the mistake to human error).

¹⁵⁰ Chris Hamby & Sheryl Gaye Stolberg, *How One Firm Put an “Extraordinary Burden” on the U.S.’s Troubled Stockpile*, N.Y. TIMES (Mar. 8, 2021), <https://www.nytimes.com/2021/03/06/us/emergent-biosolutions-anthrax-coronavirus.html>.

employees going back and forth between employment with the drug manufacturer and the federal government.¹⁵¹ The NYT article also noted how Emergent provides political donations to members of both parties sitting on committees with control over national public health stockpile decisions.¹⁵² Emergent reportedly spends three million dollars a year on political lobbying (the same as other much larger vaccine makers).¹⁵³ Many, including Emergent Biosciences, hire former Congressional representatives and their staffers as their lobbyists.¹⁵⁴

Additionally, anti-vaxxers are quick to point out that the studies relied upon by the CDC are biased in favor of the drug companies that perform them or fund them.¹⁵⁵ They also note the strong bias for government reviewers to “play ball” with the vaccine manufacturers; specifically, the revolving door between the CDC and lucrative job opportunities in the pharmaceutical industry, which could put a damper on CDC research and reporting that casts a negative light on those companies' vaccines.¹⁵⁶ For example, former CDC Chair, Julie Gerberding, who became the President of Merck's Vaccine division, has particularly been targeted for her conflict of interest and alleged lies and cover-up of the

¹⁵¹ Gayle DeLong, *Conflicts of Interest in Vaccine Safety Research*, 19 ACCOUNTABILITY IN RESCH. 65, 70 (2012); VAXXED: FROM COVER UP TO CATASTROPHE (Cinema Libre Studios 2016).

¹⁵² VAXXED: FROM COVER UP TO CATASTROPHE (Cinema Libre Studios 2016).

¹⁵³ Hamby & Stolberg, *supra* note 150.

¹⁵⁴ *Id.*; DeLong, *supra* note 151, at 70.

¹⁵⁵ DeLong, *supra* note 151, at 74 (researchers investigating their employers' products are more likely to find results favorable to their employer as a result of researcher bias); *Researcher Bias*, AM. PSYCH. ASS'N, <https://dictionary.apa.org/researcher-bias> (last visited Feb. 12, 2022) ("researcher bias, is any unintended errors in the research process or the interpretation of its results that are attributable to an investigator's expectancies or preconceived beliefs."). In modern parlance, we might refer to such unconscious bias as "implicit" bias. Pressure to maintain corporate funding for research may be another form of implicit bias. Of course, conscious manipulation sometimes also occurs as in the tobacco industry studies alleging cigarettes were not addictive and Johns Manville's cover-up of the hazards of asbestos. DELONG, *supra* note 151, at 74, (bias in tobacco injury studies); Matt Mauney, *Johns Manville*, Asbestos.com, <https://www.asbestos.com/companies/johns-manville/> (last visited Feb.25, 2022). For a detailed story of the litigation exposing the hazards of asbestos and leading to the trust fund for mesothelioma victims see PAUL BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL *PASSIM* (Pantheon Books, 1985).

¹⁵⁶ DeLong, *supra* note 151, at 67. *See also* Hamby & Stolberg, *supra* note 143, (former Emergent BioSolutions consultant is now federal decision-maker for anthrax, smallpox and other vaccines in the Strategic Stockpile).

CDC study of the Merck MMR vaccine while she was CDC chair.¹⁵⁷ Merck had a monopoly on the MMR vaccine, so Gerberding faced an overwhelming conflict of interest with her potential future employer if the CDC admitted any link to autism associated with Merck's MMR vaccine.¹⁵⁸

While vaccine concerns have been discussed in scientific and academic circles for over twenty years (and increasingly over the internet and through special interest groups of parents with children who have autism), these concerns gained more widespread public attention in the wake of the 2016 Movie—*Vaxxed: From Cover Up to Catastrophe* [hereafter "*Vaxxed*"].¹⁵⁹ One of the "stars" in *Vaxxed*, and perhaps the chief critic of the CDC, is Dr. Brian Hooker, who currently serves as Chair of the Science and Math Department at Simpson University in Redding California.¹⁶⁰ Hooker surreptitiously recorded CDC researcher, Dr. William Thompson, in conversations where Thompson admitted the CDC covered up the results of the study he performed linking the MMR vaccine to autism in African American boys under the age of three.¹⁶¹

Hooker became active in the autism community in 2004 after his son's tragic vaccine reaction drove him to investigate whether there might be a connection between the vaccine and his son's subsequent development of autism.¹⁶² For the past sixteen years, he has been researching the effects of vaccines on children in general and the adverse effects of thimerosal and the MMR vaccine in particular.¹⁶³ Like many who have seen their normal healthy children change from normal to autistic overnight after a bad reaction to a vaccine, it is unlikely he will ever believe that the CDC is being forthright in its examination of the risks of vaccines.

¹⁵⁷ Delong, *supra* note 151, at 70.

¹⁵⁸ Delong, *supra* note 151, at 70 (it is alleged Gerberding lied to Congress and covered up the causal connection discovered by then chief scientist William Thompson when investigating the MMR vaccine); *VAXXED*, *supra* note 145.

¹⁵⁹ *VAXXED*, *supra* note 145; Laurie Tarkan, *Why Robert De Niro Promoted – Then Pulled – Anti-Vaccine Documentary*, FORTUNE (Mar. 29, 2016 at 11:40 AM), <https://fortune.com/2016/03/29/robert-de-niro-anti-vaccine-documentary/>.

¹⁶⁰ *Simpson Univ. Academic Affairs*, SIMPSON UNIV., <https://simpsonu.edu/Pages/Academics/Academic-Affairs/Academic-Affairs-Team.htm> (last visited Feb. 27, 2022).

¹⁶¹ *VAXXED*, *supra* note 152.

¹⁶² *Id.*

¹⁶³ *See e.g.*, Hooker et. al., *supra* note 854.

3. Escalating Vaccine Exposure for Children

There were only seven vaccines on the CDC Schedule in 1970.¹⁶⁴ In the 1980s, protection against these seven diseases could be obtained in as few as three shots for children between zero and six years old.¹⁶⁵ In the 1990s, the CDC introduced vaccines for children against two diseases that are not rampant in children—Hepatitis B and the sexually transmitted disease (“STD”) Human Papilloma Virus (“HPV”).¹⁶⁶ In 1991, the CDC added Hepatitis B to the schedule with the shot to be administered to children at birth, before the child was released from the hospital.¹⁶⁷ The CDC also started recommending multiple doses of vaccines, including Hepatitis B at various intervals for better protection.¹⁶⁸ These changes ramped up the number of required vaccines in the CDC schedule, as well as resistance to the schedule by some parents and pediatricians.¹⁶⁹ As discussed earlier, the proliferation of vaccines and the suspected link to autism caused the vaccine injury complaints with the Vaccine Court to skyrocket.

On the current CDC schedule, children are scheduled to receive more than twenty shots with vaccines addressing fourteen different illnesses before they are fifteen months old.¹⁷⁰ Many parents cannot fathom why a newborn baby (other than one born from a mother with Hepatitis B) would need a Hepatitis B vaccine before they even leave the hospital or why a nine-year-old would need an HPV vaccine to protect against STDs.¹⁷¹ These concerns contribute to vaccine hesitancy and undermine the credibility of CDC claims that children need all of these shots. Physicians

¹⁶⁴ The Coll. of Physicians of Phila.: The Hist. of Vaccines, *The Development of the Immunization Schedule*, <https://www.historyofvaccines.org/content/articles/development-immunization-schedule> (last updated Nov. 10, 2021).

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* See *Vaccines for Children Program (VFC): VFC-ACIP Vaccine Resolutions*, CDC <https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html> (last updated July 10, 2019).

¹⁶⁷ CDC, *Newborn Hepatitis B Vaccination Coverage Among Children Born January 2003—June 2005—United States*, 30 MMWR WKLY. 825 (Aug. 1, 2008), [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5730a3.htm#:~:text=Hepatitis%20B%20vaccine%20was%20first,the%20United%20States%20\(1\).](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5730a3.htm#:~:text=Hepatitis%20B%20vaccine%20was%20first,the%20United%20States%20(1).)

¹⁶⁸ The Coll. of Physicians of Phila., *supra* note 164.

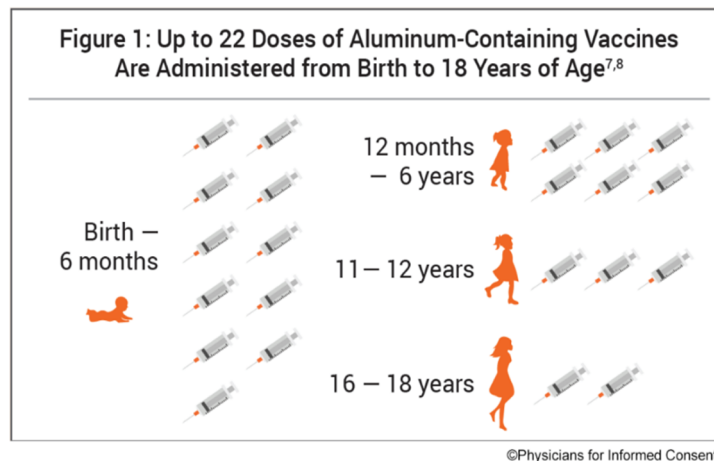
¹⁶⁹ See Franz, *supra* note 106 (Dr. Franz’s recommended alternate vaccine schedule).

¹⁷⁰ *Immunization Schedules*, *supra* note 132.

¹⁷¹ *Immunizing Against HPV*, WORLD HEALTH ORG., <https://www.who.int/activities/immunizing-against-hpv> (last visited Feb. 12, 2022) (WHO recommends HPV vaccinations before age 15).

for Informed Consent notes on its webpage that these sexually transmitted diseases are not communicable at school, so vaccine restrictions on school attendance should not be mandated for these vaccines.¹⁷²

Furthermore, the cumulative impact of adjuvants and other vaccine additives could result in reaching a neurological tipping point in individuals with other toxic metal exposures.¹⁷³ The FDA, however, looks individually at each new vaccine instead of considering the toxic load of all the vaccines collectively administered to the individual over his or her lifetime (cumulative impact analysis). Physicians for Informed Consent produced the following figure to illustrate the amount of aluminum received by a child following the CDC vaccine schedule.¹⁷⁴



¹⁷² Bark & Glaser, *supra* note 1054.

¹⁷³ Hamed Jafari Mohammadabadi et al., *The Relationship Between the Level of Copper, Lead, Mercury and Autism Disorders: A Meta-Analysis*, 11 PEDIATRIC HEALTH, MED. & THERAPEUTICS 369, 369-378 (2020); Nitika Singh, *Synergistic Effects of Heavy Metals and Pesticides in Living Systems*, FRONTIERS IN CHEMISTRY (Oct. 11, 2017), <https://doi.org/10.3389/fchem.2017.00070> (A 2017 study demonstrates the synergistic adverse effects of pesticides, mercury, and lead in interference with ordinary neural development.).

¹⁷⁴ *Education: Aluminum Vaccine Risk Statement (VRS)*, PHYSICIANS FOR INFORMED CONSENT, <https://physiciansforinformedconsent.org/aluminum-in-vaccines/> (last visited Feb. 12, 2022).

4. No Valid Control Group for Vaccine Studies

Some hazards of vaccines, such as the risk of anaphylaxis have been widely known,¹⁷⁵ but in its approval process, the FDA does not require a comparison of the effects of a proposed vaccine to that of an unvaccinated person or a group administered only a saline shot (a true placebo group, which is the scientific standard for all other drug approvals); rather, the proponent often tests a vaccine excipient without the vaccine's active agent as its "placebo" or uses a different vaccine or series of vaccines as a comparator for the control group.¹⁷⁶ Anti-vaxxers complain that this is not an honest comparison and argue that the FDA should compare vaccinated individuals with those who have not been exposed to the adjuvant or the active component of the vaccine.¹⁷⁷

One group study of nonvaccinated individuals showed that only 6% of children in the unvaccinated group experienced chronic conditions (like asthma, ADHD, autism, and even cancer) compared with 27% of America's vaccinated children.¹⁷⁸ The same study claims vaccinated adults are nine and one-half times more likely to have chronic conditions and forty-three times more likely to have two chronic conditions compared to the unvaccinated.¹⁷⁹

¹⁷⁵ *Vaccine Safety: Vaccine Adverse Event Reporting System (VAERS)*, CDC, <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html> (last visited Feb. 12, 2022) (CDC and FDA track adverse responses to vaccines in the Vaccine Adverse Event Response System (VAERS) (VAERS is a reporting platform only and is not designed to determine if a vaccine caused a health problem); *About VAERS: Background and Public Health Importance*, VAERS, <https://vaers.hhs.gov/about.html> (last visited Feb. 12, 2022) (Nevertheless VAERS publishes a "reportable events table" that lists conditions believed to be caused by vaccines.); *VAERS Table of Reportable Events Following Vaccination*, VAERS, https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf (last visited Feb. 12, 2022) (the laundry list of diseases that VAERS considers reportable events includes more diseases and conditions (like arthritis), than the Vaccine Injury Table for the Vaccine Court discussed *supra* notes 72-76 and accompanying text). See CDC WONDER: *About The Vaccine Adverse Event Reporting System (VAERS)*, CDC <http://wonder.cdc.gov/vaers.html> (last visited Feb. 12, 2022) (59,979 Serious Incidents reported in VAERS).

¹⁷⁶ Brian S. Hooker & Neil Z. Miller, *Analysis of Health Outcomes in Vaccinated and Unvaccinated: Developmental Delays, Asthma, Ear Infections and Gastrointestinal Disorders*, 8 SAGE OPEN MED., 1, 1 (2020).

¹⁷⁷ Mawson et al., *supra* note 87.

¹⁷⁸ *Id.* at 3-4.

¹⁷⁹ *Id.* at 4.

Another study, published in 2020, compared children who were unvaccinated in their first twelve months with those that had been vaccinated one or more times before their first birthday.¹⁸⁰ The odds of vaccinated children developing autoimmune problems, such as ear infections, gastrointestinal disorders, and asthma, were two to six times as high (depending on the number of vaccines given and the timing of the vaccinations) as children who were never vaccinated.¹⁸¹ Vaccinated children also experienced two to three and one-half times the rate of developmental delays as nonvaccinated children.¹⁸²

THE RIGHT TO REFUSE MEDICAL TREATMENT IN FLORIDA

Based upon concerns about mercury and the other additives and active agents in vaccines, parents and pregnant women should thoughtfully consider whether and when to vaccinate their children based upon the precautionary principle and the unique circumstances of each child, as opposed to the “one size fits all” methodology imposed by the current CDC vaccine schedule.¹⁸³ Of course, such autonomy is predicated on a parent’s right to “just say no” to their doctor’s recommendations—a right, in turn, dependent upon the parent’s right to refuse medical treatment for themselves and their children. This right is currently protected, if at all, by state law.

In its support of Massachusetts’ right to mandate smallpox vaccinations for all adults, the *Jacobson* court stated:

The authority of the state to enact this statute is to be referred to what is commonly called the police power, a power which the state did not surrender when becoming a member of the Union under the Constitution. Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a state to enact quarantine laws and ‘health laws of every description’ [*sic*]. . . .¹⁸⁴

¹⁸⁰ Hooker & Miller, *supra* note 176.

¹⁸¹ *Id.* at 7 (Tables 8 and 9).

¹⁸² *Id.* (Table 8 comparison of 12-24 months of age).

¹⁸³ In the face of unknowns, particularly risky and irreversible situations where scientists don’t know what they don’t know, the precautionary principle shifts the burden of proof to the proponent to demonstrate that a proposed action is safe.

¹⁸⁴ *Jacobson v. Massachusetts*, 197 U.S. 11, 24-25 (1905).

In Florida, there is a constitutional right to choose or refuse medical treatment.¹⁸⁵ In *Satz v. Perlmutter*, the Florida Supreme court upheld a well-reasoned opinion of the Fourth District Court of Appeals allowing an individual with ALS (Lou Gehrig's Disease) the right to die.¹⁸⁶ The Fourth District Court of Appeals rested its decision on the "constitutional right to privacy . . . an expression of the sanctity of individual free choice and self-determination."¹⁸⁷

The federal government has a similar right to refuse medical treatment that extends to the states as a constitutional right through the Fourteenth Amendment.¹⁸⁸ The federal right, however, is predicated on liberty—the right to do as you choose—whereas the Florida right is predicated on privacy—the right to be left alone. Federal law thus:

affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing and education. . . . These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.¹⁸⁹

However, Florida Constitution Article I, section 23 provides: "Right of privacy—Every natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein."¹⁹⁰

The privacy right in Florida is arguably more pervasive than the right to liberty, because liberty rights are often curtailed when balancing the

¹⁸⁵ *Satz v. Perlmutter*, 379 So. 2d 359, 360 (Fla. 1980) ("As people seek to vindicate their constitutional rights, the courts have no alternative but to respond." [citing FLA. CONST. art. I, § 23] (right to privacy)). *See also*, FLA. STAT. ANN. § 381.026(4)(b)(4) (West 2021) ("A patient has the right to refuse any treatment based on information required by this paragraph, except as otherwise provided by law.").

¹⁸⁶ *Satz v. Perlmutter*, 362 So. 2d 160, 164 (Fla. Dist. Ct. App. 1978).

¹⁸⁷ *Id.* at 362 So. 2d. 160, 164 (Fla. Dist. Ct. App. 1978).

¹⁸⁸ *Cruzan v. Mo. Dept. of Health*, 497 U.S. 261, 278 (1990) ("The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.") (citing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)). *See also* *Roe v. Wade*, 410 U.S. 113, 152–53 (1973) (identifying activities relating to marriage, procreation, contraception, family relationships, child rearing, and education as fundamental to "the concept of ordered liberty.").

¹⁸⁹ *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

¹⁹⁰ FLA. CONST. art. I, § 23 (No exceptions are identified in Article I, section 23, so any limitations would arise from other constitutional protections.).

rights and liberties of one person with those of another or society at large.¹⁹¹ It is sometimes said that one person's right to do what they please extends only so far as they do not unreasonably interfere with another person's rights. This other-centered dimension of “Liberty” makes liberty concerns external as well as internal. Zoning and nuisance laws, for example, rely on this simple principle—some individual rights must be sacrificed for the harmony of society as a whole.

On the other hand, the right to privacy is innate to the individual so there is less (or no) need to restrain one person's privacy for the benefit of others. Privacy rights are inherently internal, but sometimes respecting these rights may have external consequences (as in a pandemic, for example). Unlike the tension between one person's liberty and the collective liberty and property rights of others that are often balanced, a privacy analysis should never resort to simple balancing under the rational basis test. Unlike the balancing approach used in *Jacobson*, and the deference to state legislatures to strike the right balance (rational basis test), when it comes to constitutionally protected privacy interests, there is no balancing—the individual's right prevails unless the government proves a narrowly limited intrusion is warranted by compelling government interests (strict scrutiny).

The commentary to Florida Constitution Article I explains: “Section 23 was added to the Florida Constitution in 1980 to provide a state right of privacy, *requiring the state to justify the reasonableness of intrusions upon personal privacy.*”¹⁹² Florida cases have confirmed that the Florida right to privacy is powerfully protective against governmental intrusion.¹⁹³ “Since the people of this state exercised their prerogative and enacted an amendment to the Florida Constitution which expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it can only be concluded that the right is much broader in scope than that of the Federal Constitution.”¹⁹⁴ In 2017, the Florida Supreme Court went so far as to hold that “the Florida Constitution attaches during the life of a citizen and is not retroactively destroyed by death.”¹⁹⁵

¹⁹¹ See *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905).

¹⁹² West's F.S.A. Const. art. 1 § 23 Commentary to 1980 Addition (West 1980) (emphasis added).

¹⁹³ See e.g., *Winfield v. Div. of Pari-Mutuel Wagering, Dep't of Bus. Regul.*, 477 So. 2d 544, 548 (Fla. 1985).

¹⁹⁴ *Weaver v. Myers*, 229 So. 3d 1118, 1126 (Fla. 2017) (quoting *Winfield*, 477 So. 2d at 548).

¹⁹⁵ *Id.* at 1141.

Of course, the right to privacy in Florida is not absolute. Instead, once an individual demonstrates her privacy is threatened, the burden shifts to the government to prove a compelling justification for intruding on this right and must prove it “accomplishes its goal through the use of the least intrusive means.”¹⁹⁶ In other words, strict scrutiny applies. Unlike the rational basis test for most state actions, which only requires that the state have a rational basis justifying its restrictions,¹⁹⁷ strict scrutiny is much more likely to result in a finding that a state law is unconstitutional.¹⁹⁸

Regarding privacy protected by section 23 of the Florida Constitution, the “[Florida Supreme] Court consistently has required that any law intruding on this right is presumptively unconstitutional and must be justified by a ‘compelling state interest,’ which the law serves or protects through the ‘least restrictive means.’”¹⁹⁹ This strict scrutiny has now been mimicked in the 2021 legislation as a requirement for every Florida local government imposing emergency pandemic restrictions, such as curfews:

Notwithstanding any other law, an emergency order issued by a political subdivision must be *narrowly tailored to serve a compelling public health or safety purpose*. Any such emergency order must be limited in duration, applicability, and scope in order to reduce any infringement on individual rights or liberties to the greatest extent possible.²⁰⁰

¹⁹⁶ *Winfield*, 477 So.2d at 547 (“The right of privacy does not confer a complete immunity from governmental regulation and will yield to compelling governmental interests.”).

¹⁹⁷ Where the claimed right is not fundamental, rational basis review is applied, and the governmental regulation need only be reasonably related to a legitimate state objective.”; *See Reno v. Flores*, 507 U.S. 292, 303–06 (1993).

¹⁹⁸ *Moxie Owl v. Cuomo*, 527 F. Supp. 3d. 196, 201 (N.D.N.Y. 2021) (“Other [than heightened scrutiny cases], involve executive actions that, by precedent, are viewed only through the lens of a modest, or ‘rational basis,’ standard of review. And nearly without exception, courts in these cases have appropriately deferred to the judgment of the executive in question.”).

¹⁹⁹ *Gainesville Woman Care LLC v. State*, 210 So.3d 1243, 1268-69 (Fla. 2017) (citations omitted). “[T]here is no threshold requirement that a petitioner must show by “sufficient factual findings” that a law imposes a significant restriction on a woman’s right of privacy before strict scrutiny applies to laws that implicate the right of privacy. Any law that implicates the right of privacy is presumptively unconstitutional, and the burden falls on the State to prove both the existence of a compelling state interest and that the law serves that compelling state interest through the least restrictive means.” *Id.* at 1256 (citations omitted).

²⁰⁰ S.B. 2006 (Fla. 2021) (see 844-51) (emphasis added).

After implementing the constitutional protection of individual privacy rights, Florida subsequently codified a “Patient’s Bill of Rights,” which includes a patient’s right to informed consent and the right to refuse any medical treatment “except as otherwise provided by law.”²⁰¹ The caselaw explains that the right derives from a concept of self-determination:²⁰²

An individual has a fundamental right to be left alone so that he is free to lead his private life according to his own beliefs free from unreasonable governmental interference. Surely nothing, in the last analysis, is more private or more sacred than one's religion or view of life, and here the courts, quite properly, have given great deference to the individual's right to make decisions vitally affecting his private life according to his own conscience. It is difficult to overstate this right because it is, without exaggeration, the very bedrock on which this country was founded.²⁰³

Informed consent is essential for each patient to be able to exercise his or her patient rights.²⁰⁴ The legislative purpose justifying the Patient's Bill of Rights states:

It is the purpose of this section to promote the interests and well-being of the patients of health care providers and health care facilities and to promote better communication between the patient and the health care provider. It is the intent of the Legislature that health care providers understand their responsibility to give their patients a general understanding of the procedures to be performed on them and to provide information pertaining to their health care so that they may make decisions in an informed manner after considering the information relating to their condition, the available treatment alternatives, and substantial risks and hazards inherent in the treatments.²⁰⁵

Although the federal government has emergency authority in a declared pandemic to pre-empt state laws regarding vaccines or other countermeasures to fight the pandemic, in that situation all of the vaccine

²⁰¹ FLA. STAT. ANN. § 381.026(4)(b)(4) (West 2021).

²⁰² See e.g., *In re Guardianship of Browning*, 568 So. 2d 4, 10-12 (1990) (citing *Pub. Health Trust v. Wons*, 541 So. 2d 96, 97 (Fla.1989) (upholding Jehovah’s witness right to refuse life-saving blood transfusion).

²⁰³ *Wons*, 541 So. 2d at 97. See also *Cruzan v. Mo. Dept. of Health*, 497 U.S. 261, 279, 305 (1990) (noting strong common law liberty right to informed consent).

²⁰⁴ See e.g., FLA. STAT. ANN. § 381.026 (4)(b)(3) (West 2021).

²⁰⁵ FLA. STAT. ANN. § 381.026(3) (West 2021).

choices must be optional and based on informed consent of the volunteers.²⁰⁶ As a result, while the federal law in such an emergency situation may preempt state law, it would not compromise a Floridian's ability to choose whether to receive the emergency use vaccine or not.

This right to refuse medical treatment has been extended by statute and caselaw to allow a proxy with legal capacity to speak for the rights of a patient lacking capacity.²⁰⁷ The infamous Florida case involving Terri Schiavo resulted in the court allowing removal of life sustaining medical treatment based on Schiavo's previous oral expression of those wishes to her husband.²⁰⁸ A Florida living will serves the same purpose; communicating to the family, friends, the medical community and, if necessary, the courts what the individual has determined is in her best interest.²⁰⁹

Another valuable health care advanced directive is the health care surrogate. When an individual signs a health care surrogate, she agrees the surrogate may communicate her desires to obtain or withhold medical treatment in the event she is unable to speak for herself.²¹⁰ Florida hospitals and other medical providers may rely on these Advance Medical Directives to allow the patient's wishes to be respected even when the patient is in a coma or can't otherwise speak for themselves.²¹¹ If Terri Schiavo had one of these advanced medical directives in place, years of litigation and expensive medical life support could have been avoided.

Parents (natural or adoptive) generally speak on behalf of their child(ren) regarding immunizations.²¹² When parents are deceased or their rights have been terminated or interrupted by the Department of Children

²⁰⁶ 42 U.S.C.A. § 247d-6d(b)(1),(8) (West 2021). "VOLUNTARY PROGRAM.—The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 319F-3 and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part." 42 U.S.C.A. § 247d-6e(c) (West 2021).

²⁰⁷ FLA. STAT. §§ 381.026(4)(b)(3), 736.035. (West 2021).

²⁰⁸ *Schindler v. Schiavo*, 780 So. 2d 176, 180 (Fla. Dist. Ct. App. 2001).

²⁰⁹ FLA. STAT. §§ 765.302, 765.303 (West 2021).

²¹⁰ FLA. STAT. § 736.035 (West 2021). *See also In re Guardianship of Browning*, 568 So.2d 4, 14 (Fla. 1990) (upholding surrogate's authority to terminate medical treatment for an incompetent individual).

²¹¹ FLA. STAT. ANN. § 765.304 (West 2021); *John F. Kennedy Hosp. v. Blutworth*, 452 So.2d 921, 926 (1984) (hospitals may act in accordance with directives in living will without court involvement).

²¹² FLA. STAT. ANN. § 743.0645(1)(c) (West 2021).

and Families (“DCF”), a legal guardian or legal custodian may exercise the rights to consent (or refuse) on behalf of a child.²¹³ When parents are divorced, either parent can speak for the child—if they have contrary views on vaccination, one case in Florida addressing this issue allows the pro-vaccine parent to have the child vaccinated.²¹⁴ Florida law refers to any of these individuals as a “[p]erson who has the power to consent as otherwise provided by law.”²¹⁵ The DCF may consent to medical treatment only “when the person who has the power to consent as otherwise provided by law cannot be contacted and such person has not expressly objected to such consent.”²¹⁶ For example, DCF was not allowed to compel a child in foster care to be vaccinated to attend preschool when the child's mother objected on religious grounds.²¹⁷

If no parent, custodian, or guardian can be reached, a health care surrogate appointed by the person who has power to consent will enable the surrogate to speak on behalf of the parent or legal guardian.²¹⁸ When there is no health care surrogate, the following individuals, in descending order, may speak for the child: the stepparent, a grandparent, an adult brother or sister or an adult aunt or uncle of the minor.²¹⁹

In the face of COVID-19, as citizens across the United States faced the specter of vaccine mandates and vaccine passports, Florida Governor Ron DeSantis signed Senate Bill 2006 into law.²²⁰ Effective July 1, 2021, no school, government agency, or business could require vaccination or proof of vaccination from Covid as a condition of entry.²²¹ Details of the new law are explained in Part 3.A.(1) below.

TENSION BETWEEN INDIVIDUAL RIGHTS AND STATE PROTECTION OF PUBLIC WELFARE

A. Continued Viability and Applicability of Jacobson

The paradox of the need for significant numbers of people to be vaccinated to achieve herd immunity and the possibility that it might not

²¹³ FLA. STAT. ANN. § 743.0645(2) (West 2021).

²¹⁴ *Winters v. Brown*, 51 So. 3d 656, 658 (Fla. Dist. Ct. App. 2011).

²¹⁵ FLA. STAT. ANN. § 743.0645(1)(c) (West 2021).

²¹⁶ FLA. STAT. ANN. § 743.0645(3) (West 2021).

²¹⁷ *Int. of T.C.*, 290 So. 3d 580, 588 (Fla. Dist. Ct. App. 2020).

²¹⁸ FLA. STAT. § 743.0645(3) (West 2021).

²¹⁹ FLA. STAT. § 743.0645(2)(b-e) (West 2021) (listed in priority order).

²²⁰ S.B. 2006 (Fla. 2021) (to be codified at scattered sections of FLA. STAT. §. Ch. 252 and 381).

²²¹ S.B. 2006 (Fla. 2021) (lines 141-149) (to be codified at FLA. STAT. § 318.00316).

be achieved through voluntary vaccination alone make the prospect of mandates like the criminal fines imposed in *Jacobson* more likely. A mandate should be preceded with a thoughtful deliberative process addressing the following issues: What are immuno-compromised patients to do in the face of a pandemic—are those with HIV, AIDS, and other autoimmune disorders entitled to additional protection? Is a vaccine mandate that may harm or kill a vulnerable person “cruel and unusual punishment?” Dicta in *Jacobson* suggests that this is the case: “[i]t is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and inhuman in the last degree.”²²²

If a person has the right to refuse life-prolonging medical treatment and allow nature to take its course, the right to refuse an immunization should likewise be upheld. After all, the natural consequence of a rejected vaccination is not an epidemic, but rather an individual that will be susceptible to the possibility of disease and perhaps even death should they be exposed to a deadly epidemic. Of course, the “herd immunity” goal for vaccines presupposes that the risk of epidemic disease can be curtailed only when a substantial amount of the populace has been immunized or naturally develops the antibodies through exposure to the virus. This is the principal justification for mandating immunization of children in accordance with CDC recommendations before children start public school. Reading the tea leaves, one would imagine that granting medical exemptions while unrolling any vaccine mandates for COVID-19 or the next epidemic would insulate the legislation from being overturned as “not narrowly tailored” and would be consistent with sensitive treatment of medically vulnerable members of society—avoiding the Pandora’s box of “cruel and unusual punishment” defenses that would likely be raised if a medically sensitive person were to refuse the vaccine and no medical exemption were allowed.

²²² *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905). “[W]e are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health, or probably cause his death. No such case is here presented.” *Id.* at 39.

1. Florida's Current Situation

After July 1, 2021, Florida law protects its citizens in several ways from involuntary COVID-19 vaccination.²²³ “[A]ny business operating in this state, may not require patrons or customers to provide any documentation certifying COVID-19 vaccination or post-infection recovery to gain access to, entry upon, or service from the business operations in this state.”²²⁴ This new law, dubbed “COVID-19 vaccine documentation,” precludes any business in Florida from demanding to see a “vaccine passport” before providing services.²²⁵ However, initial pushback from the cruise industry resulted in litigation in Miami where a federal district court judge allowed Norwegian Cruise Lines to maintain its international standards requiring 100% vaccination for travel.²²⁶ Norwegian argued it was in compliance with the March 2020 cruise guidance from the CDC requiring such vaccine mandates.²²⁷ In addition to vaccination requirements, cruise ships have also implemented COVID-19 testing measures and mask requirements as vaccination alone has not been effective in preventing the spread of COVID-19.²²⁸

The next two provisions of the new COVID-19 vaccine documentation restrictions are less vulnerable to litigation as they do not implicate federal Commerce Clause or international legal concerns. Provisions (2) and (3) relate directly to restrictions on Florida governmental entities and Florida schools (public and private).

²²³ See S.B. 2006 (Fla. 2021) (adding requirement for Governor to explain any restrictions on schools and businesses, mandating a 5-day administrative review of emergency declarations lest a declaration be deemed invalid, and enhancing the ability of the legislature to terminate the state of emergency) (to be codified at FLA. STAT. § 252.36 (1, 3(a)-(b))). A new provision allows the Governor, Surgeon General and other designated officials to disseminate public service announcements without going through the procedural hurdles of Florida statute sections 112.3148 and 112.3215. *Id.* (to be codified at Fla. Stat. § 252.36 (12)).

²²⁴ S.B. 2006 § 18 (Fla. 2021) (to be codified as FLA. STAT. § 318.00316).

²²⁵ S.B. 2006 § 18 (Fla. 2021) (to be codified as FLA. STAT. § 318.00316(1)).

²²⁶ *Norwegian Cruise Line Holdings, Ltd. v. Rivkees*, No. 21-22492-CIV, 2021 WL 3471585 (S.D. Fla. 2021).

²²⁷ *Id.* at *4.

²²⁸ Hannah Sampson, *27 People Test Positive for Coronavirus on Carnival Cruise Ship*, THE WASH. POST, (Aug. 13, 2021), <https://www.washingtonpost.com/travel/2021/08/13/carnival-vista-cruise-covid-cases/> (A Carnival cruise ship with virtually everyone vaccinated nevertheless experienced twenty-seven cases of Covid on board, all among vaccinated individuals.).

(2) A governmental entity . . . may not require persons to provide any documentation certifying COVID-19 vaccination or post-infection recovery to gain access to, entry upon, or service from governmental entity's operations in this state.

(3) An educational institution . . . may not require students or residents to provide any documentation certifying COVID-19 vaccination or post-infection recovery for attendance or enrollment, or to gain access to, entry upon, or service from such educational institution in this state. . . .²²⁹

In addition to the specific Covid-related provisions above, the legislature ratified and clarified the scope of the Governor's emergency powers using the COVID-19 pandemic to illustrate the legislative intent to keep public schools and businesses open to the greatest extent possible.²³⁰

The Legislature intends that, during an extended public health emergency, such as the COVID-19 pandemic, there should be a presumption that K-12 public schools, to the greatest extent possible, should remain open so long as the health and safety of students and school personnel can be maintained by specific public health mitigation strategies recommended by federal or state health agencies for educational settings. The Legislature also intends that during such an event, there be a presumption that businesses should remain open to the greatest extent possible so long as the health and safety of employees and customers can be reasonably protected by specific public health mitigation strategies recommended by federal or state health agencies, including, but not limited, to the Occupational Safety and Health Administration.²³¹

The State Health Officer (“SHO”) still has authority to declare a public health emergency (ordinarily in consultation with the Governor) and is now charged as the sole authority for counting cases and deaths related to infectious disease.²³² It is the SHO’s duty to consider medical, religious, and conscientious objections to vaccination and the SHO’s sole authority to order anyone to be vaccinated or quarantined.²³³

²²⁹ S.B. 2006, § 18 (Fla. 2021) (to be codified as FLA. STAT. § 318.00316(2-3)).

²³⁰ S.B. 2006, § 8(1)(c) (Fla. 2021) (to be codified at FLA. STAT. § 252.36).

²³¹ S.B. 2006, § 8(1)(c) (Fla. 2021) (to be codified at FLA. STAT. § 252.36 (1)(c)).

²³² S.B. 2006, § 17(2)(c) (Fla. 2021) (to be codified at FLA STAT. § 381.00315(2)(c)).

²³³ See S.B. 2006, § 17, (Fla. 2021) (leaving Fla. Stat. § 381.00315 unchanged).

Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to isolation or quarantine If the individual poses a danger to the public health, the State Health Officer may subject the individual to isolation or quarantine. If there is no practical method to isolate or quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual.²³⁴

Political subdivisions still have emergency authority to implement curfews and the like, but such orders may be countermanded by the Governor if they “unnecessarily restrict individual rights or liberties.”²³⁵ Such local measures may be extended in seven-day increments not to exceed forty-two days total.²³⁶

Deliberation about the merits of the arguments concerning quarantines as well as risks and rewards of vaccines is properly a matter of the state police powers. The explanation of legislative intent and the clarifying language in the various emergency response statutes like those explained above could be helpful in the event there is an issue of statutory construction or if any of the pandemic response legislation is found to be ambiguous.

In addition, to the extent the legislature has squarely addressed these issues, there is less room for judicial intervention and judicial inconsistencies. Just as the *Jacobson* Supreme Court deferred to the state legislature in its balancing of the needs of the individual with the health and safety needs of the public, here Florida’s legislature has the right to decide these important (and oft-times controversial) matters. The best protection that Florida children have, is the absence of state- or federally-mandated vaccinations for COVID-19.

Should the federal government mandate childhood COVID-19 vaccines for school children, any number of legal arguments could be made to oppose the mandates using the recent legislation, the Florida Constitution, and the existing legal framework in Florida. Perhaps the best tool concerned parents could use would be Florida’s three statutory exemptions: medical, religious, and conscientious objector exemptions.²³⁷

²³⁴ Fla. Stat. §381.00315 4, 4(b). *See also* S.B. 2006, § 17.

²³⁵ S.B. 2006, § 12(4)(c) (to be codified at Fla Stat. § 252.48 4(c)).

²³⁶ *Id.*

²³⁷ FLA. STAT. ANN. § 381.00315(4) (West 2021). Note, before this would be necessary the 2021 Florida Law preventing vaccine passports as a requirement for admission to schools would have to be superseded.

2. Florida Constitutional Limits on Vaccine Mandates

The topic of vaccine mandates hit the headlines as children and adults returned to school in September 2021 and bipolarized public opinion predominately along political lines. Governor Ron DeSantis in Florida, Governor Greg Abbott in Texas, and other republican governors, have done the most to reopen the schools and the economy without requiring vaccinations or mask mandates. These freedom-loving states are acting proactively in the face of ever more coercive measures at the federal level as the Biden Administration has even gone so far as to state: “[t]his is not about freedom or personal choice. It’s about protecting yourself and those around you—the people you work with, the people you care about, the people you love.”²³⁸ President Biden’s problem is, he views it as his job to decide how to best protect you and your family instead of leaving those choices up to you.²³⁹

It is safe to assume that Florida will not change its vaccine laws under Governor DeSantis with a republican majority in the Florida State Legislature; however, it is not fanciful to imagine that if democrats took control of the Governor’s mansion and both the House and Senate in Florida, the recent Florida legislation discussed above could be repealed and replaced with state-mandated vaccinations and mask requirements.

Nevertheless, the Florida Constitutional protections against vaccine mandates would be unaffected in the instance of such political change. Florida courts must start with the proposition that the intrusion of privacy is unlawful until the government shows that its public health and safety interest is compelling and there is no alternative to achieving it without vaccine mandates. The level of scrutiny is strict.

In Florida’s Right to Die Cases, so long as the individual’s medical wishes are clear, they must be respected, and the government may not intrude on the individuals free exercise of this right. These cases are important in establishing the individual’s significant privacy right in making medical choices. However, Florida’s caselaw on the right to die is not controlling, because the exercise of free will by individuals who are terminally ill or in a persistent vegetative state will not impact the health and safety of any other Florida citizens (unlike a contagious disease which could affect others or undermine herd immunity). Likewise, *most medical decisions* do not broadly impact anyone other than the patient. In other

²³⁸ *Remarks by President Biden on Fighting the COVID-19 Pandemic*, THE WHITE HOUSE, (Sept. 09, 2021), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/>.

²³⁹ *Id.* (“My job as President is to protect all Americans.”).

words, individual medical choices do not typically have an external consequence of possibly threatening or undermining public health and safety. Since the goal of “herd immunity” is for an overarching public safety purpose, it is more likely that the government could meet its burden of demonstrating that vaccines are not only helpful to society, but compelling in the face of an epidemic; especially, an epidemic where the risks of death and serious public injury are significant.²⁴⁰ If a narrow vaccine mandate with exemptions were imposed, it may survive strict scrutiny. When the government meets its dual obligations of addressing a compelling state need and its chosen methods are the least intrusive possible under the circumstances, then the proposed measures should survive.

3. Some Vaccines, Including the EUA Vaccines, Do Not Serve a Compelling State Interest

One can easily imagine the “safe and effective” arguments made by the CDC and the vaccine industry would be influential if used by the State of Florida to justify vaccine mandates in the midst of a deadly pandemic. Indeed, as they relate to previously approved childhood vaccines, many courts might find them compelling.²⁴¹ However, current mandates being discussed or employed throughout the nation pertain to COVID-19 vaccines (Comirnaty) and the EUA-approved Pfizer and BioNTech alternatives and booster shots of the same vaccine.²⁴² Only the Pfizer-BioNTech vaccine has been approved for use in children aged five to eleven and that approval is an emergency use authorization.²⁴³

The Comirnaty vaccine produced by Pfizer and BioNTech is basically a rehash of the unapproved Pfizer and BioNTech EUA

²⁴⁰ Reasonable minds can differ about whether SARS-Cov-2 poses such a threat or whether voluntary vaccinations suffice to quell that threat.

²⁴¹ See e.g., California cases curtailing religious exemptions from school-mandated childhood vaccines *infra* note 273 and accompanying text.

²⁴² *FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age*, FDA (Oct. 29, 2021), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>. See also *FDA Approves First COVID-19 Vaccine: Approval Signifies Key Achievement for Public Health*, FDA (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine?s_cid=11700:is%20covid%20vaccine%20fda%20approved:sem.ga:p:RG:GM:gen:PTN:FY22.

²⁴³ *FDA Authorizes Pfizer-BioNTech*, *supra* note 235.

vaccines.²⁴⁴ Its “approval” by the FDA was under suspicious circumstances prompting two FDA officials to quit or retire in protest of the untoward pressure from Washington interfering with the FDA approval process.²⁴⁵

The FDA approved use of *either the Comirnaty vaccine* (of which there was no existing supply) *or continued use of the Pfizer-BioNTech COVID-19 EUA vaccine* to fill the gap until sufficient Comirnaty vaccine is produced.²⁴⁶ In this questionable manner, the FDA allowed the Pfizer-BioNTech EUA vaccines to be “approved” without following its typical approval process and without terminating the continued use of all the EUA vaccines, including the Pfizer-BioNTech EUA vaccines, as required under federal statutes once an approved vaccine has been found.²⁴⁷ According to critics, this end-around typical FDA procedures, by bootstrapping the EUA vaccines as an approved alternative to the new nonexistent Comirnaty vaccine is deceptive or illegal.²⁴⁸

²⁴⁴ *Vaccine Information Fact Sheet for Recipients and Caregivers About Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older*, PFIZER, <http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf> (last updated Jan. 31 2022) (“The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.”).

²⁴⁵ Ashley Collman, *2 Top FDA Officials Resigned Over the Biden Administration's Booster-Shot Plan, Saying it Insisted on the Policy Before the Agency Approved it, Reports Say*, BUS. INSIDER (Sept. 1, 2021, 6:32 AM), <https://www.businessinsider.com/2-top-fda-officials-resigned-biden-booster-plan-reports-2021-9>.

²⁴⁶ See *Biologics License Application (BLA) Letter to BioNTech GmbH*, FDA (Aug. 23, 2021), <https://www.fda.gov/media/151710/download> (at time of “approval” no doses of Comirnaty had even been manufactured.). FDA LOT RELEASE: “Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).” *Id.*

²⁴⁷ 21 U.S.C.A. § 300bbb(c)(3) (West 2021).

²⁴⁸ See *The Defender, Children's Health Defense Sues FDA Over Approval of Pfizer Comirnaty Vaccine*, THE DEFENDER: CHILDREN'S HEALTH DEF (Sep. 7, 2021), <https://childrenshealthdefense.org/defender/childrens-health-defense-sues-fda-pfizer-comirnaty-covid-vaccine/>. “The lawsuit, filed Aug. 31, alleges the U.S. Food and Drug Administration violated federal law when the agency simultaneously licensed Pfizer’s Comirnaty COVID vaccine and extended Emergency Use Authorization for the Pfizer-BioNTech vaccine.” *Id.*

Even more disturbing is the fact that the use of these alternatives are being promoted in the face of undisputed evidence that the vaccines cause serious side effects in some people. Perhaps, most disturbing is the risk of myocarditis and pericarditis, especially for boys ages 12-17 and men under the age of 40.²⁴⁹ Pfizer-BioNTech's most recent warning to individuals contemplating taking the two-shot Pfizer/BioNTech vaccines or the two-shot Comirnaty series of shots states: “[s]erious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.”²⁵⁰

Therefore, it is quite a stretch to claim, much less to prove, that the EUA vaccines are safe and effective. Instead, the vaccines introduced to the market for emergency use during COVID-19 only had to demonstrate that the “balance of the risks” favored vaccination.²⁵¹ Such interim approval is by law required to be temporary, and further study and review must be completed before the EUA vaccines may lawfully be approved and licensed.²⁵² Even Pfizer-BioNTech's most recent information sheet divulges the emergency-based nature of the authorization of its vaccines:

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines

²⁴⁹ See *Teens More Likely to Be Injured by Vaccines Than by COVID*, *Neuroscientist Says*, THE DEFENDER: CHILDREN’S HEALTH DEF. (Oct. 13, 2021), https://childrenshealthdefense.org/defender/against-wind-paul-thomas-pamela-popper-christopher-shaw-covid-vaccine-injury-kids/?utm_source=salsa&eType=EmailBlastContent&eId=107ca061-669d-468b-885c-e6e479cc2f45.

²⁵⁰ Letter from FDA U.S. Food & Drug Administration to BioNTech (Aug. 23, 2021), <https://www.fda.gov/media/151710/download>.

²⁵¹ *Emergency Use Authorization for Vaccines to Prevent COVID-19*, FDA GUIDANCE FOR INDUS. (Feb. 22, 2021), <https://www.fda.gov/media/142749/download>. (Arguably, we have reached a point where enough people have already been vaccinated or have had the infection and developed antibodies to COVID such that there are no longer facts to justify the COVID threat as an emergency. The author feels that all children should be tested before being vaccinated and any with immunity already should be exempt from vaccination requirements altogether as the vaccine in that case poses more risks than rewards both for the child and for society.); see *Teens More Likely to Be Injured by Vaccines Than by COVID*, *Neuroscientist Says*, THE DEFENDER: CHILDREN’S HEALTH DEF. (Oct. 13, 2021), https://childrenshealthdefense.org/defender/against-wind-paul-thomas-pamela-popper-christopher-shaw-covid-vaccine-injury-kids/?utm_source=salsa&eType=EmailBlastContent&eId=107ca061-669d-468b-885c-e6e479cc2f45.

²⁵² *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry*, FDA (May 25, 2021), <https://www.fda.gov/media/142749/download>.

that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.²⁵³

The risk-benefit analysis of any of the EUA vaccines is especially doubtful for children, teens, and young adults, as the benefit is questionable since so few children are hospitalized from the Covid infection while the harmful side-effects to these younger generations of Americans are potentially more severe than the risks posed to older populations.²⁵⁴ As a result, it is not a foregone conclusion, even if Florida enacted vaccine mandates, that the state would have a compelling interest for requiring any EUA vaccines, such as the COVID-19 EUA vaccines or the Comirnaty vaccine.

Florida and other state governments are on better footing if mandating licensed vaccines as a requirement for school attendance (with exemptions as previously described). However, even with fully licensed childhood vaccines, not all vaccines on the current CDC schedule serve a compelling public safety interest. Mandating shots for tetanus, which is not communicable, is a good example.²⁵⁵ The individualized nature of tetanus, which could result in lock jaw to the child infected by tetanus, does not threaten anyone who that child might contact because tetanus is not contagious.²⁵⁶ There can never really be a tetanus pandemic. Likewise, because the most effective flu shot is less than 50% effective, and those who have had the vaccine can still get the flu, it follows that herd immunity cannot be achieved until there is a much more capable flu vaccine.²⁵⁷ The same can be said of the COVID-19 vaccines. Since they do not prevent COVID-19 infection or the spread of COVID-19, vaccine mandates will never generate herd immunity.

There has not been a case in Florida finding herd immunity to be a compelling government interest; nor has it ever been shown that such a comprehensive immunization program is the least intrusive means of

²⁵³ *Vaccine Information Fact Sheet*, *supra* note 245 at 5.

²⁵⁴ See *The Defender, Children's Health Defense*, *supra* note 249.

²⁵⁵ See Physicians for Informed Consent, Vaccines: What about Immunocompromised Children, Risk Group Information Statement at p.2; available at <https://physiciansforinformedconsent.org/immunocompromised-schoolchildren/>.

²⁵⁶ *Id.* at 2.

²⁵⁷ See Physicians for Informed Consent, 9 Flu Vaccine Facts: Are Mandates Science Based? at 2; available at <https://physiciansforinformedconsent.org/influenza-flu-vaccine/>.

attaining such protection.²⁵⁸ Indeed, if vaccines work as advertised, the right to choose that treatment for your child should ensure that your child is not affected by any epidemic that might occur. For example, even if everyone in the U.S. except your child developed the mumps, if the MMR vaccine works and you immunized your child, your child would face no risk.

Inasmuch as over 100 years have elapsed since *Jacobson* was decided and given the clear mandate of the people of Florida to pass the constitutional privacy protection explained above, it is possible, even for COVID-19, that Florida courts would not find mandatory vaccination to achieve herd immunity to be a compelling government interest. If Florida courts decided the public health concern in thwarting COVID-19 is compelling, any vaccine mandate would still need to exclude the medically vulnerable; for example, those allergic to the vaccine or with other contraindications would need exemptions. Otherwise, the legislation would not be narrowly tailored. In other words, to be facially valid it would need to exclude from the mandates those who might likely be killed or injured by the vaccination. Even *Jacobson* alluded to such a limitation to protect vulnerable children. Any indiscriminate mandate would necessitate a finding that the government's compelling interest outweighs *everyone's* individual freedoms, even those who would certainly or most likely be harmed or killed by the vaccines. Such a result is doubtful.

4. Narrow Tailoring: Vaccine Mandates Must Exempt the Medically Vulnerable to Survive Strict Scrutiny

Since herd immunity is always attained at somewhat less than full vaccination of the entire population, any mandate not exempting medically "at risk" children should necessarily fail. In short, the fact that herd immunity is generally attained with anywhere between 80-95% immunization, depending on the vaccine and the illness, demonstrates that at least 5-20% of the community could remain unvaccinated without adverse effect to the herd. Medical exemptions for vulnerable children should top the considerations for narrow tailoring of mandates in Florida. If 95% immunization was necessary to achieve herd immunity in schools,

²⁵⁸ A Westlaw search by the author revealed only 35 Florida cases mentioning "herd" or "immunity," none employed strict scrutiny (April 15, 2021). See *Love v. State Dep't of Educ.*, 29 Cal. App. 5th 980, 984 (2018); *Brown v. Smith*, 24 Cal. App. 5th 1135, 1138 (2018) (finding California's school vaccine mandates and elimination of religious exemptions to school vaccination requirements satisfies strict scrutiny).

for example, and 5% of all children were medically at-risk for this vaccine, any vaccine mandate would not be narrowly tailored if it failed to exempt these vulnerable children. The exemption of persons with religious or philosophical concerns could likewise be accommodated where the numbers of medical exemptions are small, or the herd immunity can be attained at lower rates (for example 80% immune versus 95%) so long as the number of religious and conscientious objectors is relatively small.

With a conservative herd immunity goal of 60-75% for COVID-19 (counting both vaccinated individuals and those with previous COVID exposure to the virus of concern), at least 25% of the population should not need the vaccine. Even under the newer heightened estimate of 90% for herd immunity to COVID, a blanket requirement for universal vaccination (without medical and perhaps other exemptions) would still violate the Florida constitutional right to privacy, because it is not narrowly tailored. As it stands, Florida has an obligation to its people to attain herd immunity using voluntary measures when such measures can be protective of public health, because any other measures are not the least restrictive invasion of privacy.

With the state court as the ultimate authority on state constitutional rights, it should open the door for evidence of the risks posed by a particular vaccine to a particular individual, much as the Vaccine Court has allowed. The Florida court's authority would include enjoining application of a vaccine mandate as it deliberates, as well as the authority to strike any laws invading the citizen's privacy. Other than emergency federal preemption,²⁵⁹ state courts should not face an emergency exception to judicial review of its own legislative decisions and executive orders.

It has yet to be seen whether the courts in other states will frame the issue of vaccine mandates for school attendance in the same way as the New York cases discussed below, focusing on the consequence of school non-admission (rational basis test) versus a vaccine mandate (strict scrutiny). Since Florida also has a state constitutional entitlement to a high school education, application of the rational basis test in Florida is arguably not appropriate.²⁶⁰

However, even under the rational basis test, the outcome of any particular vaccine mandate would likely be determined based on its precise language, especially if the legislation allows exemptions to the mandate. A vaccine mandate would likely be upheld under the rational basis test, such as the criteria for admission to a nursing home in a time of an

²⁵⁹ See *infra* note 278-79 and accompanying text.

²⁶⁰ FLA. CONST. art. IX, § 1.

epidemic or pandemic (protecting the rights of current residents, a vulnerable population, from exposure out of an abundance of caution). Application to the K-12 school setting is less likely without an exclusion for vulnerable children (medical exemptions). Even the law at issue in *Jacobson* excluded vulnerable children from the mandate.

Given the questionable risk to school-aged children from COVID-19 (with most cases being mild or asymptomatic), imposing mandates for COVID-19 shots as a threshold for school readmission seems somewhat *irrational*, even if there are medical exemptions.²⁶¹ An argument has been made that the mandates are necessary to protect the teachers, but the availability of the COVID-19 vaccine to all Florida populations seems to erode that argument. The teachers' right to choose to be vaccinated should obviate any need to vaccinate all the school children.²⁶² The fact that vaccinated children could still contract COVID-19 also weighs in favor of temperature checks for COVID as a more reliable and less intrusive way to protect teachers.

5. Other States

Unlike Florida, most states do not have their own state constitutional provisions protecting privacy.²⁶³ Applying the rational basis test in these other states (following *Jacobson* and its progeny), it will be rare for an individual to prevail. For example, in a 2021 vaccine case in New York, plaintiffs argued that “because the medical exemption burdens fundamental rights, it is subject to strict scrutiny.”²⁶⁴ Defendants contended that the rational basis test applied “because the consequence of

²⁶¹ Paul M. Kempen, *Open Letter from Physicians to Universities: Allow Students Back Without COVID Vaccine Mandate*, ASS'N OF AM. PHYSICIANS & SURGEONS (Apr. 24, 2021), <https://aapsonline.org/open-letter-from-physicians-to-universities-reverse-covid-vaccine-mandates/> (noting among other factors, strong health and immunology of college students and two-year estimated time until any COVID-19 vaccines are licensed).

²⁶² Although the schools will need to reasonably accommodate vulnerable teachers with medical infirmities of their own under the Americans with Disabilities Act (2021) (perhaps by extending their ability to teach from home until the pandemic has passed).

²⁶³ *Privacy Protections in State Constitutions*, Nat'l Conf. of State Legislatures (NCLS) (Jan. 3, 2022), <https://www.ncsl.org/research/telecommunications-and-information-technology/privacy-protections-in-state-constitutions.aspx> (Eleven states, including Florida, have constitutional privacy protections.).

²⁶⁴ *Doe v. Zucker*, 520 F. Supp. 3d 217, 249 (N.D.N.Y. 2021) (citing *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S. Ct. 2791 (1992) & *Stenberg v. Carhart*, 530 U.S. 914 (2000)).

‘not complying with the immunization’ is that the child cannot attend school, the only infringement is on the right to education—which is not a fundamental right.”²⁶⁵ Agreeing with the defendants, the court explained: “[i]t is well-established that there is no fundamental right to education, and thus the deprivation of a ‘right to pursue an education,’ by itself, does not trigger strict scrutiny.”²⁶⁶

Although plaintiffs argued that medical treatment decisions implicated strict scrutiny, the court dodged the tough issue of compulsory vaccinations by looking only at the consequences for school enrollment—ultimately, students were not forced to get the shots—just face the consequences if they did not.²⁶⁷ The court quoted *Jacobson* in this regard:

In this country there is a long history of disagreements—scientific and otherwise—regarding vaccinations and their risk of harm, and courts have repeatedly found that it is for the legislature, “in the light of all the information it had,” to “choose between” “opposing theories” within medical and scientific communities in determining the most “effective . . . way in which to meet and suppress” public health threats.²⁶⁸

Unless state law changes, so long as New York links its vaccine requirements to school attendance, the odds of a government victory are high, because such a mandate would likely survive the rational basis test where any legitimate government concern (even one they didn’t think about) could be used to sustain the validity of the legislation in court.

In addressing the COVID-19 pandemic, executives at the local, state, and national levels have had difficult decisions to make in responding to public health concerns while respecting individual liberties. Many of these decisions have now been the subject of legal challenges. Some such challenges involve individual rights for which precedent requires courts to apply a heightened level of scrutiny to government actions, such as the free exercise of religion (citations omitted), or access to abortion (citations omitted). Other cases, however, involve executive actions that, by precedent, are viewed only through the lens of a modest, or “rational basis,” standard of review. And nearly without exception,

²⁶⁵ *Doe*, 520 F. Supp. 3d 217 at 249.

²⁶⁶ *Id.* at 250.

²⁶⁷ *Id.* at 251.

²⁶⁸ *Id.* (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 30-31 (1905)).

courts in these cases have appropriately deferred to the judgment of the executive in question.²⁶⁹

As the New York cases further indicate, even medically vulnerable individuals may be barred from attending school when the school superintendent's doctor disagrees with the individual's medical doctor.²⁷⁰ One possibility of relief from vaccine mandates for parents in New York, and other states, is for grass roots organizations to have their states adopt constitutional privacy protections as was done in Florida. At present, eleven states have constitutional privacy protections: Alaska, Arizona, California, Florida, Hawaii, Illinois, Louisiana, Montana, New Hampshire, South Carolina, and Washington.²⁷¹ These states should require strict scrutiny, or at least heightened scrutiny when balancing the public health interest in school vaccinations with the state constitutional right to choose or refuse medical treatment. Imposing strict scrutiny will make the odds better but will not guarantee that a parent will prevail in the face of a school mandate. California, for example, found its state measures survived this heightened level of scrutiny when citizens challenged the elimination of religious exemptions from school vaccine mandates.²⁷²

A less obvious, but potentially effective, remedy would be to create a constitutional right to K-12 education for all children in the state. In addition to Florida, seven states have constitutional provisions which make education a primary or fundamental right.²⁷³ These states are Georgia, Illinois, Maine, Michigan, Missouri, New Hampshire, and Washington.²⁷⁴ Any constitutional protections of a right to education should implicate a higher level of scrutiny than the rational basis test. The most obvious, though still challenging, procedure would be to convince

²⁶⁹ *Moxie Owl, Inc. v. Cuomo*, 527 F. Supp. 3d 196, 201 (N.D.N.Y. 2021) (citations omitted).

²⁷⁰ *Id.*; see also, *Doe*, 520 F. Supp. 3d at 250.

²⁷¹ *Privacy Protections in State Constitutions*, NAT'L CONFERENCE OF STATE LEGISLATURES (NCLS) (Jan. 3, 2022), <https://www.ncsl.org/research/telecommunications-and-information-technology/privacy-protections-in-state-constitutions.aspx>.

²⁷² *Love v. Dept of Education*, 29 Cal. App. 5th 980, 984 (Cal. Ct. App. 2018); *Brown v. Smith*, 24 Cal. App. 5th 1135, 1138 (Cal. Ct. App. 2018) (finding California's school vaccine mandates and elimination of religious exemptions to school vaccination requirements satisfies strict scrutiny).

²⁷³ *State Constitutional Language Providing for Public Schools*, NAT'L CONFERENCE OF STATE LEGISLATURES (NCLS); <https://www.ncsl.org/research/education/state-role-in-education-finance.aspx> (scroll down to Category IV States in Chart).

²⁷⁴ *Id.* (scroll down to Category IV States in Chart).

state legislatures to better protect medically vulnerable children by allowing statutory vaccine exemptions based on the medical evaluation of the child's doctor alone.

6. Federal Preemption

The tension between states' rights and federal powers are a source of potential litigation and political controversy. The federal government gave itself authority to preempt state law in a declared emergency in the 2019 Pandemic and All-Hazards Preparedness Act and then, in March of 2020, declared such an emergency based on the COVID-19 Pandemic.²⁷⁵ Nevertheless, then-President Trump was careful to emphasize the autonomy of the states in managing their respective hot spots once the federal government had prioritized the various state needs and distributed ventilators and other national security stockpile resources.²⁷⁶

Federal erosion of state rights, in ordinary (non-emergency) situations, over the past several decades forces us to consider the prospect of an attempt at federal vaccine mandates when the country is not facing an epidemic emergency. It is unconstitutional for the federal government to require the states to legislatively impose vaccination requirements,²⁷⁷ but financial incentives, such as highway funding, have been instrumental in the past in motivating states to adopt certain legislation (highway speed limits, motorcycle helmet laws, and 21-years-of-age drinking requirements, come to mind).²⁷⁸

It is also possible that the federal government will attempt to usurp the decision-making authority of the states in vaccine laws through federal preemption (by completely occupying the field with federal law and regulations, as it has done in many areas of environmental law).²⁷⁹ Finally, the federal legislation could institute a cooperative effort with the states to

²⁷⁵ Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub.L. 116-22 Title II, § 926, June 24, 2019, Stat. 1379 (to be codified in scattered sections of 42 U.S.C.); 42 U.S.C.A. § 247-6d(B)(8).

²⁷⁶ *President Trump Coronavirus News Conference*, C-SPAN (August 4, 2020), <https://www.c-span.org/video/?474531-1/president-trump-comments-covid-19-mortality-rate-calls-lebanon-explosion-attack>.

²⁷⁷ *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 288 (1981).

²⁷⁸ *See e.g.*, *S.D. v. Dole*, 483 U.S. 203, 206 (1987) (making highway funding contingent on a minimum drinking age was a valid use of Congress's spending power).

²⁷⁹ *See e.g.*, 15 U.S.C.A. § 2601 (West 2021).

address a national problem (allowing federal efforts in parallel with state and local efforts as it has done with strategic law enforcement efforts).²⁸⁰

B. A Post-Jacobson Restraint on Vaccine Mandates

Much has changed in the past century since *Jacobson* was decided. Many of the intrusions and brutalities formerly condoned would no longer be accepted as the United States has a kinder and gentler disposition. For example, the United States no longer has compulsory military service, and draft dodgers from the Vietnam War have been pardoned.²⁸¹ Even during the later years of the draft there were medical exemptions, religious exemptions, and conscientious objector exemptions from military service.²⁸² Changing military service to be consent-based undermines the *Jacobson* court's reasoning that people can be involuntarily forced into harm's way to protect society.

The nation has also looked down upon previous Supreme Court decisions curtailing individual liberties, even when thought to be essential to American safety at the time. The *Korematsu* internment, for example, may have been seen as "legal" in the wake of the massive Japanese attack on U.S. service members and naval assets at Pearl Harbor, but would likely be found unconstitutional today under strict scrutiny.²⁸³

Another of the justifications the *Jacobson* court used to uphold compulsory vaccinations has likewise been undermined; while forced sterilization was allowed back then for psychiatric patients, it is no longer justified.²⁸⁴ "Between 1907 and 1939, more than 30,000 people in 29 U.S. states were sterilized, unknowingly or against their will, while they were

²⁸⁰ See e.g., *Operations*, DEA, <https://www.dea.gov/operations> (last visited Feb. 13, 2022) (the DEA compliments the efforts of the states in suppressing drug trafficking). The DEA High Intensity Drug Trafficking Area (HIDTA) program was authorized in 1988 to reduce drug trafficking. *HIDTA*, DEA, <https://www.dea.gov/operations/hidta> (last visited Mar. 28, 2022). At the local level, the HIDTAs are directed and guided by Executive Boards composed of an equal number of regional Federal and non-Federal (state, local, and tribal) law enforcement leaders. *Id.* The 2021 HIDTA annual budget is \$290 million. *Id.*

²⁸¹ Proclamation No. 4483, 42 Fed. Reg. 4391 (Jan. 24, 1977).

²⁸² 50 U.S.C.A. § 3806(j) (West 2021).

²⁸³ *Korematsu v. United States*, 323 U.S. 214 (1944), abrogated by *Trump v. Hawaii*, 138 S. Ct. 2392 (2018);

United States Code: Restitution for World War II Internment of Japanese-Americans and Aleuts, 50 U.S.C. Chapter 52 (1988)

²⁸⁴ *Jacobson v. Massachusetts*, 197 U.S. 11, 37-38 (1905).

incarcerated in prisons or in institutions for the mentally ill.”²⁸⁵ After the passage of the Family Planning Services and Population Research Act of 1970, Indian Health Service physicians sterilized about twenty-five percent of Native American women of childbearing age from 1973-1977.²⁸⁶ The Natives argued it was genocide and brought their case to the United Nations.²⁸⁷ Most of these sterilizations occurred under pressure or duress, or without the women’s knowledge while they were undergoing other medical procedures.²⁸⁸ A U.S. General Accounting Office study in 1976 disclosed that several women under age 21 had been sterilized despite a court moratorium against this practice.²⁸⁹

Black and Latina women were also targets of coercive sterilization.²⁹⁰ Southern states administered “‘Mississippi appendectomies,’ the name for unnecessary hysterectomies performed on women of color [to control black populations and] as practice for medical students at Southern teaching hospitals. A third of the sterilizations were done on girls under age 18, some girls reportedly as young as 9 years old.”²⁹¹ “California prisons authorized sterilizations of nearly 150 female inmates between 2006 and 2010, driven in part by anti-Asian and anti-Mexican prejudice, in a practice that wasn’t outlawed until 2014.”²⁹² The above state and federal practices are deplorable invasions of privacy, and it is remarkable that any such forced medical procedures have been allowed in light of federal privacy protections for individuals to have the right to choose what happens to their body. It is surprising that such

²⁸⁵ Ellen J. Kennedy, *On Indigenous Peoples Day, Recalling Forced Sterilizations of Native American Women*, MINNPOST (Oct. 14, 2019), <https://www.minnpost.com/community-voices/2019/10/on-indigenous-peoples-day-recalling-forced-sterilizations-of-native-american-women/#:~:text=9%20years%20old.,The%20U.S.,12%20Indian%20Health%20Service%20regions> (hereafter *Forced Sterilization*).

²⁸⁶ Brianna Theobald, *A 1970 Law Led to the Mass Sterilization of Native American Women. That History Still Matters*, TIME (Nov. 28, 2019, 11:47 AM), <https://time.com/5737080/native-american-sterilization-history/>.

²⁸⁷ *Id.*

²⁸⁸ *Id.*

²⁸⁹ *Native Voices, Timeline, 1976: Government Admits Unauthorized Sterilization of Indian Women*, U.S. NAT’L LIBR. OF MED., <https://www.nlm.nih.gov/nativevoices/timeline/543.html> (last visited Nov. 19, 2021).

²⁹⁰ *Id.* See also Kennedy, *supra* note 287 (comparing U.S. practices as a model for Nazi mass sterilization practices in WWII).

²⁹¹ Kennedy, *supra* note 287.

²⁹² *Id.*

measures have only lately been condemned and corrected in some states.²⁹³

C. Is the Supposed Tension Between Individual Autonomy and Public Health a False Tension Concerning Vaccine Mandates?

A thoughtful medical ethics article in 2005 (the 100th anniversary of *Jacobson*) looked at whether *Jacobson* is still relevant in the modern age.²⁹⁴ The article explained that the tension in *Jacobson* might not really exist, and the evolution of medical and scientific practices suggests that the tension between vaccine mandates and herd immunity may be a false tension.²⁹⁵ Authors in the article represented both perspectives—continued vitality of *Jacobson* and that *Jacobson* is obsolete because it is based on false trade-offs between public safety and individual rights.²⁹⁶

If we accept the conventional position that there is an inherent tension between civil liberties and public health and that the struggle to reconcile them is the most significant challenge of law and ethics, then *Jacobson* remains vital and relevant. But if the very foundation of the conventional conception of public health is mistaken, and if the tension it seeks to resolve is a false tension, then *Jacobson* no longer provides a basis for addressing the central dilemmas of protecting the people's health.²⁹⁷

Imagine that the vaccine industry happened to arrive on the scene at just the right time, when major advances in sanitation, the public water supply, and significant improvements in health and nutrition all reduced child and infant mortality.²⁹⁸ In *Dissolving Illusions: Disease, Vaccines, and the Forgotten History* (hereafter "*Dissolving Illusions*"), authors Suzanne Humphries, M.D., and Roman Bystryanyk contend that there is no proof of the effectiveness of vaccines in eradicating smallpox; instead, health statistics, particularly morbidity and mortality rates for children were already rapidly improving as a result of urban development of safer water and sewer systems, better nutrition, and less crowded living conditions, resulting in better overall general health.²⁹⁹

²⁹³ *Id.*

²⁹⁴ James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v. Massachusetts*, 95 AM. J. PUB. HEALTH 571, 574-75 (Apr. 2005).

²⁹⁵ *Id.* at 576-77.

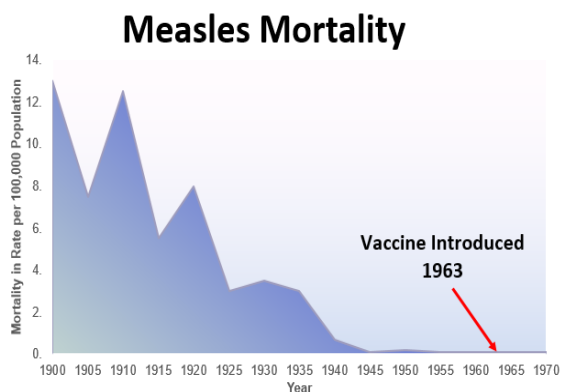
²⁹⁶ *Id.*

²⁹⁷ *Id.* at 576.

²⁹⁸ See HUMPHRIES & BYSTRYANYK, *supra* note 41, at 216-17.

²⁹⁹ *Id.* at 184-85.

Anyone who is immunocompromised understands that a healthy body is better able to fight against disease. In *Dissolving Illusions*, the authors explain how the citizens of Leicester who refused mandatory vaccines were healthier and more resistant to subsequent epidemic infections than anyone who had been vaccinated.³⁰⁰ The results in both the U.S. and U.K. seemed to suggest that improving public health was more a byproduct of improved individual health and immunity from disease than the result of any vaccine.³⁰¹ Freed from widespread contaminants, unhealthy water, rodent infestation, child labor in unhealthy working conditions, and clean-up of the general disease-ridden conditions of the early days of urbanization, the incidence of infection simply fell naturally as healthier people were better able to fight infectious disease.³⁰² The following graphs marked “Measles Mortality” and “Scarlet Fever Mortality (U.S.)” followed the same downward drop in morbidity and mortality rates over time even though vaccines were introduced much later, or not at all.³⁰³

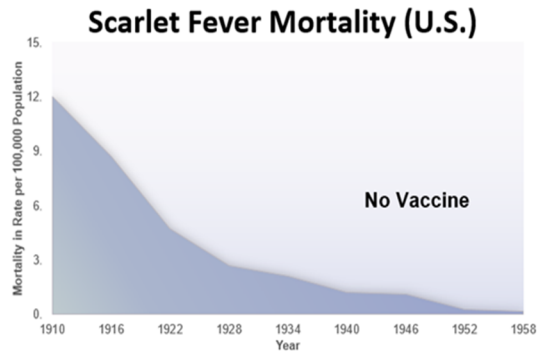


³⁰⁰ *Id.* at 115-34.

³⁰¹ *Id.* at 190-91.

³⁰² *Id.* at 216-17.

³⁰³ *Deaths from Childhood Diseases Were Declining Before Vaccines* CHILDREN'S HEALTH DEF. (March 9, 2021), <https://childrenshealthdefense.org/child-health-topics/false-narratives/deaths-from-childhood-diseases-were-declining-before-vaccines/>.

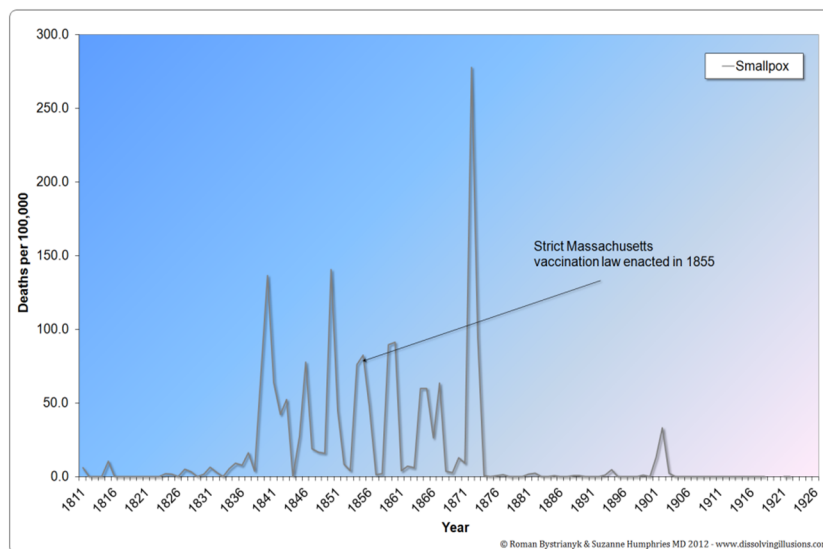


From these figures, it appears vaccines did little to help wipe out measles in the United States and nothing to wipe out scarlet fever. The figures from Massachusetts after mandatory smallpox vaccines began until the *Jacobson* case are even more illuminating (next page). Smallpox vaccinations started in the 1800s and several severe outbreaks occurred notwithstanding vaccines. Even after strict vaccine mandates were instituted in Massachusetts in 1855, major outbreaks of smallpox continued right up until the vaccines Jacobson was complaining about.

In light of the dramatic public health improvements already occurring, perhaps the supposed tension between individual freedoms and public health was overstated in *Jacobson*. Or, as argued by the AVLA and other vaccine opponents, perhaps people would have been even healthier without vaccines.³⁰⁴ No one will ever know now what would have happened with vaccine exemptions or an all-voluntary vaccine program, but the generally healthier populace in Leicester, comprised of those who refused vaccines, casts some doubt on the long-held popular world view that vaccines are the only answer to overcoming infectious disease.³⁰⁵

³⁰⁴ See Tolley, *supra* note 40.

³⁰⁵ HUMPHRIES & BYSTRANYK, *supra* note 41, at 80 graph 4.1.



CONCLUSION

To avoid systemic pressures to “over vaccinate,” fostered by the CDC over the past few decades, parents should do their homework so that they can make their own risk-reward analysis about the timing of vaccinations for their children, rather than relying on the “one size fits all” recommendations of the CDC. Every person is unique: newborns can have radically different genetic make-up, different birth weights, and different developmental maturities when born; they face different exposures to chemicals and other environmental toxins both before and after birth; and they grow and mature at different rates. These same factors confound any attempt to show an exclusive or dispositive causal explanation for autism.

Genetics, differentiated development at the time of vaccine exposure, and exposure to other environmental toxins could all contribute to neurodevelopmental risks of an adverse vaccine response. It is precisely because of these uncertainties that the Vaccine Court has ruled against victims of injuries corresponding to vaccinations. For the same reason, any asserted victory over disease attributed to vaccines alone is often dubious.³⁰⁶

It is worth noting that many doctors including pediatricians have chosen not to follow the CDC childhood vaccine guidelines.³⁰⁷ This is not to suggest that these doctors are right and the many pediatricians who

³⁰⁶ See HUMPHRIES & BYSTRYANYK, *supra* note 41 at ch. 22 (explaining polio eradication when DDT was banned).

³⁰⁷ See *e.g.*, THE FRANZ CENTER, *supra* note 106.

support the CDC vaccine schedule should be ignored, only that the matter is most properly one for the parent(s) who should meet with their doctors and discuss the risks versus rewards of their unique and individual child having any particular vaccine. Vaccine manufacturers, like other drug manufacturers, caution parents to discuss their child's health situation with their doctor regarding the potential for any contraindications based on manufacturer inserts for the various vaccines. The parent(s) can and should make this informed choice, because the parents and their dearest treasures, their children, will bear the consequences of these private choices, not their doctors. The old saying "an ounce of prevention is worth a pound of cure" is peculiarly appropriate in this context since it applies to the parents and their pediatricians and affords the underlying justifications for vaccines in the first place—getting vaccinated (an ounce of prevention) is to prevent avoidable illness or death (a pound of cure).³⁰⁸

EPILOGUE

The wisdom of the universe reveals itself slowly and in small steps to mankind. For all of recorded history scientific beliefs have evolved. Even supposed "truths" of long standing, that the world was flat, and the planets and sun revolved around the Earth, eventually were shown to be wrong. Galileo was persecuted by inquisition and the Catholic church put horrific pressures on him to conceal and recant the truth.³⁰⁹ More recently, the asbestos and tobacco industries exerted significant pressures of their own to suppress the truth about the hazards of their products. But, unlike tobacco and asbestos, where the truth came out only during litigation, the vaccine industry enjoys a brave new world where the government defends them in a special court where they do not face any liability.

³⁰⁸ If vaccine manufacturers had the burden to prove that the vaccines did not contribute to or otherwise trigger an adverse vaccine reaction (as reported in VAERS) the Vaccine Court would do what was initially intended in allowing recovery to the unfortunate victims of vaccines who are simply part of the overall balancing of public health risks and rewards—but this is the subject of another article. At present, such victims are treated as collateral damage in modern vaccine campaigns. The parallel with wartime is becoming even starker as the Biden Administration launches a war against the unvaccinated. Such a war is tyrannical and oppressive and casts aside freedom and constitutional protections of Americans in the politics and rhetoric of the day. This is also best suited to a follow-up article discussing the many missteps in the mishandling of Covid-19.

³⁰⁹ See Hal Hellman, *Two Views of the Universe: Galileo and the Pope*, WASH. POST, (Sept. 9, 1998), <https://www.washingtonpost.com/wp-srv/national/horizon/sept98/galileo.htm>.

The emergency use authorization for the current COVID-19 vaccines provides even more insular protection to the industry, allowing expedited emergency authorization for marketing and use of novel vaccines that enables the industry to avoid more detailed scrutiny, select what is recommended and reported to the FDA, and provides blanket immunity to the industry for everything but willful misconduct.³¹⁰ The FDAs rush to try to normalize these abnormal vaccines by "approving" a nonexistent surrogate to the Pfizer-BioNTech vaccines makes a mockery of the FDA approval process, caused some FDA officials to resign or retire in protest, and casts doubt upon the integrity of our own government.³¹¹ It suggests a not so hidden agenda to get a shot in the arm of every American.

In traditional Christian morality, the ends never justify the means.³¹² President Biden seems to have strayed far from his ostensibly Catholic roots in adopting coercive means to vaccinate the unvaccinated in the face of these people's obvious desire to remain unvaccinated. Biden's coercive vaccination efforts announced on September 9, 2021, trample on citizen's freedom of choice as to what to introduce into their own bodies. Forcing federal employees to comply or be fired and imposing similar impossible dilemmas on employees working on federal contracts or contractors receiving federal aid extends this bullying even further. Even if these vaccination efforts are intended to benefit the public health and are well-intended, the end result is only properly obtained by following the constitutional rules in place to protect Floridians' and Americans' freedoms.

Requiring a free people to succumb to intrusive measures that affect their health, their safety, and the safety of their children, is a dangerous step backwards from the freedoms and privacy rights enjoyed by the citizens of Florida and our nation. Whenever governments intrude into personal and private matters contrary to an individual's choice, free will is eroded and the journey toward tyranny begins.

That is not what America is about, and it is important not to forfeit our individual self-determination to the state (or worse federal)

³¹⁰ 42 U.S.C.A. § 247d-6d (West 2020) (codified Public Readiness and Emergency Preparedness Act).

³¹¹ Alex J. Rouhandeh, *Disagreement With WH Over Booster Shots Prompt Senior FDA Directors to Step Down*, NEWSWEEK (Aug. 31, 2021 at 4:54 PM), <https://www.newsweek.com/disagreement-wh-over-booster-shots-prompt-senior-fda-directors-step-down-1624750>. One can only speculate as to whether the resignations occurred along political lines.

³¹² Catholic Culture, *Catechism of the Catholic Church*, ¶1759, <https://www.catholicculture.org/culture/library/catechism/index.cfm?recnum=4902> (last visited Nov. 19, 2021).

government which could lead to a slippery slope of eroded independence in determining what can and cannot be done within our own bodies. Our very selves are threatened at every level—from our unique DNA and RNA at the subcellular level, to our mental and physical health, to our legal rights and autonomy as individuals and moral actors within society, to our most sacred philosophical and spiritual beliefs. Given the magnitude of what is at stake, our freedom to make these medical choices should be compromised only under compelling circumstances and in the narrowest way possible. For this reason, the Florida Constitution strikes the right balance and other states should consider constitutional privacy protections or heightened scrutiny requirements for all vaccine and vaccine exemption decisions and the federal government should limit its intrusion into these state police powers to only the gravest of emergencies.