Brooklyn Law Review

Volume 86 | Issue 1 Article 3

12-31-2020

The Regulatory Production of Vaccine Hesitancy

Eugene McCarthy

The Regulatory Production of Vaccine Hesitancy

Eugene McCarthy[†]

INTRODUCTION

During the 2016 presidential election, the Russian government deployed internet trolls to "[a]mplify" the vaccine debate in an effort to divide Americans.[1] The Russian trolls tweeted that "there was a secret government database of #vaccine-damaged children" and that pharmaceutical companies develop vaccines for "cash, not to prevent deaths," among other vaccine conspiracies in an attempt to sow discord among the electorate.[2] Public health advocates have linked the Russian "anti-vax" campaign to deadly measles outbreaks, highlighting the dangers of so-called "vaccine hesitancy" and the anti-vaccination movement.[3] The Russians exploited the fact that, as one medical doctor put it, "a tiny minority continue to put the rest of us at risk."[4] Experts warn that "anti-vaxxers" pose a serious

---

[†] Eugene McCarthy is an Assistant Professor of Business Law at James Madison University. J.D., UCLA; Ph.D., Berkeley.

[1] David A. Broniatowski et al., *Weaponized Health Communication: Twitter Bots and Russian Trolls Amplify the Vaccine Debate*, 108 AM. J. OF PUB. HEALTH 1378, 1378–79 (2018).

[2] *Id.* at 1383.

[3] Kashmira Gander, *Russian Trolls and Bots Spread Anti-Vaccine Lies on Twitter in Run-Up to 2016 Election*, NEWSWEEK (Aug. 23, 2018, 4:00 PM), https://www.newsweek.com/russian-trolls-and-bots-spread-anti-vaccine-lies-twitter-run-2016-election-1088082 [https://perma.cc/3BQ2-3SNV]. The World Health Organization (WHO) defines "vaccine hesitancy" as a "delay in acceptance or refusal of vaccines despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence." WORLD HEALTH ORG., REPORT OF THE SAGE WORKING GROUP ON VACCINE HESITANCY 59 (2014), https://www.who.int/immunization/sage/meetings/2014/october/SAGE_working_group_revised_report_vaccine_hesitancy.pdf?ua=1 [https://perma.cc/PTU8-6KB3]. The term "anti-vaxxer" as used in this article connotes a colloquial use of the term as it has evolved in popular culture and does not appear in the source material. This article will use the term interchangeably with "vaccine-hesitant" or "vaccine critics" to refer to individuals who oppose government-mandated vaccination.

[4] Arthur Caplan, *Liability for Failure to Vaccinate*, HARV. L. PETRIE–FLOM CTR. BILL OF HEALTH (May 23, 2013), https://blog.petrieflom.law.harvard.edu/2013/05/23/liability-for-failure-to-vaccinate/ [https://perma.cc/L8DP-47YL].

public health threat, one that will continue to grow if the government does not stop this small, but vocal, minority.[5]

The threat is legitimate, as vaccines are indispensable public health tools. According to the U.S. Centers for Disease Control and Prevention (CDC), every year U.S. vaccines prevent 42,000 deaths, 20 million illnesses, $14 billion in medical costs, and $69 billion in social costs.[6] Public health scholars point to these outcomes to demonstrate that vaccines are extremely safe and effective public health interventions—despite Russian attempts to convince Americans otherwise.[7] Indeed, these same scholars observe that "[f]ew dispute that vaccinations are one of the greatest public health achievements of all time, perhaps ranking second only to the advent of clean water."[8] So why would the Russians seek to "amplify" a vaccine debate that appeals only to a fringe group of misinformed parents?

The Russians targeted this debate, perhaps, because no such public consensus regarding vaccine safety and efficacy exists in the United States. Remarkably, a large group of Americans dispute both the safety, efficacy, and even the necessity of childhood vaccines. A recent peer-reviewed epidemiological study found that almost four out of five parents in the United States have concerns about vaccines.[9] Instead of a tiny minority, a majority (52 percent) of American parents believe that the government should permit them to refuse vaccines that are today required by law.[10] Two out of five parents delay childhood vaccinations.[11] (Indeed, 4 percent of U.S. *pediatricians* refuse vaccinations for their own children.)[12] Many assume that anti-vaxxers are "ill-informed dilettantes clinging to unscientific Internet chatter or a debunked study that linked vaccines and autism."[13] Instead, studies routinely demonstrate that vaccine-

---

[5] James Lobo, *Vindicating the Vaccine: Injecting Strength Into Mandatory School Vaccination Requirements to Safeguard the Public Health*, 57 B.C. L. REV. 261, 262–64 (2016).

[6] Nili Karako-Eyal, *Increasing Vaccination Rates Through Tort Law: Theoretical and Empirical Insights*, 86 UMKC L. REV. 1, 6 (2017).

[7] *See* Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 427–29 (2004).

[8] *Id.* at 438.

[9] Daniel A. Salmon et al., *Vaccine Hesitancy Causes, Consequences, and a Call to Action*, 33 VACCINE D66, D67 (2015) (this study used data from 2010 and surveyed parents with children ages 1–6 years old).

[10] Louise Kuo Habakus & Mary Holland, *The Case for Vaccine Choice*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN 1, 10 (Louise Kuo Habakus et al. eds., 2d ed. 2012).

[11] *See* Salmon et al., *supra* note 9, at D68 (this study used data from 2009).

[12] Douglas S. Diekema, *Responding to Parental Refusals of Immunization of Children*, 115 PEDIATRICS 1428, 1428 (2005).

[13] Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153, 2162 (2017).

hesitant parents are typically married mothers with substantially higher education levels, higher household incomes, and more parental experience than parents without vaccine concerns.[14] These statistics challenge the traditional anti-vaxxer narrative described above, which is that the vaccine-hesitant are misinformed about vaccines and science. Indeed, the inquiry should not ask why a fringe minority of conspiracy theorists ignore science, but rather why a majority of parents (consisting of the most educated, experienced, and financially secure ones) harbor skepticism about U.S. vaccine policy.

This article argues that U.S. vaccine legislation directly produces (and perpetuates) vaccine hesitancy. The laws that govern and regulate vaccines in the United States foster a false perception of government overreach, fraud, and corruption. U.S. vaccine policy rests precariously—and unnecessarily—on the legal foundations of strict immunization mandates, lax regulatory oversight, and blanket limited liability for vaccine manufacturers. These legal structures facilitate widespread and systemic doubt about childhood vaccines. They also enable some parents to claim that the government prioritizes pharmaceutical industry interests and abstract notions of public health over the concerns of individual Americans. As a result, these legal structures have transformed vaccination—a modern medical miracle—into a locus of distrust and confusion that is turning the nation's most educated parents against an indispensable public health tool.[15] Indeed, in the midst of the COVID-19 pandemic, 44 percent of Americans would

---

[14] *See* Philip J. Smith et al., *The Association Between Intentional Delay of Vaccine Administration and Timely Childhood Vaccination Coverage*, 125 PUB. HEALTH REP. 534, 539 (2010); *see also* Jessica E. Atwell et al., *Nonmedical Vaccine Exemptions and Pertussis in California, 2010*, 132 PEDIATRICS 624, 628 (2013) (noting that vaccine-hesitant parents tend to be associated with factors such as a "higher percentage of high school, college, or graduate school graduates; higher median household income; and lower percentage of families in poverty"); Philip J. Smith et al., *Children Who Have Received No Vaccines: Who Are They and Where Do They Live?*, 114 PEDIATRICS 187, 187 (2004) ("Unvaccinated children tended to be white, to have a mother who was married and had a college degree, to live in a household with an annual income exceeding $75,000, and to have parents who expressed concerns regarding the safety of vaccines and indicated that medical doctors have little influence over vaccination decisions for their children."); Philip J. Smith et al., *Parental Delay or Refusal of Vaccine Doses, Childhood Vaccination Coverage at 24 Months of Age, and the Health Belief Model*, 126 PUB. HEALTH REP. 135, 139–40 (2011) ("Generally, the consecutive ordering of parental/delay refusal described previously defined a continuum that also was associated with factors related to higher socioeconomic status. For example, children whose parents delayed and refused vaccines were significantly more likely to live in a household with an annual income >400% of the federal poverty level; to have a mother who was married, ≥ 30 years of age, English-speaking, or a college graduate; to be covered by private health insurance; and to live in a household with ≥ 4 children who were 18 years of age or younger. Also, children whose parents delayed and refused were more likely to be of non-Hispanic white race/ethnicity than those who neither delayed nor refused." (internal citations omitted)).

[15] *See* sources cited *supra* note 14.

refuse a vaccine due to concerns about government vaccine policies.[16] U.S. vaccine legislation is, in and of itself, a dangerous public health crisis that directly produces vaccine hesitancy.

This argument has four major components. Part I examines the nature and extent of U.S. vaccine mandates. The government mandates childhood vaccines to ensure widespread "herd immunity." However, the United States is a global outlier with regard to imposing extensive vaccine mandates on its population. As a result, vaccine critics argue that U.S. compulsory vaccination policy unduly infringes upon individual liberty. Part II investigates vaccine testing and approval protocols. Critics believe that industry-sponsored clinical trials that test vaccine safety and efficacy are subject to fraud due to the financial conflicts of interest that occasionally arise in vaccine approval procedures. Part III discusses legislation, like the National Childhood Vaccination Injury Act of 1986, which eliminates drug company liability for vaccine-related injuries. This legislation shifts risk away from drug companies, since the government (not the pharmaceutical industry) compensates injury victims with taxpayer money. Some parents feel that this risk allotment negates the industry's commitment to vaccine safety and innovation. Part IV demonstrates how these legal structures—compulsion, lax oversight, and limited liability—sometimes converge and produce conspicuous social movements that cast doubt on vaccines. This is evident in the rise of pervasive distrust in the United States related to both autism and the flu shot. The recognition that these legal structures produce and foment unnecessary suspicions about vaccines is the first step in mitigating this public health crisis. If the government makes changes to one or more of these three legal structures, it can reduce (and potentially eliminate) vaccine hesitancy in the United States.

I. VACCINE MANDATES

Vaccine compulsion is the first legal structure that produces vaccine hesitancy in the United States. Vaccine-hesitant parents claim that immunization mandates undermine fundamental individual liberties and violate the right to informed medical consent.[17] Additionally, the U.S. vaccine mandate

---

[16] Laura Santhanam, *Why Americans Have Grown More Hesitant About The COVID-19 Vaccine*, PBS (Oct. 9, 2020, 4:57 PM), https://www.pbs.org/newshour/health/why-americans-have-grown-more-hesitant-about-the-covid-19-vaccine [https://perma.cc/KCP5-GQJV].

[17] Kyla L. Kelch, *Privacy Implications of Mandatory Immunizations, Exemptions, and Immunization Information Systems*, 4 I/S: J. L. & POL'Y FOR INFO. SOC'Y 851, 866–67 (2008).

diverges from the voluntary vaccine policies that most other developed democratic nations employ.[18] The federal government currently recommends (and all fifty states legally *require*) that parents vaccinate their children against a variety of diseases before enrolling them in school or daycare.[19] These mandates mirror the CDC vaccine schedule and typically require parents to vaccinate children against sixteen diseases: Diphtheria, Haemophilus influenzae type b (Hib), Hepatitis A, Hepatitis B, Human Papillomavirus (HPV), Influenza (flu), Measles, Meningococcal Disease, Mumps, Pertussis (whooping cough), Polio, Pneumococcal, Rotavirus, Rubella, Tetanus, and Varicella (chicken pox).[20] Government agencies argue that public health outcomes justify these extensive mandates. The CDC estimates that these vaccines have prevented 732,000 deaths in the United States between 1994 and 2014.[21]

A. Vaccine Science

Vaccines are effective from a public health perspective because immunization is preventative. Vaccines deliberately introduce a similar or weakened form of a virus or bacteria into a healthy person's system, which produces antibodies that give them immunity if or when they encounter that disease later in life.[22] Public health history confirms that vaccines work, as they

> have dramatically reduced morbidity and mortality rates of some of the worst diseases in history by preventing them on the front end. The benefits have been remarkable: millions of deaths have been prevented, millions more lives markedly improved, and billions of dollars of societal resources have been saved for use in countless other valuable endeavors.[23]

Vaccines have essentially eliminated deadly diseases like polio and smallpox in the United States, dramatically improving

---

[18] Frej Klem Thomsen, *Childhood Immunization, Vaccine Hesitancy, and Provaccination Policy in High-Income Countries*, 23 PSYCHOL. PUB. POL'Y & L. 324, 330 (2017).

[19] OFFICE FOR STATE, TRIBAL, LOCAL & TERRITORIAL SUPPORT, CTRS. FOR DISEASE CONTROL & PREVENTION, STATE SCHOOL IMMUNIZATION REQUIREMENTS AND VACCINE EXEMPTION LAWS 7–9 (2015), http://www.cdc.gov/phlp/docs/school-vaccinations.pdf [https://perma.cc/TF9X-U9GP]. The District of Columbia likewise mandates vaccines. *Id.* at 7.

[20] *See 2020 Recommended Vaccinations for Infants and Children (Birth Though 6 years) Parent-Friendly Version*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread.html [https://perma.cc/59KZ-DC9A]; *see also 2020 Recommended Vaccinations for Children (7–18 Years Old) Parent-Friendly Version*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/schedules/easy-to-read/adolescent-easyread.html [https://perma.cc/C64V-F93S].

[21] Erwin Chemerinsky & Michele Goodwin, *Compulsory Vaccination Laws Are Constitutional*, 110 NW. U. L. REV. 589, 600 (2016).

[22] *See* Calandrillo, *supra* note 7, at 362–63.

[23] *Id.* at 369.

the nation's public health.[24] Indeed, given these public health outcomes, "[o]ne cannot overestimate the beneficial changes vaccines have introduced into our lives."[25]

Childhood immunizations are also extremely cost-effective public health interventions. Some estimates suggest that "[t]he measles vaccine alone has saved the United States billions of dollars," while the polio vaccine has produced *trillions* of dollars in national savings.[26] Some immunizations produce a ratio as high as $27 saved for every $1 the nation spends on the vaccine.[27]

In addition to being inexpensive, vaccines are relatively safe. As with all medications, vaccines do cause occasional adverse reactions in children, but public health advocates attest that these negative outcomes are generally minor and statistically rare.[28] As such, "research overwhelmingly has shown that the public health benefit of administering vaccines outweighs the marginal risks imposed by them."[29] This low-cost, low-risk, and high-reward profile appears to be the driving force behind U.S. vaccine mandates.

B. The History of U.S. Vaccine Mandates

Compulsory immunization laws in the United States became the standard approach to disease prevention in the late 1960s, after states with vaccine mandates presented up to 51 percent fewer cases of measles than states without mandates.[30] However, the legal precedent establishing a state's right to administer compulsory vaccines dates back to 1905.[31] In *Jacobson v. Massachusetts*, a Massachusetts resident challenged a state law requiring adults to get the smallpox vaccine or pay a $5 fine.[32] The Court upheld the state law as constitutional and determined that states have the power to enact a compulsory vaccination law.[33]

In 1922, the Court again addressed compulsory vaccine laws in *Zucht v. King*.[34] This case differed from *Jacobson*, as it involved a state law mandating *children* receive vaccinations in

---

[24] *Id.* at 366, 375.

[25] Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFF. L. REV. 881, 886 (2015).

[26] *See* Calandrillo, *supra* note 7, at 380–81.

[27] *Id.* at 380.

[28] *See* Parasidis, *supra* note 13, at 2241; *see also* Karako-Eyal, *supra* note 6.

[29] *See* Lobo, *supra* note 5, at 272.

[30] *See* Calandrillo, *supra* note 7, at 382.

[31] *See generally* Jacobson v. Massachusetts, 197 U.S. 11 (1905).

[32] *Id.* at 12.

[33] *Id.* at 39.

[34] *See generally* Zucht v. King, 260 U.S. 174 (1922).

order to attend school.[35] The government typically defers to parental judgment with regard to healthcare decisions concerning their children, but *Zucht* made vaccines the rare exception to this rule.[36] In upholding the vaccination law, the Court established that states can impose childhood vaccine mandates as preventative measures against disease, thereby establishing lasting precedent on the issue.[37] *Zucht* also made compliance with the vaccine mandate a valid prerequisite for school attendance.[38] Courts have consistently reinforced the rule that a state can implement any mandatory vaccination policy it deems necessary to ensure public health.[39] As a result, "[b]y the mid-1950s, it was arguably settled law that school vaccination mandates were presumptively valid."[40] This presumption remains in effect today and states have nearly unbridled discretion with regard to imposing childhood vaccine mandates.[41]

C. The Herd Immunity Theory

Vaccine mandates are necessary to ensure "herd immunity."[42] Herd immunity is the primary scientific rationale behind compulsory vaccination laws.[43] The theory is that if enough people in a population are immune from an infection, the disease cannot easily spread.[44] If there is widespread immunity, then there will be an insufficient number of hosts to carry and transmit the infection from person to person.[45] This prophylactic barrier protects members of the "herd" who are too young to receive the vaccine or who are otherwise immunocompromised and cannot participate in immunization programs.[46] The threshold for achieving herd immunity varies from disease to disease, but vaccination rates (and, therefore, immunity rates)

---

[35] *Id.* at 175.

[36] *Id.* at 176–77; *see* Reiss & Weithorn, *supra* note 25, at 909.

[37] James Muela, *Updating Vaccine Law: Restructuring* Jacobson v. Massachusetts *to Create a Safe Harbor for States*, 69 BAYLOR L. REV. 462, 464 (2017).

[38] *Id.*

[39] *See, e.g.*, Sadlock v. Bd. of Educ. of Borough of Carlstadt, 58 A.2d 218, 220–22 (N.J. 1948) (holding that a New Jersey school vaccine mandate "was a proper exercise of the police power for the protection of the public welfare and will be sustained").

[40] Mary Holland, *Compulsory Vaccination, The Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y, L. & ETHICS 39, 52 (2012).

[41] *See* Muela, *supra* note 37, at 467.

[42] Elizabeth Hatch, *To Vaccinate or Not to Vaccinate?: The Challenges and Benefits of the Implementation of the Jamie Schanbaum Act*, 15 TEX. TECH. ADMIN. L.J. 187, 201 (2013).

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *See* Chemerinsky & Goodwin, *supra* note 21.

must generally cover 80–99 percent of the population.[47] For measles, the herd immunity threshold sits somewhere between 83–94 percent; for whooping cough, it ranges from 92–94 percent of the population.[48] Indeed, many U.S. public health advocates unwaveringly embrace vaccine mandates because of the herd immunity theory, since

> herd immunity can exist only if a sufficiently high proportion of the population is immunized such that the transmission of the disease is effectively interrupted. Therefore, society *cannot allow* every one of its members (or even a sizeable minority) to rely on the indirect protection afforded by other vaccinated members of the herd—because then community protection unravels as all try to "free ride" off of the benevolent acts of others.[49]

States institute strong laws to prevent individuals from forgoing vaccination because the potential social costs of the free rider problem are high.[50]

In the past, state vaccine mandates included medical, religious, and/or philosophical exemptions, but today public health advocates are calling for states to eliminate nonmedical exemptions for children based largely on herd immunity justifications.[51] Following the 2014–2015 California measles outbreak, legal scholars Erwin Chemerinsky and Michelle Goodwin urged "every state to revise its vaccination law to make sure that every child, and every person, is vaccinated unless there is a medical reason not to do so."[52] In 2015, California passed Senate Bill 277, which restructured religious and personal belief exemptions, making them more difficult to obtain from the State Department of Public Health.[53] Indeed, public health experts assert that Senate Bill 277's restructuring eliminated the personal belief exemption.[54] Mississippi and West Virginia have likewise eliminated religious and personal belief exemptions.[55] Washington eliminated personal belief exemptions for some vaccines in 2019.[56] Maine is scheduled to eliminate personal belief

---

[47] Mary Holland & Chase E. Zachary, *Herd Immunity and Compulsory Childhood Vaccination: Does the Theory Justify the Law?*, 93 OR. L. REV. 1, 17 (2014).

[48] *Id.*

[49] *See* Calandrillo, *supra* note 7, at 420 (emphasis added).

[50] *See* Holland & Zachary, *supra* note 47, at 10.

[51] *See* Chemerinsky & Goodwin, *supra* note 21, at 597–98, 615.

[52] *Id.* at 615.

[53] *See* S.B. 277, 2015–16 Leg., Reg. Sess. (Cal. 2015).

[54] Pamela McDonald et al., *Exploring California's New Law Eliminating Personal Belief Exemptions to Childhood Vaccines and Vaccine Decision-Making Among Homeschooling Mothers in California*, 37 VACCINE 742, 743 (2019).

[55] *See* Chemerinsky & Goodwin, *supra* note 21, at 598.

[56] *MMR Vaccine Exemption Law Change 2019*, WASH. STATE DEP'T OF HEALTH, https://www.doh.wa.gov/CommunityandEnvironment/Schools/Immunization/ExemptionL

vaccine exemptions in 2021.[57] Meanwhile, the Food and Drug Administration (FDA) indicated that the "[f]ederal [g]overnment may try to intervene if states refuse to reconsider laws that allow for exemptions from vaccination requirements."[58] Almost in lockstep, public health advocates and scholars are calling for states to abolish vaccine exemptions, both religious and philosophical.[59] Even in states where exemptions still exist, government institutions obstruct access to them.[60] Some pediatricians have stated that they will file a child neglect report with the state if parents refuse to vaccinate their child or seek to delay vaccinations.[61] In the name of herd immunity, states are strengthening vaccine mandates and curtailing exemptions to protect the public health.

D. Objections to U.S. Vaccine Mandates

1. Informed Medical Consent

Vaccine critics view the legal compulsion to immunize children as a violation of a parent's fundamental civil liberties

---

awChange#:~:text=In%20May%202019%2C%20the%20Washington,private%20schools%20and%20child%20cares [https://perma.cc/L89B-83R8].

[57] Evan Simko-Bednarski, *Maine Bars Residents from Opting Out of Immunizations for Religious or Philosophical Reasons*, CNN (May 27, 2019, 11:36 AM), https://www.cnn.com/2019/05/27/health/maine-immunization-exemption-repealed-trnd/index.html [https://perma.cc/M7VA-36DX].

[58] Megan Trimble, *FDA Commissioner: Government May Act if States Don't Change Vaccine Laws*, U.S. NEWS (Feb. 20, 2019), https://www.usnews.com/news/national-news/articles/2019-02-20/fda-commissioner-government-may-act-if-states-dont-strengthen-vaccine-laws [https://perma.cc/YZ2T-LLHM].

[59] Hillel Y. Levin, *Why Some Religious Accommodations for Mandatory Vaccinations Violate the Establishment Clause*, 68 HASTINGS L.J. 1193, 1196 (2017) (noting that this article "offers a practical foundation for challenging religious accommodations in the vaccination context in order to protect vulnerable children from contracting preventable diseases"); *see also* Victor Diego Gonzalez, Note, *Religion in the Time of Measles: Prescriptions for Minimizing the Public Health Threats Associated with Religious Exemptions from Mandatory Vaccinations*, 15 CARDOZO PUB. L. POL'Y & ETHICS J. 413, 418 (2017) (calling "for the elimination of philosophical exemptions to mandatory vaccination laws, a strengthening of the standards used in determining bona fide religious exemptions, and the adoption of exemplary policies from various states that decrease the public health risks that religious exemptions pose").

[60] *See* Habakus & Holland, *supra* note 10, at 3. At a recent Senate hearing, Senator Rand Paul (who is a physician) expressed misgivings about government vaccine compulsion; *see also* Igor Derysh, *Sen. Bill Cassidy, An Actual Physician, Schools Rand Paul Over Anti-Vaxxer Claims*, SALON (Mar. 6, 2019, 11:00 AM), https://www.salon.com/2019/03/06/sen-bill-cassidy-an-actual-physician-schools-rand-paul-over-anti-vaxxer-claims/ [https://perma.cc/STR9-QXCS]. Paul noted that "[a]s we contemplate forcing parents to choose this or that vaccine, I think it's important to remember that force is not consistent with the American story, nor is force consistent with the liberty our forefathers sought when they came to America." *Id.*

[61] Sara Schreiber, *Pediatrician's Extreme Stance on Anti-Vaxxers Has Riled People Up*, GOOD HOUSEKEEPING (Apr. 21, 2017), https://www.goodhousekeeping.com/health/news/a43825/pediatrician-vaccines-viral/ [https://perma.cc/4TAD-X5Y5].

and as a denial of informed medical consent.[62] These concerns are not isolated to contemporary vaccine mandates. Indeed, the aforementioned plaintiff in *Jacobson* objected to the state-mandated smallpox vaccine on these very grounds, noting that the vaccine mandate violated his personal liberty and bodily integrity.[63] Vaccine mandates are sometimes met with resistance because the government is compelling a healthy person to engage in a preemptive medical intervention that may in fact harm them.[64] Some believe, as Jacobson did, that "[a]ll medical interventions, including vaccination, require free and informed consent. To abridge that right is to violate the essential human rights to life, liberty, and bodily integrity. By denying truly free and informed consent to vaccination, U.S. vaccine policy violates fundamental rights."[65] This response is perhaps not surprising given the fact that the nation's constitutional structure aims to promote the twin concepts of limited government power and expansive individual civil liberties.[66] Indeed, the Supreme Court has recognized that Americans have a constitutional right to refuse any unwanted medical treatment—except, that is, for vaccines.[67]

2. Immunization Policies in Peer Nations

As it turns out, compulsion is not consistent with vaccine policies in most other nations. In fact, while other nations do require parents to vaccinate their children against some diseases, the United States is the only developed democratic nation that compels parents to vaccinate their children against such a large number of diseases.[68] Great Britain, for instance, does not have a mandatory vaccine policy.[69] Instead, the government "officially recommend[s]" that its citizens vaccinate their children "for the good of society."[70] Until recently, the German government likewise had no vaccine mandates, asking instead only that

---

[62] *See* Holland & Zachary, *supra* note 47, at 36.

[63] *See* Holland, *supra* note 40, at 45.

[64] Heidi J. Larson et al., *Addressing the Vaccine Confidence Gap*, 378 LANCET, 526, 526–27 (2011).

[65] *See* Habakus & Holland, *supra* note 10, at 1.

[66] Lawrence M. Friedman, A HISTORY OF AMERICAN LAW 89 (4th ed. 2019).

[67] Cruzan v. Dir., Mo. Dept. of Health, 497 U.S. 261, 278 (1990); Prince v. Massachusetts, 321 U.S. 158, 167–70 (1944) (holding that the Constitution does not permit a parent to expose the community or one's children to harm from disease).

[68] *See* Holland & Zachary, *supra* note 47, at 5–6.

[69] Rob Henson, *Inoculated Against Recovery: A Comparative Analysis of Vaccine Injury Compensation in the United States and Britain*, 15 TULSA J. COMP. & INT'L L. 61, 61–62 (2007).

[70] *Id.*

parents submit proof to the child's school that they consulted a doctor about the benefits of vaccines.[71] However, in March 2020, the German government began mandating the measles vaccine for school children.[72] Australia also has no vaccine mandates and instead incentivizes vaccination by offering tax-exempt payments to parents who comply with government vaccine recommendations.[73] Russia—the nation that amplified the U.S. vaccine debate—similarly permits parents to decline childhood vaccinations.[74] After protracted national debate and outcry, the Italian government continues to pursue an effective mandatory vaccination program.[75]

Some nations that purport to have "mandatory" vaccination laws, such as Latvia, admit that they do not enforce these mandates.[76] If they did enforce the mandates, noncompliance would result in a small fine—not (as in the United States) the denial of the right to childhood education in the nation's public school system.[77] Nations that do enforce mandates generally do so only for a small number of immunizations. Belgium, for instance, requires just one childhood vaccine (polio) throughout the country, in contrast to the sixteen childhood vaccines typically mandated in the United States.[78] France recently joined the United States in mandating a large number of childhood vaccines, but many French doctors fear "that the measure is authoritarian and could backfire, not least by

---

[71] Susan Scutti, *How Countries Around the World Try to Encourage Vaccination*, CNN (Jan. 2, 2018, 3:32 PM), https://www.cnn.com/2017/06/06/health/vaccine-uptake-incentives/index.html [https://perma.cc/QZ98-64RR] (detailing nation-by-nation approach to vaccine legislation).

[72] Jasmin Bauomy, *Measles Vaccination Becomes Mandatory in Germany*, EURONEWS (Mar. 2, 2020), https://www.euronews.com/2020/03/02/measles-vaccination-becomes-mandatory-in-germany [https://perma.cc/TQ7V-MLRE] (detailing how Germany now requires the measles vaccine for school children, subjecting noncompliant parents to a fine).

[73] Erin Walkinshaw, *Mandatory Vaccinations: The International Landscape*, 183 CANADIAN MED. ASS'N J. E1167, E1167 (2011).

[74] Evan Gershkovich, *Russia Has a Vaccination Problem*, MOSCOW TIMES (Sept. 28, 2018), https://www.themoscowtimes.com/2018/09/28/russia-has-a-vaccine-problem-a63017 [https://perma.cc/FX96-ADKS].

[75] Gianluca Mezzofiore, *Why Italy's U-Turn on Mandatory Vaccination Shocks the Scientific Community*, CNN (Aug. 7, 2018, 1:59 PM), https://www.cnn.com/2018/08/07/health/italy-anti-vaccine-law-measles-intl/index.html [https://perma.cc/26A2-6W2G]. However, this matter appears to remain in flux. In March 2019, the Italian government considered changing its mind (at least temporarily) once again. *See* Nick Squires, *Italy's Populist Coalition Renounces Anti-Vaccination Stance Amid Measles 'Emergency'*, TELEGRAPH (Nov. 15, 2018, 5:31 PM), https://www.telegraph.co.uk/news/2018/11/15/italys-populist-coalition-renounces-anti-vaccination-stance/ [https://perma.cc/V42X-SCHW].

[76] *See* Walkinshaw, *supra* note 73.

[77] *Id.*

[78] *See id.* at E1168; *Vaccinations in Belgium*, EXPATICA (Nov. 17, 2020), https://www.expatica.com/be/healthcare/healthcare-basics/vaccinations-in-belgium-105159/ [https://perma.cc/8VSC-UK9E] (noting that "[o]nly one vaccination is mandatory throughout Belgium: polio"); sources cited *supra* note 20.

alienating parents and increasing wariness of vaccines in a country where various health scandals . . . have spread mistrust of health authorities."[79] In the wake of the law, France now ranks among the most vaccine-hesitant nations in Europe.[80] Japan is likewise reticent to impose large-scale vaccine mandates, such that "[m]any common vaccines, including those for measles, mumps, and rubella (MMR), the inactivated poliovirus vaccine, and combination vaccines are not yet available in Japan."[81] The United States stands out among high-income democratic nations with regard to imposing such far-reaching vaccine mandates.[82]

3. Challenges to the Herd Immunity Theory

According to some vaccine critics, many of these nations might avoid imposing compulsory vaccination laws because herd immunity, the key justification for compulsory childhood vaccines, is presently unattainable.[83] Other nations aim to achieve "herd effect," which limits outbreaks and requires lower vaccination rates and less extensive public health mandates.[84] The U.S. policy, critics argue, will never achieve herd immunity because the nation staggers the timing of childhood vaccines and because vaccines offer imperfect immunity (and sometimes no immunity at all) against many diseases.[85] As such, the impracticability of attaining herd immunity has caused "many researchers to reject the theory [of herd immunity] altogether."[86] Some U.S. disease outbreaks lend credence to skepticism about herd immunity. Public health officials have recorded measles outbreaks in school populations where the vaccination rates were 99 percent and 100 percent, respectively.[87]

---

[79] *Laws are Not the Only Way to Boost Immunization*, NATURE (Jan. 17, 2018), https://www.nature.com/articles/d41586-018-00660-y [https://perma.cc/2AMX-379H].

[80] AURORA MANTAS, EUR. HEALTH MGMT. ASS'N, VACCINE HESITANCY IN EUROPE 1 (2017), https://ehma.org/wp-content/uploads/2017/03/Vaccine-Hesitancy-in-Europe_-Final.pdf [https://perma.cc/J4BD-TPTA].

[81] Rumiko Shimazawa & Masayuki Ikeda, *The Vaccine Gap Between Japan and the UK*, 107 HEALTH POL'Y 312, 312 (2012).

[82] *See* Thomsen, *supra* note 18.

[83] *See* Holland & Zachary, *supra* note 47, at 4–5 (noting that "[g]iven contemporary, imperfect vaccine technology and geographical and age-stratified vaccination mandates, herd immunity does not exist and is not attainable," and that "[o]ur viewpoint may help explain why many developed countries, including those with political systems closest to our own, have only voluntary childhood vaccination programs").

[84] T. Jacob John & Reuben Samuel, *Herd Immunity and Herd Effect: New Insights and Definitions*, 16 EUR. J. EPIDEMIOLOGY 601, 601 (2000).

[85] *Id.* at 605.

[86] *See* Holland & Zachary, *supra* note 47, at 19.

[87] Tracy L. Gustafson et al., *Measles Outbreak in a Fully Immunized Secondary School Population*, 316 NEW ENG. J. MED. 771, 771 (1987); *Measles Outbreak Among Vaccinated High School Students–Illinois*, CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WK. REP. (June 22, 1984), http://www.cdc.gov/mmwr/preview/mmwrhtml/00000359.htm [https://perma.cc/AKU2-VRGC] (detailing the government

In response, the CDC conceded that measles can occur even with 100 percent vaccine compliance.[88]

Indeed, the phenomenon of "vaccine failure" is a consistent public health reality in the United States.[89] Recent whooping cough outbreaks demonstrate the phenomenon of vaccine failure and the limits of the herd immunity theory. In 2010, California experienced a large whooping cough outbreak, prompting some to blame vaccine-hesitant parents for the state's lack of herd immunity against whooping cough.[90] Scientists later found that the outbreaks arose because the whooping cough vaccine—which has been in use for two decades—simply does not work very well.[91] In fact, repeated studies of the whooping cough vaccine show that it offers only a small amount of immunity for one year and essentially no immunity against the disease just "2–3 years after vaccination."[92] The same phenomenon occurred during a mumps outbreak in a population in which every infected child had been vaccinated against the disease, prompting the CDC to issue a statement "conced[ing] that the mumps portion of the [measles, mumps, rubella (MMR)] vaccine is less effective than the other parts."[93]

4. U.S. Public Health Outcomes

The U.S. approach toward vaccine mandates breeds widespread doubt about the efficacy of immunizations. Some of these misgivings revolve around the fact that the United States, despite its vaccine mandates, has poor health outcomes for both infants and adults relative to peer nations. Vaccine critics who observe that the United States is a global outlier with regard to its compulsory vaccine laws point to the government's alarming

---

summary of the measles outbreak and the hard-to-explain outcome given the high vaccination rates at the school).

[88] *See Measles Outbreak Among Vaccinated High School Students–Illinois*, *supra* note 87.

[89] *See* Karako-Eyal, *supra* note 6, at 4.

[90] Jessica E. Atwell et al., *Nonmedical Vaccine Exemptions and Pertussis in California, 2010*, 132 PEDIATRICS 624, 628 (2013) ("Although statewide immunization coverage in California is high among children entering kindergarten, in many communities within the state, coverage is far lower. Our findings are consistent with a previous study in which [non-medical exemptions] were associated with pertussis clusters. Several studies have previously demonstrated the increased risk of vaccine-preventable diseases among those who refuse vaccines.").

[91] Maryn McKenna, *Why Whooping Cough Vaccines Are Wearing Off*, SCIENTIFIC AM. (Oct. 1, 2013), https://www.scientificamerican.com/article/why-whooping-cough-vaccines-are-wearing-off/#googDisableSync [https://perma.cc/43VD-4W67].

[92] Nicola P. Klein et al., *Waning Tdap Effectiveness in Adolescents*, 137 PEDIATRICS 1, 1 (2016).

[93] Annemarie Colbin, *A Holistic Health Perspective*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 275, 280.

concession that "[t]he U.S. infant mortality rate is higher than those in most other developed countries, and the gap between the U.S. infant mortality rate and the rates for the countries with the lowest infant mortality appears to be widening."[94] Admittedly, the U.S. infant mortality rate does lag far behind most developed (and many undeveloped) nations. The United States currently ranks 56th in the world for infant mortality rates, with an estimated 5.8 deaths per 1,000 live births.[95] These figures show that the United States is tied with Serbia and trails Bosnia and Herzegovina.[96] U.S. infant mortality rates rank distressingly far behind nations such as Germany (3.4/1000) and Japan (2.0/1000).[97]

In addition to these relatively poor infant mortality rates, American adults also die earlier than adults in peer nations.[98] In fact, "[t]he U.S. ranked last in life expectancy among developed nations through 2015 and is the only one of 18 countries with an average life span less than 80 years."[99] These are paradoxical outcomes, since the United States spends far more money on health interventions per capita than any other nation.[100] The United States spends $10,224 annually per person on healthcare while peer nations spend on average $5,280 per person.[101] Statistics such as these raise suspicions related to vaccines and pharmaceutical industry profiteering among vaccine-hesitant individuals.[102] For instance, one vaccine critic observes:

> Consider, for a moment, schools' vaccination mandates from the drug manufacturers' perspective. Day care and school systems become free vaccine marketing departments. There is no need to train a sales force or to incur other marketing expenses. If you can force your customers to acquire your product, it eliminates all of the messy

---

[94] MARIAN F. MACDORMAN & T.J. MATHEWS, U.S. DEP'T OF HEALTH & HUMAN SERVS.: NAT'L CTR. FOR HEALTH STATISTICS, DATA BRIEF NO. 9, RECENT TRENDS IN INFANT MORTALITY IN THE UNITED STATES 1 (2008), https://www.cdc.gov/nchs/data/databriefs/db09.pdf [https://perma.cc/R5Z9-SKEE].

[95] *The World Factbook*, CIA, https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html [https://perma.cc/6T92-MVG4] (the United States ranks 170 out of 225 nations).

[96] *Id.*

[97] *Id.*

[98] Julian Wylie, *U.S. Lags in Life Expectancy*, AARP (Sept. 21, 2018), https://www.aarp.org/health/healthy-living/info-2018/life-expectancy-down.html [https://perma.cc/A45P-NT3M].

[99] *Id.*

[100] Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON–KFF HEALTH SYS. TRACKER (Dec. 7, 2018), https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start [https://perma.cc/C72V-HJZZ].

[101] *Id.*

[102] Michael Belkin, *The Vaccine Bubble and The Pharmaceutical Industry*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 158, 169.

> uncertainty and hassle of a competitive market. Instead of free market competition, *their business strategies are built on compulsion*. The public school system is an ATM for pharmaceutical companies—who are laughing all the way to the bank.[103]

Of course, evidence does not support correlating vaccine mandates, mortality rates, and vaccine-industry profits. However, the discrepancy between U.S. vaccine mandates and policies in similarly situated nations, coupled with a steep divergence in public health spending and outcomes, does perhaps warrant closer examination to the extent that an explanation might help allay the concerns of the vaccine-hesitant.

The government inadvertently feeds these unfounded doubts about immunizations by consistently amending the vaccine schedule to include more mandatory immunizations. As one medical doctor observes, in 1983 the vaccination schedule included twenty-four doses of seven vaccines; today, the federal government "recommends that children receive *seventy doses* of *sixteen* different vaccines by the time they graduate high school."[104] During that same time period, the United States saw its global ranking for infant mortality rates plummet.[105]

Vaccine critics also believe that the government reinforces vaccine mandates through coercive fearmongering tactics.[106] Fear is indeed a strong motivator; as one public health scholar puts it, "[p]eople will line up willingly, if not desperately, for a vaccine if they are sufficiently frightened of the disease it prevents."[107] To that point, critics likewise observe that European nations estimate that measles kills between 1 in 3,000 to 1 in 4,500 infected individuals, while the United States

---

[103] *Id.* at 166 (emphasis added).

[104] Sherri Tenpenny, *A Doctor's View of Vaccines and the Public Health*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 262, 262 (emphasis added).

[105] Vera Hassner Sharav, *Medical Ethics and Contemporary Medicine*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 84, 94 ("If vaccines have greatly improved the health of America's children, then it is fair to ask why the United States' ranking among world nations in infant mortality has plummeted from twelfth in 1960 to twenty-ninth in 1990, down to forty-sixth in 2010. The U.S. Centers for Disease Control and Prevention (CDC) acknowledges, 'The U.S. infant mortality rate is higher than those in most other developed countries, and the gap between the U.S. infant mortality rate and the rates for the countries with the lowest infant mortality rates appears to be widening.'").

[106] *See* Barbara Loe Fisher, *Politics, Profits & Pandemic Fear Mongering*, NAT'L VACCINE INFO. CTR. (May 1, 2009, 11:34 PM), https://www.nvic.org/NVIC-Vaccine-News/May-2009/Friday,-May-01,-2009-Politics,-Profits—-Pandemic-.aspx [https://perma.cc/Q7JZ-MBFN].

[107] Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS U. J. HEALTH L. & POL'Y 113, 139 (2010).

estimates the measles kills 1 in 333 infected Americans.[108] This discrepancy stands out given the fact that there has only been one confirmed measles death in the United States since 2003—and that victim had been vaccinated against measles.[109] As this section demonstrates, vaccine mandates serve as a legal foundation upon which parental doubt about vaccines continues to grow, especially as U.S. vaccine policies and health outcomes diverge sharply from the rest of the developed world.

II. PERCEIVED WEAKNESSES IN REGULATING CLINICAL VACCINE TESTS AND APPROVALS

The law governing vaccine testing and approval is the second structure of official U.S. regulatory policy that contributes to vaccine hesitancy. Despite extensive FDA safety protocols, vaccine critics perceive regulatory loopholes and occasional financial conflicts of interest as cause for concern in the vaccine approval process. In particular, critics express concerns over industry-sponsored clinical trials, post-market vaccine safety analysis, and the revolving door between the FDA, CDC, and the pharmaceutical industry.

A. Federal Vaccine Safety Regulations

The government has a large regulatory apparatus in place to ensure that vaccines are both safe and effective. Vaccines follow the same general path toward FDA approval as other pharmaceutical drugs.[110] Section 351 of the Public Health Service Act and the Food, Drug and Cosmetic Act (FDCA) currently set the regulatory guidelines for vaccines.[111] In addition, the Kefauver-Harris Amendments to the FDCA require that a vaccine producer conduct an investigation to prove that a drug is "both safe and effective before it may be

---

[108] *See* Thomsen, *supra* note 18, at 325.

[109] Tara Haelle, *First Confirmed U.S. Measles Death In More Than A Decade*, FORBES (July 2, 2015, 3:17 PM), https://www.forbes.com/sites/tarahaelle/2015/07/02/first-u-s-measles-death-in-more-than-a-decade/#228df2e9a196 [https://perma.cc/AHJ4-FX6Z]; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, MEASLES DATA AND STATISTICS 5 (2009), https://www.cdc.gov/measles/downloads/measlesdataandstatsslideset.pdf [https://perma.cc/SED6-DRXR] (noting that "the last measles death in the United States occurred in 2015"); Manisha Patel et al., *National Update on Measles Cases and Outbreaks—United States, January 1–October 1, 2019*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 11, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6840e2.htm [https://perma.cc/WL9V-UPPV] (observing that in 2019, the United States experienced a measles outbreak with 1,249 cases—yet no deaths were reported).

[110] *Vaccine Product Approval Process*, U.S. FOOD & DRUG. ADMIN. (Jan. 30, 2018), https://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblaprocess/ucm133096.htm [https://perma.cc/G2DV-RUJL].

[111] *Id.*

approved for marketing."[112] Prior to conducting clinical trials, a vaccine producer must subject a vaccine to preclinical development and testing.[113] If these tests are successful, the vaccine producer initiates three phases of clinical trials (a fourth phase sometimes occurs after licensing and continues to track the vaccine for adverse reactions).[114] Phase 1 involves tests on a small group of subjects (usually fewer than 100 people) to look for acute safety issues related to the vaccine.[115] Children do not participate in Phase 1 testing.[116] Phase 2 expands the testing (usually to several hundred people, including children) and focuses on vaccine dose range and safety.[117] Phase 3 testing evaluates the vaccine's safety and efficacy across a larger population (usually 1000+ people).[118]

If at any point during clinical trials the "data raise significant concerns about either safety or effectiveness, [the] FDA may request additional information or studies, or may halt ongoing clinical studies."[119] If the drug producer conducts a successful clinical trial, the FDA will approve the drug or vaccine for sale to the public.[120] The gold standard for clinical trials is to utilize a "randomized, double-blinded, and placebo-controlled" testing process.[121] That is, the clinical trial should compare a patient taking the experimental vaccine with a control group that takes a placebo, and the researchers should not know which patient receives the vaccine and which takes the placebo.[122]

The FDA's Center for Biologics, Evaluation, and Research (CBER) evaluates vaccine clinical trial data that drug companies submit to it.[123] CBER then presents that data to the FDA's Vaccines and Related Biological Products Advisory

---

[112] Russel Katz, *FDA: Evidentiary Standards for Drug Development and Approval*, 1 NEURORX 307, 307 (2004); *see also* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938); Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780, 781 (1962).

[113] Larry K. Pickering & Walter A. Orenstein, *Development of Pediatric Vaccine Recommendations and Policies*, 13 SEMINARS PEDIATRIC INFECTIOUS DISEASES 148, 148 (2002).

[114] Investigational New Drug Application, 21 C.F.R. § 312.21(a); *see also* Pickering & Orenstein, *supra* note 113.

[115] *See* sources cited *supra* note 114.

[116] *See* Pickering & Orenstein, *supra* note 113.

[117] Investigational New Drug Application, 21 C.F.R. § 312.21(b); *see also* Pickering & Orenstein, *supra* note 113.

[118] Investigational New Drug Application, 21 C.F.R. § 312.21(c); *see also* Pickering & Orenstein, *supra* note 113.

[119] *See Vaccine Product Approval Process*, *supra* note 110.

[120] DAVID HEALY, PHARMAGEDDON 77 (2012).

[121] *See* Pickering & Orenstein, *supra* note 113.

[122] Marc A. Rodwin, *Independent Clinical Trials to Test Drugs: The Neglected Reform*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 113, 125 (2012).

[123] *See* Pickering & Orenstein, *supra* note 113, at 149.

Committee (Advisory Committee).[124] The Advisory Committee makes a vaccine-approval recommendation to the FDA Commissioner based on considerations about the vaccine's safety, efficacy, and public health benefits.[125] The fifteen Advisory Committee members are typically leading authorities in the fields of immunology, epidemiology, biochemistry, and other areas of vaccine-related expertise.[126]

If the Advisory Committee recommends the vaccine and the FDA Commissioner approves that recommendation, the CDC's Advisory Committee on Immunization Practices (ACIP) proceeds to review the vaccine and makes a recommendation to the CDC Director about whether or not to include the vaccine on the federal vaccine schedule (Vaccine Schedule).[127] ACIP considers vaccine safety and efficacy, the severity of the disease the vaccine prevents, and the prevalence of the disease in making its recommendation.[128] In addition, the American Academy of Pediatrics (a professional association of doctors) must concur with ACIP's recommendation before the government adds the vaccine to the Vaccine Schedule, at which time the vaccine is effectively mandated for all U.S. children via state laws that implement the Vaccine Schedule.[129] The Department of Health and Human Services (HHS) Secretary serves as an additional level of safety review.[130] After reviewing the various recommendations, the HHS Secretary also approves the inclusion of a new vaccine on the Vaccine Schedule.[131]

The government carefully monitors vaccine safety after doctors begin administering the vaccine to children. Public health officials use the Vaccine Adverse Event Reporting System

---

[124] *Id.*

[125] *Id.*

[126] *Id.*; *Roster of the Vaccines and Related Biological Products Advisory Committee*, U.S. FOOD & DRUG ADMIN. (Sept. 17, 2020), https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/roster-vaccines-and-related-biological-products-advisory-committee [https://perma.cc/ZXA4-HWE5] (listing the current committee members).

[127] *See* Pickering & Orenstein, *supra* note 113, at 150.

[128] *Who Sets the Immunization Schedule?*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/parents/vaccine-decision/sets-schedule.html [https://perma.cc/B2FY-RBXZ].

[129] *See* Pickering & Orenstein, *supra* note 113, at 150–54.

[130] *Id.* at 150.

[131] *Id.* at 149; *see also* CTRS. FOR DISEASE CONTROL & PREVENTION, THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) AND THE CHILDHOOD IMMUNIZATION SCHEDULE 2 (2018), https://www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-acip-color-office.pdf ("The work group presents its findings to the entire ACIP at several meetings before ACIP members vote on whether to recommend the vaccine and who should receive the vaccine. Once the CDC Director and DHHS have approved the ACIP recommendations, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR). Upon publication, the recommendations represent the official CDC recommendations for immunizations in the U.S.").

(VAERS) for post-market vaccine safety analysis.[132] VAERS is a national vaccine safety surveillance program cosponsored by the FDA and CDC.[133] VAERS allows "doctors and patients to file a report if they suspect symptoms have been caused by a vaccine."[134] The FDA website states that reports of adverse vaccine reactions "are welcome from all concerned individuals: patients, parents, health care providers, pharmacists and vaccine manufacturers."[135] However, participation in VAERS is voluntary; the government does not require any of these parties to use it to report adverse reactions.[136] As these extensive testing, approval, and monitoring protocols indicate, the government takes childhood vaccine safety very seriously.

B. Regulatory and Ethical Concerns About Federal Vaccine Safety Regulations

Critics of the vaccine approval process (and the FDA's clinical trial system, more generally) believe that this multitiered apparatus of "evidence-based medicine" is highly susceptible to dishonesty and fraud.[137] These critics identify pharmaceutical company control over clinical trials as the primary source of concern.[138] Clinical trials are time consuming and expensive, which some believe results in companies cheating the system to make sure their drugs secure approval.[139] Cheating is possible because the FDA does not consider unsuccessful clinical trials in evaluating a drug's safety or efficacy. This means that a company can conduct numerous failed trials before securing a successful trial needed for approval.[140] With no third-party oversight, companies can utilize biased clinical trials, misinterpret and misreport clinical trial data, or engage in fraud before submitting the clinical trial results to the

---

[132] *See Vaccine Adverse Events*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2018), https://www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/vaccineadverseevents/default.htm [https://perma.cc/RCH2-E7D4].

[133] *Id.*

[134] Joanna B. Apolinsky & Jeffrey A. Van Detta, *Rethinking Liability for Vaccine Injury*, 19 CORNELL J. L. & PUB. POL'Y 537, 627 (2010).

[135] *See Vaccine Adverse Events*, *supra* note 132.

[136] *See* Parasidis, *supra* note 13, at 2210.

[137] Jerome P. Kassirer, *Commercialism and Medicine: An Overview*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 377, 381 (2007).

[138] Drummond Rennie, *When Evidence Isn't: Trials, Drug Companies and the FDA*, 15 J. L. & POL'Y, 991, 1006–08 (2007).

[139] *See generally* Rodwin, *supra* note 122 (examining the conflicts of interest that arise in the vaccine testing and approval process as a result of industry-sponsored clinical trials).

[140] JOSEPH DUMIT, DRUGS FOR LIFE: HOW PHARMACEUTICAL COMPANIES DEFINE OUR HEALTH 100 (2012).

FDA.[141] According to the deputy editor of the *Journal of the American Medical Association*, this kind of cheating (or fraud) happens on a routine basis.[142] He describes the process through which paid researchers send the clinical trial results to the sponsoring drug company "who analyses the evidence, drops what is inconvenient, and keeps it all secret . . . . If the drug seems no good or harmful, the trial is buried and everyone reminded of their confidentiality agreements."[143] The drug companies, which profit from successful clinical trials, are "often the only source of information about their drugs."[144]

Companies like Merck and GlaxoSmithKline, the world's leading vaccine manufacturers by revenue,[145] have admitted to engaging in precisely these practices with regards to drugs such as Vioxx and Paxil, respectively.[146] In these cases, the drug companies admitted to engaging in clinical trial fraud that resulted in thousands of fatalities.[147] In the case of Vioxx, some researchers estimate that Merck's clinical trial fraud may have resulted in a staggering 60,000 U.S. fatalities, while the Paxil

---

[141] Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, 4 PLOS MED. 1429, 1429 (2007); *see also* Rodwin, *supra* note 122, at 114 ("Nevertheless, the conflicts of interest persist because the firm that seeks to market a drug designs and controls the clinical trials used to test its safety and efficacy. The FDA relies upon these trials when it evaluates whether or not to authorize marketing the drug. An ample record reveals that drug firms can design clinical trials in ways that bias the conclusions. They can also misinterpret or misreport the trial data, or engage in fraud."); *Merck Manipulated the Science about the Drug Vioxx*, UNION CONCERNED SCIENTISTS (Oct. 12, 2017), https://www.ucsusa.org/resources/merck-manipulated-science-about-drug-vioxx#:~:text=Scientists%20from%20the%20pharmaceutical%20giant,patients'%20risk%20of%20heart%20attack [https://perma.cc/RC39-8FEQ] (noting that, in connection with its drug Vioxx, "[s]cientists from the pharmaceutical giant Merck skewed the results of clinical trials in favor of the arthritis drug, Vioxx, to hide evidence that the drug increased patients' risk of heart attack," and that "[a] Merck scientist was also found to have removed the evidence of three heart attacks among patients in a dataset from the results presented"); Press Release, U.S. Dept. of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report [https://perma.cc/E782-QYYB] ("Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.").

[142] *See* Rennie, *supra* note 138, at 1007–08.

[143] *Id.* at 1007.

[144] *Id.* at 1010.

[145] Eric Sagonowsky, *The Top 5 Vaccine Companies by 2017 Revenue*, FIERCE PHARMA (Aug. 1, 2018, 7:00 AM), https://www.fiercepharma.com/special-report/top-5-vaccine-companies-by-2017-revenue [https://perma.cc/DM96-PDTW].

[146] Eugene McCarthy, *A Call to Prosecute Drug Company Fraud and Organized Crime*, 69 SYRACUSE L. REV. 439, 452–54 (2019).

[147] *Id.*

clinical trial fraud possibly contributed to thousands of American adolescent suicides.[148]

Industry critics believe that vaccine producers regularly engage in this same kind of clinical bias (or designing a clinical trial to ensure positive findings) and fraud. Raw clinical trial data is considered proprietary information, so companies do not share it with the FDA or other third parties.[149] This has led some researchers to question drug company claims about vaccine safety. In one instance, the Association of American Physicians and Surgeons (AAPS) had concerns about the Hepatitis B vaccine.[150] AAPS filed a Freedom of Information Act (FOIA) request for the safety data that the CDC used in deciding to add the vaccine to the Vaccine Schedule.[151] The government never produced the data in response to the FOIA request, which some critics believe indicates that no such safety data exists and proves that Hepatitis B vaccine researchers engaged in clinical fraud.[152] Indeed, subsequent independent third-party studies found serious safety and efficacy concerns related to the Hepatitis B vaccine.[153]

Vaccine critics are also concerned about the sparse data that companies do make available after clinical trials. The case of Prevnar, a vaccine for pneumococcal infections (which cause childhood earaches and pneumonia), is illustrative.[154] U.S. vaccine laws indicate that children should receive four injections of Prevnar before the age of two.[155] The vaccine producer revealed that, after clinical trials, it could not attest to the vaccine's carcinogenic potential or to whether it might impair fertility, but conceded that the vaccine may interfere with the effectiveness of other mandated childhood vaccines.[156] As to efficacy, testing showed that Prevnar reduced a child's chances of getting pneumococcal disease from just 00.15 percent to 00.02 percent.[157] Despite these questionable safety and efficacy outcomes, the government approved and mandated Prevnar, which, since 2015,

---

148 Matthew Herper, *David Graham On The Vioxx Verdict*, FORBES (Aug. 19, 2005), https://www.forbes.com/2005/08/19/merck-vioxx-graham_cx_mh_0819graham.html#2b3ed9175698 [https://perma.cc/XF2J-RLDL]; David Dobbs, *The Human Cost of a Misleading Drug-Safety Study*, ATLANTIC (Sept. 18, 2015), https://www.theatlantic.com/health/archive/2015/09/paxil-safety-bmj-depression-suicide/406105/ [https://perma.cc/N5UU-EVCD] (explaining the extent and repercussions of the Paxil clinical-trial fraud).

149 Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 CAL. W. L. REV. 321, 354 (2001).

150 *See* Holland, *supra* note 40, at 71–72.

151 *Id.*

152 *Id.*

153 *Id.* at 72.

154 *See* Horwin, *supra* note 149, at 342–46.

155 *Id.* at 343.

156 *Id.* at 345.

157 *Id.* at 346.

generated at least $23.4 billion in revenue for Pfizer, including nearly $6 billion in 2018.[158]

Some parents likewise worry about the fact that the Vaccine Schedule calls for children to receive multiple vaccines during a single doctor's visit, but clinical trials do not test the vaccine in concert with these other required immunizations.[159] As a result, some critics argue that vaccine producers are not really testing some vaccines—or, at least, not under relevant conditions.[160]

Addressing clinical and publication bias in the vaccine industry, the *British Medical Journal* published a study that found, with regard to an H1N1 vaccine, "that most registered and completed [vaccine] trials were not published in the peer reviewed literature within two years from the onset of the pandemic" for which the vaccine was approved.[161] The researchers noted that "a delay in publication of relevant randomized controlled trials may distort the available evidence that is used for recommendations, allocation of resources, stockpiling of drugs and vaccines, and other public action."[162] Indeed, the problem of incomplete information related to vaccine development, and the contracts underlying that development, has concerned some observers as the United States rapidly seeks safe and effective COVID-19 vaccines.[163]

In addition to clinical bias, vaccine critics have raised concerns about the post-market safety analyses of vaccines. VAERS is a "passive" reporting system.[164] This means "that no active effort is made to search for, identify and collect information, but rather information is passively received from those who choose to voluntarily report their experience."[165] The

---

158 Bob Herman, *A Vaccine is Pfizer's Best-Selling Drug*, AXIOS (Feb. 5, 2019), https://www.axios.com/pfizer-vaccine-prevnar-top-selling-drug-161f7f05-c68e-4deb-93bb-c121664b7f15.html[https://perma.cc/WBC9-VJZM].

159 Allen Tate, "*The Greater Good*," *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 97, 99.

160 *Id.*

161 Lamberto Manzoli et al., *Non-Publication and Delayed Publication of Randomized Trials on Vaccines: Survey*, 348 BRITISH MED. J. 1, 2 (2014) (this study encompassed "randomized controlled trials that evaluated the efficacy (including immunogenicity) or safety in healthy humans of selected vaccines (HPV, H1N1, meningococcal, pneumococcal, and rotavirus)" from a wide array of vaccine databases, but this particular quotation relates specifically to the delayed publication of results related to an H1N1 vaccine).

162 *Id.* at 1.

163 Sydney Lupkin, *A Federal Coronavirus Vaccine Contract Released at Last, But Redactions Obscure Terms*, NPR (Oct. 24, 2020 6:16 PM), https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t [https://perma.cc/5XUK-YJE9].

164 Tom T. Shimabukuro et al., *Safety Monitoring in the Vaccine Adverse Event Reporting System (VAERS)*, 33 VACCINE 4398, 4398 (2015).

165 *Id.*

government concedes that adverse vaccine reactions are drastically underreported and that "VAERS receives reports for only a small fraction of actual adverse events."[166] To suggest that VAERS receives only a "small portion" of reports is probably a gross understatement; the FDA estimates it receives only 1 percent of adverse drug reaction reports (meaning that *almost all* adverse reactions go unreported).[167]

Setting aside the general public, it appears that even healthcare providers do not utilize VAERS. Surveys indicate that 26 percent of healthcare providers do not even know that VAERS exists and 82 percent of healthcare providers who identify an adverse event after immunization do not report it to VAERS.[168] Fueling doubts about vaccines, both scholars and federal officials suggest that it is "not unreasonable" to conclude that the government *intentionally* structured VAERS to discourage adverse reaction reporting.[169] In the 1970s, an active tracking system exposed a spate of adverse vaccine reactions that effectively scuttled a national swine flu vaccination program and undermined long-term government immunization efforts.[170] Indeed, a former CDC Director stated that an accurate tracking system would be dangerous, as widespread parental awareness of the frequency and degree of adverse vaccine reactions might lead to the demise of the U.S. vaccination program altogether.[171] In other words, the CDC feared that if people knew precisely how dangerous vaccines could sometimes be, they might not agree to immunize their healthy children.

Perhaps the most common safety concerns that critics raise are the financial conflicts of interest that occasionally arise between the government and the pharmaceutical industry. This "revolving door" might be a legitimate concern, as demonstrated by the fact that, in 2017, 66 percent of pharmaceutical industry lobbyists were previously federal officials.[172] Additionally, industry executives play a role in making public policy with regard to vaccines. For instance, the FDA vaccine Advisory

---

[166] *Guide to Interpreting VAERS Data*, VACCINE ADVERSE EVENT REPORTING SYS., https://vaers.hhs.gov/data/dataguide.html [https://perma.cc/8GME-5U6C].

[167] STEPHEN A. GOLDMAN, FOOD & DRUG ADMIN.: MEDWATCH, THE CLINICAL IMPACT OF ADVERSE EVENT REPORTING 5 (1996).

[168] Michael M. McNeil et al., *Who is Unlikely to Report Adverse Events After Vaccinations to the Vaccine Adverse Event Reporting System (VAERS)?*, 31 VACCINE 2673, 2677 (2013).

[169] *See* Parasidis, *supra* note 13, at 2207.

[170] *See id.*

[171] *See id.*

[172] *Industry Profile: Pharmaceuticals/Health Products*, OPENSECRETS.ORG, https://www.opensecrets.org/lobby/indusclient_lobs.php?id=h04&year=2017 [https://perma.cc/8DML-T8GN].

Committee currently includes Dr. Paula Annunziato (Vice President and Therapeutic Area Head at Merck) and Dr. Gregg Sylvester (Vice President of Medical Affairs at Seqirus Inc.), who are executives of companies that profit from vaccine sales.[173] In 2019, Merck was an industry leader in annual vaccine revenues ($7.96 billion),[174] while Seqirus is "one of the world's largest influenza vaccine companies."[175] Dr. Paul Offit, who is considered to be "perhaps the most widely-quoted defender of vaccine safety" in the United States, also sits on the Advisory Committee.[176] In addition to his role in approving vaccines and recommending them to the government, Offit develops vaccines for profit.[177] Indeed, Offit developed the RotoTeq rotavirus vaccine (a mandated vaccine), for which, according to some estimates, he may have earned up to $45 million when Merck purchased the royalty rights to the vaccine he developed.[178] Offit has failed to provide details to news agencies who have requested information concerning his financial ties to Merck.[179] For vaccine-hesitant critics, the presence of drug company executives on a government panel that approves childhood vaccines raises ethical concerns.

The revolving door between government and industry exists at the highest levels. The CDC Director plays a determinative role in adding vaccines to the Vaccine Schedule.[180]

---

[173] *Roster of the Vaccines and Related Biological Products Advisory Committee*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/roster-vaccines-and-related-biological-products-advisory-committee [https://perma.cc/J239-VZP3].

[174] Matej Mikulic, *Leading Companies Based on Global Vaccine Revenue in 2019*, STATISTA (Aug. 13, 2020), https://www.statista.com/statistics/1104110/top-global-pharma-companies-by-vaccine-revenue/ [https://perma.cc/BH5M-NUNG].

[175] SEQIRUS, https://www.seqirus.com/ [https://perma.cc/C69B-2E24].

[176] *See Roster of the Vaccines and Related Biological Products Advisory Committee*, *supra* note 173; Sharyl Attkisson, *How Independent Are Vaccine Defenders?*, CBS NEWS (July 25, 2008, 6:20 PM), https://www.cbsnews.com/news/how-independent-are-vaccine-defenders/ [https://perma.cc/48HA-QC87].

[177] David Kroll, *Dr. Paul Offit: 'Journalism Jail' For Faulty Medical Reporting*, FORBES (Mar. 29, 2014, 8:20 PM), https://www.forbes.com/sites/davidkroll/2014/03/29/dr-paul-offit-journalism-jail-for-false-equivalence-medical-reporting/#1689cbc01308 [https://perma.cc/9WE4-86JR].

[178] *Id.*

[179] *Corrections for April 18*, ORANGE COUNTY REG. (Apr. 18, 2011, 3:49 PM), https://www.ocregister.com/2011/04/18/corrections-for-april-18-2/ [https://perma.cc/YKC5-JSXV] ("However, documents provided by CBS News indicate Offit did not disclose his financial relationships with Merck, including a $1.5 million Hilleman chair he sits in that is co-sponsored by Merck. According to the CBS News' documentation recently reviewed by the OC Register, the network requested (but Offit did not disclose) the entire profile of his professional financial relationships with pharmaceutical companies including: The amount of compensation he'd received from which companies in speaking fees; and pharmaceutical consulting relationships and fees. The CBS News documentation indicates Offit also did not disclose his share of past and future royalties for the Merck vaccine he co-invented.").

[180] *See* Pickering & Orenstein, *supra* note 113, at 150; *see also* discussion *supra* Section II.A.

Julie Gerberding was CDC Director from 2002-2009.[181] During her tenure, Merck secured CDC approval of its human papilloma virus vaccine, Gardasil.[182] At the time the CDC approved Merck's vaccine, industry critics observed that "Gardasil [was] the most expensive childhood vaccine for the least prevalent disease" that the CDC had included on the Vaccine Schedule.[183] After resigning as CDC Director, Gerberding—in short order—joined Merck as president of its vaccine division.[184] Then, in 2015, Gerberding sold 38,368 Merck shares for $2.3 million.[185] Brenda Fitzgerald, CDC Director from 2017-2018, stepped down in scandal after investigations uncovered, among other conflicts of interest, that she likewise invested heavily in Merck stock shortly after becoming CDC Director.[186] Robert Redfield is the current CDC Director.[187] In his previous career as an Army vaccine researcher, colleagues accused him of overstating clinical trial results related to an HIV vaccine, which helped secure $20 million in government funding for his research unit.[188] At the FDA level, "9 out of the last 10 FDA commissioners—representing nearly four decades of agency leadership—have gone on to work for pharmaceutical companies."[189]

These conflicts of interest are not limited to the CDC and FDA. The HHS Secretary has "unilateral authority" to add vaccines to the Vaccine Schedule.[190] The current HHS Secretary is Alex Azar.[191] Azar previously served as a top executive at Eli

---

[181] *Past CDC Directors/Administrators*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/history/pastdirectors.htm [https://perma.cc/PR8H-8DM4].

[182] *See* Holland, *supra* note 40, at 78.

[183] *Id.*

[184] *Julie L. Gerberding, M.D., M.P.H.*, MERCK, https://www.merck.com/leadership/julie-l-gerberding-m-d-m-p-h/ [https://perma.cc/K62X-EQP4].

[185] Thomas Dobrow, *Merck & Co. EVP Julie L. Gerberding Sells 38,368 Shares (MRK)*, DAKOTA FIN. NEWS (May 11, 2015), https://web.archive.org/web/20150528003538/http://www.dakotafinancialnews.com/merck-co-evp-julie-l-gerberding-sells-38368-shares-mrk/159207/ [https://perma.cc/8LH5-NPYE].

[186] *See Past CDC Directors/Administrators*, *supra* note 181; Debra Goldschmidt & Ben Tinker, *CDC Director Brenda Fitzgerald Resigns*, CNN (Jan. 31, 2018, 9:16 PM), https://www.cnn.com/2018/01/31/health/cdc-director-fitzgerald-resigns-bn/index.html [https://perma.cc/7U8J-FXAR].

[187] *Director*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/leadership/director.htm [https://perma.cc/26EV-LWUV].

[188] *See* Kristen Holmes et al., *CDC Woes Ring Director Redfield's Troubled Past as an AIDS Researcher to Light*, CNN (June 5, 2020, 3:14 PM), https://www.cnn.com/2020/06/04/politics/cdc-redfield-aids-walter-reed-army-investigation/index.html [https://perma.cc/693S-S67T].

[189] Katherine Ellen Foley, *Trust Issues Deepen as yet Another FDA Commissioner Joins the Pharmaceutical Industry*, QUARTZ (July 1, 2019), https://qz.com/1656529/yet-another-fda-commissioner-joins-the-pharmaceutical-industry/ [https://perma.cc/K29A-ZPS4].

[190] *See* Henson, *supra* note 69, at 92.

[191] *HHS Secretary*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/leadership/secretary/index.html [https://perma.cc/U4H7-8RFN].

Lily, one of the nation's largest pharmaceutical companies.[192] Critics described Azar's appointment as HHS Secretary as the pharmaceutical industry's "biggest lobbying victory ever."[193]

Similar financial conflicts of interest arise at the state level with regard to implementing Vaccine Schedule mandates for children. For instance, Texans were surprised in 2007 when Governor Rick Perry issued an executive order "mandating the HPV vaccine for all girls entering sixth grade, unless their parents completed a conscientious-objection affidavit form."[194] The vaccine mandate required all adolescent females to receive Gardasil, Merck's aforementioned human papillomavirus vaccine.[195] This surprise turned to outrage when news surfaced that Mike Toomey, Perry's confidant and former chief of staff, was now working as a Texas-based Merck lobbyist.[196] Merck and Toomey were in the "midst of a multimillion-dollar campaign to persuade states to make the vaccine mandatory."[197] Part of Merck's vaccine campaign included donating "$377,000 to the Republican Governor's Association, which Perry chaired."[198] Perry has since stated that the HPV vaccine executive order was a "mistake."[199]

A year later, New Jersey surprised many by becoming the first state to mandate the flu vaccine for all children in daycare.[200] The law sparked outrage among parents, but New Jersey public health officials stood firm against the public

---

[192] Gabriel Levitt, *Alex Azar Is Big Pharma Personified. He Must Not Become US Health Secretary*, GUARDIAN (Dec. 1, 2017), https://www.theguardian.com/commentisfree/2017/dec/01/alex-azar-health-secretary-drug-prescription-prices-medicaid [https://perma.cc/7SH3-VBH7].

[193] *Id.*

[194] Jay Root, *Under Scrutiny, Perry Walks Back HPV Decision*, TEX. TRIB. (Aug. 15, 2011, 5:00 AM), https://www.texastribune.org/2011/08/15/facing-new-scrutiny-perry-walks-back-hpv-decision/ [https://perma.cc/5V5K-TDKG].

[195] *See* Muela, *supra* note 37, 465–66.

[196] Wade Goodwyn, *In Texas, Perry's Vaccine Mandate Provoked Anger*, NPR (Sept. 16, 2011, 3:22 PM), http://www.npr.org/2011/09/16/140530716/in-texas-perrys-vaccine-mandate-provoked-anger [https://perma.cc/EN46-L9YR].

[197] Dan Eggen, *Rick Perry and HPV Vaccine-Maker Have Deep Financial Ties*, WASH. POST (Sept. 13, 2011), https://www.washingtonpost.com/politics/perry-has-deep-financial-ties-to-maker-of-hpv-vaccine/2011/09/13/gIQAVKKqPK_story.html?utm_term=.80453d735648 [https://perma.cc/98CH-3HMC].

[198] *See* Goodwyn, *supra* note 196.

[199] *See* Root, *supra* note 194.

[200] *See* N.J. ADMIN. CODE § 8:57-4.19; N.J. DEP'T OF HEALTH (NJDOH), QUESTIONS AND ANSWERS ON IMMUNIZATION REGULATIONS PERTAINING TO CHILDREN ATTENDING SCHOOL/HIGHER EDUCATION 1 (2017), https://www.nj.gov/health/cd/documents/vaccine_qa.pdf [https://perma.cc/79AJ-D963] (providing a detailed explanation of changes to New Jersey's childhood immunization policies); Sharyn Alfonsi, *N.J. Mandatory Flu Shots for Preschoolers Cause Outrage*, ABC NEWS (Oct. 16, 2008, 6:59 PM), https://abcnews.go.com/Health/ColdandFluNews/story?id=6051917&page=1 [https://perma.cc/T7QP-8Q8E].

backlash.[201] A year later, Eddy Bresnitz, New Jersey's deputy health commissioner who spearheaded the flu vaccine mandate effort, followed in Gerberding's footsteps and took a job at Merck overseeing a vaccine unit.[202] After Bresnitz helped institute the New Jersey flu shot mandate, the New Jersey-based Merck (at which Bresnitz then worked) secured the exclusive right to market Afluria, one of the few FDA-approved and CDC-recommended flu vaccines.[203]

The lax regulatory oversight of vaccine testing and problematic financial conflicts of interest in the vaccine approval process constitute the second legal structure upon which vaccine hesitancy rests. This structure enables critics to claim that vaccines are for-profit medical interventions that are sometimes unnecessary and unsafe. The regulatory regime creates the appearance of "revolving door" fraud and self-dealing. These accusations are perhaps not entirely far-fetched, as the House of Representatives Government Reform Committee shared similar concerns and its investigation into vaccine testing and approval procedures found that "conflict of interest rules employed by the FDA and CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings."[204] Despite the government's unquestionable commitment to ensuring vaccine safety, the conflicts of interest that it permits in the testing and approval process might appear problematic to some observers.

III. LIMITED LIABILITY OF VACCINE PRODUCERS

The third structure of U.S. law that produces vaccine hesitancy relates to the limited liability that the government grants drug companies related to vaccine injuries. Vaccine critics suggest that this blanket immunity from civil liability creates little incentive for vaccine producers to innovate and market the safest possible vaccines. Given the compulsory

---

[201] *See* Alfonsi, *supra* note 200.

[202] *See* Belkin, *supra* note 102, at 163; *see also* Eddy Bresnitz, LINKEDIN, https://www.linkedin.com/in/eddy-bresnitz [https://perma.cc/AN9R-M7LE] (showing Bresnitz's resume, which indicates that Bresnitz stopped working as Deputy Commissioner of the New Jersey Department of Health and Senior Services in June 2008 and began working at Merck later that month).

[203] *Merck & Co. to Market CSL's Seasonal Flu Vaccine in the U.S.*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Sept. 28, 2009), https://www.genengnews.com/topics/translational-medicine/merck-co-to-market-csls-seasonal-flu-vaccine-in-the-u-s/ [https://perma.cc/F29C-2W8A].

[204] U.S. House of Rep. Comm. on Gov't Reform, Majority Staff Rep. on Conflicts of Interest in Vaccine Policy Making (June 15, 2000).

nature of vaccines, critics argue that limited liability also transfers undue risk to the public, since the government compels it to purchase and use vaccines yet does not permit the public to hold vaccine producers accountable when the product causes an injury. Indeed, the government asks vaccine injury victims to compensate themselves through a taxpayer-funded compensation system, which likely contributes to hesitancy about using the product.

A. The Evolution of Vaccine-Related Limited Liability Legislation

The government's decision to provide limited liability to vaccine manufacturers arose from a public health necessity. The U.S. vaccination program was in a state of crisis during the late 1970s and early 1980s.[205] During this period, adverse reactions to the diphtheria-tetanus-pertussis (DTP) vaccine were on the rise.[206] Several lawsuits, based on new vaccine-related causes of action, exposed drug companies to unanticipated financial liability for alleged injuries related to these vaccines.[207] This new vaccine-related liability arose under the legal theories of the "implied warranty of merchantability" and the "failure to warn" of potential harm.[208] As a result of these emerging causes of action, drug companies faced an aggregate of $3.5 billion in vaccine damage claims in 1985.[209] This liability exposure prompted insurance companies to impose higher premiums on vaccine manufacturers, which consequently made vaccine production less profitable.[210]

Manufacturers found these additional costs "burdensome," which led them to seek recourse and market protection from the government.[211] Some drug companies threatened to leave the vaccine market altogether and began

---

[205] Jaclyn Shoshana Levine, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?*, 4 B.U. J. SCI. & TECH. L. 9, ¶¶ 2–3 (1998).

[206] Emily Marcus Levine & Andrea Sudell Davey, *The National Vaccine Injury Compensation Program and Maternal Immunizations*, 11 J. HEALTH & LIFE SCI. L. 32, 34–35 (2017).

[207] *See* Calandrillo, *supra* note 7, at 407.

[208] *See* Reyes v. Wyeth Labs., 498 F.2d 1264, 1272 (5th Cir. 1974) (holding a vaccine producer liable for $200,000 in damages under the failure-to-warn legal theory after the plaintiff developed polio from the polio vaccine); Gottsdanker v. Cutter Labs., 6 Cal. Rptr. 320, 322 (Cal. Dist. Ct. App. 1960) (holding a vaccine producer liable for approximately $147,000 in damages under the theory of breach of implied warranty after two children contracted polio from the company's polio vaccine).

[209] *See* Henson, *supra* note 69, at 73.

[210] *Id.* at 73–74.

[211] *See* Levine & Davey, *supra* note 206, at 35.

exerting political pressure for changes in vaccine-liability laws.[212] The pharmaceutical and medical industries "opposed any liability for vaccine manufacturers, citing threats to the vaccine supply and public health" as political leverage.[213] Indeed, by the 1980s, there were only four DTP vaccine producers and two polio vaccine producers.[214] The confluence of these factors produced legitimate concern about the future of the U.S. vaccine program:

> Vaccine stockpiles were at a critically low level and Congress found that the withdrawal of even one manufacturer from the market would likely cause nationwide vaccine shortages. Thus, Congress recognized that the tragic injuries suffered by children, the extreme liability exposure facing vaccine manufacturers, and the danger facing society if any more manufacturers stopped producing vaccines all combined to create the perfect storm.[215]

Pharmaceutical executives aggressively lobbied Congress to all but eliminate tort liability for vaccine producers.[216] A Merck executive proposed that the government create a no-fault compensation program, through which vaccine-injured children could receive government compensation paid for through an excise tax on vaccines.[217] Other drug company executives testified that it would be more "fiscally sound" if the government—rather than the pharmaceutical industry—compensated vaccine-injured children.[218] Notably, Jonas Salk, who developed the first safe and inactive polio vaccine, strongly opposed these limited liability proposals out of fear that industry indemnification would disincentivize future vaccine research, safety, and innovation.[219]

Congress eventually adopted the Merck executive's proposal and enacted the National Childhood Vaccine Injury Act of 1986 (Injury Act).[220] The Injury Act is a no-fault vaccine injury compensation program through which the government directly compensates vaccine-injured children.[221] The government finances the vaccine-injury compensation program through an excise tax (or surcharge) of seventy-five cents levied on each

---

[212] *See* Levine, *supra* note 205, ¶ 2.

[213] Mary S. Holland, *Liability for Vaccine Injury: The United States, the European Union, and the Developing World*, 67 EMORY L.J. 415, 422 (2018).

[214] *See* Henson, *supra* note 69, at 74.

[215] *Id.*

[216] Lainie Rutkow et al., *Balancing Consumer and Industry Interests in Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 PENN ST. L. REV. 681, 693 (2007).

[217] *Id.* at 693, 704.

[218] *Id.* at 704.

[219] *See* Holland, *supra* note 213, at 421–22.

[220] *See* 42 U.S.C. §§ 300aa-1 to -34.

[221] *See* Hatch, *supra* note 42, at 194.

vaccine purchase.[222] The tax finances a trust fund that the government uses to compensate vaccine-injury victims.[223] The program insulates drug companies from vaccine-related civil liability in order to encourage industry participation in the vaccine market.[224] The Injury Act directly addressed the root causes of the "vaccine crisis." Today, it ensures that the government has access to a stable supply of vaccines, incentivizes companies to continue producing vaccines for the national immunization program, and provides an efficient mechanism for compensating vaccine-injured individuals.[225]

Congress designed the Injury Act to create a "less-adversarial, expeditious, and informal proceeding for the resolution" of vaccine-injury claims.[226] Congress also believed that the Injury Act's market incentives would keep vaccine prices low.[227] The government's intent was to compensate vaccine-injured children "quickly, easily, and with certainty and generosity."[228] The program produces a streamlined compensation system by enabling (and requiring) petitioners to bring an administrative claim against the government rather than to sue a drug company in court.[229] Judges and juries do not preside over the cases brought against the government; instead, an injured party informally presents her case to a "special master" (i.e., a government-appointed lawyer who adjudicates vaccine claims).[230] The program simplifies—and often eliminates—complex rules of evidence and discovery to promote a user-friendly system that does not require the training of a lawyer.[231] The petitioner simply states her case (in person, over the phone, or on video) and submits the relevant medical records, vaccination records, or a

---

[222] *About the National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVS. ADMIN., https://www.hrsa.gov/vaccine-compensation/about/index.html [https://perma.cc/59DF-TU6L] ("[The program is] [f]unded by a $.75 excise tax on vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children, the excise tax is imposed on each dose (i.e., disease that is prevented) of a vaccine. Trivalent influenza vaccine for example, is taxed $.75 because it prevents one disease; measles-mumps-rubella vaccine, which prevents three diseases, is taxed $2.25.").

[223] *Id.*

[224] *See id.*

[225] *See* Henson, *supra* note 69, at 74.

[226] 42 U.S.C. § 300aa-12(d)(2)(A).

[227] *See* Holland, *supra* note 40, at 57.

[228] *See* Holland, *supra* note 213, at 425–26; *see also* Charlotte A. Moser, *News & Views: National Vaccine Injury Compensation Program*, CHILD. HOSP. PHILA. (June 24, 2015), https://www.chop.edu/news/news-views-national-vaccine-injury-compensation-program [https://perma.cc/ZRK3-SCA2].

[229] *See* 42 U.S.C. §§ 300aa-12(a)–(b)(1).

[230] *See* 42 U.S.C. § 300aa-12(c)(1); *see also* Holland, *supra* note 213, at 426 (explaining the adjudication process and the qualifications of the government's special masters).

[231] *See* 42 U.S.C. §§ 300aa-12(d)(2)(A)–(E).

child's death certificate and autopsy results.[232] The informal rules and expedited proceedings dictate that the special master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both [the petitioner and the government]."[233] The compensation program appears to favor petitioners, since the process provides for a "swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation."[234]

The process of filing a vaccine-injury claim under the Injury Act begins when the injured party or their representative files a petition with the U.S. Court of Federal Claims (the Vaccine Court).[235] The special master then decides if the petitioner can establish by a "preponderance of the evidence" that a vaccine caused the injury or death.[236] The government maintains a Vaccine Injury Table, which lists the "injuries, disabilities, illnesses, conditions, and deaths" that the government anticipates will result from vaccines and the time frame in which they typically occur.[237] If the injury appears on the Vaccine Injury Table (i.e., if the injury was "on table"), the petitioner automatically satisfies her burden of proof.[238] The burden then shifts to the government to refute causation between the vaccine and the injury.[239] If the injury is not listed on the Vaccine Injury Table, the petitioner must demonstrate both that there is a valid medical theory linking the vaccine to her injury and that the vaccine specifically caused the injury.[240] It is extremely difficult for a claimant to meet the burden of proving causation for "off-table" injuries.[241] In essence, the Vaccine Injury Table exists to "weed out good claims from bad."[242]

---

[232] 42 U.S.C. § 300aa-11(c)(2); FED. CL. VACCINE R. 8(b)(2).

[233] FED. CL. VACCINE R. 8(b)(1).

[234] *Vaccine Claims/Office of Special Masters*, U.S. CT. FED. CLAIMS, https://www.uscfc.uscourts.gov/vaccine-program-readmore [https://perma.cc/S7ME-MULH].

[235] 42 U.S.C. § 300aa-11(a)(1).

[236] 42 U.S.C. § 300aa-13(a)(1).

[237] HEALTH RES. & SERVS. ADMIN., VACCINE INJURY TABLE 1 (2017), https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf. [https://perma.cc/CY2H-V5G4].

[238] *See* 42 U.S.C. § 300aa-14(a); Dileo v. Sec'y of Health & Human Servs., 23 Cl. Ct. 796, 798 (1991). As used throughout this article, "on table" refers to injuries and injury time frames that are listed on the government's Vaccine Injury Table.

[239] *See Dileo*, 23 Cl. Ct. at 798.

[240] OFFICE OF SPECIAL MASTERS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 44 (2019), https://www.uscfc.uscourts.gov/sites/default/files/19.01.18%20Vaccine%20Guidelines.pdf [https://perma.cc/BGP8-NWPV]; Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[241] *See* Apolinsky & Van Detta, *supra* note 134, at 577. As used throughout this article, "off-table" refers to injuries and injury time frames that are not listed on the government's Vaccine Injury Table.

[242] *Id.*

The government awards damages related to past and future medical expenses, lost earnings, and pain and suffering.[243] The Injury Act sets a compensation limit of $250,000 for both vaccine-related deaths and pain and suffering.[244] If the petition fails, the party can seek review from the Federal Court of Claims and the Federal Circuit.[245] However, higher courts afford great deference to the special master's rulings and will only overturn the decision if it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[246] After exhausting these administrative procedures, the claimant may file a federal lawsuit against the drug company.[247]

However, experts agree that, practically speaking, Injury Act petitions are the exclusive remedy available to people who suffer vaccine injuries.[248] This is because in addition to granting the Vaccine Court original jurisdiction over all vaccine-injury claims, the Injury Act specifically eliminates the causes of action that might subject drug companies to liability for vaccine injuries (as well as the aforementioned causes of action that produced the "vaccine crisis").[249] If a vaccine producer abides by FDA guidelines, the Injury Act also bars punitive damage awards against manufacturers, unless they engage in fraud, criminal activity, or intentionally and wrongfully withhold information.[250] The Injury Act likewise prohibits suits against a vaccine producer for a failure to warn a patient about potential vaccine harm.[251] In 2011, the Supreme Court extended the Injury Act's limited liability protections in *Bruesewitz v. Wyeth*.[252] In *Bruesewitz*, the Court held that a vaccine producer is also shielded from liability for vaccine design defects that may result in injury or death.[253] That is, even "if a company fails to manufacture a vaccine using a safer, but equally effective,

---

[243] *See* 42 U.S.C. § 300aa-15(a)(1)(A).

[244] 42 U.S.C. §§ 300aa-15(a)(2), (4).

[245] 42 U.S.C. §§ 300aa-12(e)–(f), -21.

[246] 42 U.S.C. § 300aa-12(e)(2)(B). The standard of review for the Federal Circuit is largely the same, as noted in Whitecotton v. Sec'y of Dep't of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) ("Our review of the special master's findings of fact is very limited. As we have recognized in the past, 'Congress assigned to a group of specialists, the Special Masters . . . the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims.' For this reason, Congress has instructed us to affirm a special master's factual findings unless they are arbitrary, capricious, or an abuse of discretion." (alteration in original) (internal citations omitted)).

[247] 42 U.S.C. § 300aa-21(a)(2).

[248] *See* Holland, *supra* note 213, at 424.

[249] *See* Holland, *supra* note 40, at 56–58.

[250] 42 U.S.C. §§ 300aa-15(d),-23(d).

[251] 42 U.S.C. § 300aa-22(c).

[252] *See* Bruesewitz v. Wyeth, 562 U.S. 223 (2011).

[253] *Id.* at 243.

formula, that company is nonetheless shielded from liability."[254] The Injury Act grants vaccine producers blanket immunity from vaccine-related liability in an effort to encourage vaccine production. This immunity protects the vaccine supply, which ensures the nation's public health.

B. Criticisms of Vaccine Limited Liability Legislation

Vaccine critics believe that the Injury Act belies congressional intent and goes too far in sheltering vaccine producers from liability.[255] These critics claim that the compensation program is neither quick, easy, certain, nor generous for petitioners who suffer vaccine injuries.[256] Some even suggest that the Injury Act consistently produces inequitable outcomes:

> In the name of protecting children's health, the [Injury] Act changed the legal landscape fundamentally. Instead of keeping doctors and the vaccine industry directly liable for adverse reactions to vaccines, the [Injury] Act created a tax-payer financed compensation program for injuries. Unprecedented at the time, the [Injury] Act was, in effect, a corporate bailout for the pharmaceutical industry, because it forced the public—rather than the industry—to pay for damage from "unavoidably unsafe" products.[257]

These critics observe that the Injury Act's limited liability structure subverts the traditional approach to product liability, whereby exposure to lawsuits incentivizes manufacturers to innovate the safest possible product.[258] As one critic identifies, "[w]hat makes this law-science standoff particularly interesting is that rather than forcing vaccine technology to bend to the law's demands, as has historically been the case for other inherently dangerous medical products, Congress decided to reshape the law" to protect drug companies.[259]

For some, this legal "reshaping" undermines Congress's stated intent behind the Injury Act. In fact, many believe that the Injury Act produces the "antithesis" of the less-adversarial,

---

[254] Efthimios Parasidis, *Public Health Law and Institutional Vaccine Skepticism*, 41 J. HEALTH POL., POL'Y & L. 1137, 1145 (2016).

[255] James B. Currier, *Too Sick, Too Soon?: The Causation Burden Under the National Vaccine Injury Compensation Program Following* De Bazan v. Secretary of Health & Human Services, 19 FED. CIR. B.J. 229, 248 (2009).

[256] *See* Holland, *supra* note 213, at 425–26, 432–35.

[257] Mary Holland & Robert Krakow, *The Right to Legal Redress*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 42, 42.

[258] *See* Levine, *supra* note 205, ¶¶ 8–9.

[259] *Id.* ¶ 2.

expeditious, and informal process Congress sought to create.[260] Instead of a "less adversarial" process, the government routinely uses aggressive and highly technical trial-like defenses in Vaccine Court.[261] Over the years, the government has grown increasingly "zealous" in its refutation of vaccine-related injuries.[262] For instance, to refute on-table vaccine injuries, the government relies on technicalities to avoid paying compensation. In *Ultimo v. Secretary of Health and Human Services*, the special master denied compensation because a child's seizures occurred seventy-eight hours after vaccination, which was not within the "three-day" window that the Vaccine Injury Table dictated.[263] The special master determined that the "three-day" window was not "three calendar days" as the petitioner argued, but rather seventy-two hours from the precise time of vaccination.[264] Such technicalities apply only to on-table vaccine injury claims (where, recall, the burden shifts to the government if an anticipated injury occurred within a specific timeframe).

In contrast, off-table injuries require the petitioner to prove both specific and general causation linking the vaccine to the injury.[265] Today, the off-table burden of proof is effectively insurmountable.[266] The U.S. Court of Appeals for the Federal Circuit established this heavy burden in *De Bazan v. Secretary of Health & Human Services*.[267] After *De Bazan*, off-table vaccine-injury claimants must disprove "all other possible causes for their injuries except for the vaccine."[268] Off-table petitioners must now prove a negative in order to recover.[269]

Some critics also believe that the government strategically amends the Vaccine Injury Table to remove or redefine on-table vaccine injuries to limit the government's financial exposure.[270] These amendments transform on-table injuries into off-table injuries, which shifts the burden of proof and makes the Vaccine Injury Table "more restrictive and more difficult for vaccine injury

---

[260] Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 GEO. WASH. L. REV. 426, 445–46 (2007); *see also* 42 U.S.C. § 300aa-12(d)(2)(A).

[261] *See* Apolinsky & Van Detta, *supra* note 134, at 578–79.

[262] *See* Parmet, *supra* note 107, at 134.

[263] *See* Ultimo v. Sec'y of Health & Human Servs., 28 Fed. Cl. 148, 150–51 (1993).

[264] *Id.* at 151.

[265] *See* OFFICE OF SPECIAL MASTERS, *supra* note 240; *see also* Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[266] *See* Apolinsky & Van Detta, *supra* note 134, at 577.

[267] De Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1351–52 (Fed. Cir. 2008) (holding that a plaintiff must prove "causation-in-fact" for off-table claims).

[268] *See* Currier, *supra* note 255, at 231.

[269] *Id.* at 251.

[270] *See* Henson, *supra* note 69, at 92.

victims to prevail."[271] For instance, in 1995 the government amended the Vaccine Injury Table to remove "seizure disorder" and to set a more restrictive encephalopathy (brain damage) definition.[272] Prior to these burden-shifting amendments, special masters conceded one in three vaccine-injury claims; after the amendments, they concede just one in seven claims.[273] All told, "[a]lmost four out five claimants lose in what was meant to be a petitioner-friendly administrative forum."[274]

The Injury Act has likewise proven to be slower and more parsimonious than anticipated.[275] Some observers point to instances in which the government fails to provide quick, certain, and generous compensation to vaccine-injured individuals.[276] Critics observe that petitioners generally have to wait two years to receive a decision from the special master.[277] They note that the proceedings are not certain because the government sometimes threatens to appeal decisions if the petitioner refuses to keep the findings confidential.[278] This eliminates precedential source material upon which future petitioners might rely.[279] Compensation is not generous, as the government often denies seemingly insignificant vaccine-injury costs.[280] For instance, after a vaccine rendered an individual wheelchair-bound, the government argued that a $150 cost for annual "wheelchair maintenance" was excessive.[281] After another vaccine resulted in permanent incontinence, the government challenged an annual $135 bedsheet allowance, suggesting that rubber sheets—which can be wiped off with a cloth—would be a cheaper alternative to washing and changing fabric bedsheets.[282] The government even disputed a $40 shoe

---

[271] *Id.*

[272] National Vaccine Injury Compensation Program: Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7694 (Feb. 8, 1995) (codified at 42 C.F.R. § 100 (1995)); National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table–II, 62 Fed. Reg. 7685, 7688 (Feb. 20, 1997) (codified at 42 C.F.R. § 100 (1997)).

[273] Myron Levin, *Vaccine Injury Claims Face Grueling Fight*, L.A. TIMES (Nov. 29, 2004, 12:00 AM), http://articles.latimes.com/2004/nov/29/business/fi-vaccinecourt29 [https://perma.cc/HQT3-C6S6].

[274] *See* Holland & Krakow, *supra* note 257, at 43.

[275] *See* Levin, *supra* note 273.

[276] *Id.*

[277] Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 512 (2008).

[278] *See* Parasidis, *supra* note 13, at 2159.

[279] *Id.*

[280] *See* Levin, *supra* note 273.

[281] *Id.*

[282] *Id.*

expenditure for a child who had suffered "profound mental retardation" after a state-mandated vaccine injured her.[283]

In another case, the government may even have attempted to stall an administrative proceeding for eight years in the hopes that the vaccine-injured child would die, as the one-time $250,000 award for death was cheaper than a lifetime annuity payment.[284] The government eventually lost the case (after the child died), but threatened to appeal unless the child's mother agreed to keep the decision confidential.[285] The government admits that it makes similar threats about maintaining confidentiality to bereaved parents "on very rare occasions."[286] Some critics likewise perceive undue frugality in the fact that the government has not adjusted the $250,000 cap on death allowances for inflation in the thirty years since the Injury Act's inception.[287] Meanwhile, the taxpayer-financed Injury Act compensation fund currently has a surplus of $4.0 billion.[288] Ironically, this difficult-to-access, tax-generated surplus is greater than the liability that drug companies faced during the "vaccine crisis," which prompted the Injury Act in the first place.[289] Vaccine critics and legal commentators seem to agree that while the Injury Act has a "spotty" record with regard to helping victims, it has been "a stupendous success in protecting the industry."[290]

Some observers claim that the Injury Act has likewise fallen short of its stated goals of incentivizing market participation and reducing vaccine costs. In 1985 (one year prior to the Injury Act), there were four manufacturers that primarily produced state-mandated vaccines.[291] Today, there are still just four companies that "dominate the [vaccine] market (Merck, Sanofi-Pasteur, Pfizer, and GlaxoSmithKline)."[292] Despite claims to the contrary, vaccine profits remain high (and are continuously growing) for these companies.[293] Vaccines are profitable because consumer costs for purchasing state-

---

[283] *See* Parasidis, *supra* note 13, at 2160.

[284] *See* Levin, *supra* note 273.

[285] *Id.*

[286] *Id.*

[287] *See* Henson, *supra* note 69, at 91–92.

[288] *Vaccine Injury Compensation Reports*, TREASURYDIRECT, https://www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm [https://perma.cc/B7MM-LLS3] (providing a current accounting of compensation fund resources).

[289] *See* discussion *supra* Section III.A.

[290] *See* Levin, *supra* note 273 (quoting George Washington University Law Professor Peter H. Myers).

[291] *See* Holland, *supra* note 213, at 420.

[292] *See* Parasidis, *supra* note 13, at 2161.

[293] *See* Sagonowsky, *supra* note 145.

mandated vaccines have risen steeply since the Injury Act took effect.[294] Prior to the Injury Act, it cost $100 to vaccinate a child; today, it costs nearly $2,200 to vaccine each child.[295] It seems possible that the Injury Act has actually helped transform a vaccine market that was once in "crisis" into a highly profitable pharmaceutical industry sector.[296] Financial analysts predict that the vaccine market will reach $104.8 billion in annual revenues by 2027, with a steep compound annual growth rate of 10.7 percent.[297] GlaxoSmithKline's vaccine unit is now the drug company's top growing pharmaceutical segment.[298] The number of vaccines in development has "mushroomed" in the years since the Injury Act.[299] By 2019, there were 240 new vaccines in development.[300] Add to this the 180 COVID-19 vaccines that the global community is currently developing.[301]

Vaccine market growth in North America is predicated on "the increasing investments by *government organizations* and *companies* to promote immunization as well as develop new vaccines."[302] In the wake of the Injury Act, these "public-private partnerships" have certainly succeeded in promoting immunization and developing new vaccines.[303] In 1984, the government recommended seven vaccines.[304] Today, the government recommends sixteen vaccines.[305] Prior to the Injury

---

[294] *See* Parasidis, *supra* note 13, at 2161.

[295] *Id.*

[296] Amruta Joshi, *Vaccine Market Projected to Reach $77.5 billion by 2024*, PHARMA TIMES (Apr. 16, 2018), http://www.pharmatimes.com/web_exclusives/vaccine_market_projected_to_reach_$77.5_billion_by_2024_1232012 [https://perma.cc/9UB9-PU9L]; *see also* Sagonowsky, *supra* note 145 (forecasting vaccine industry profits).

[297] *Vaccines Market to Reach USD 104.87 Billion by 2027; Introduction of World's First Malaria Vaccine In Malawi to Lighten Business Possibilities, States Fortune Business Insights*, GLOBENEWSWIRE (July 16, 2020, 9:47 AM), https://www.globenewswire.com/news-release/2020/07/16/2063440/0/en/Vaccines-Market-to-Reach-USD-104-87-Billion-by-2027-Introduction-of-World-s-First-Malaria-Vaccine-in-Malawi-to-Lighten-Business-Possibilities-states-Fortune-Business-Insights.html [https://perma.cc/Q5ZU-HL67].

[298] *See* Sagonowsky, *supra* note 145.

[299] *See* Larson et al., *supra* note 64, at 527–28.

[300] Michael Phan et al., *New Vaccines in the Pipeline 2019*, PHARMACY TIMES (Aug. 8, 2019), https://www.pharmacytimes.com/publications/supplements/2019/August2019/new-vaccines-in-the-pipeline-2019 [https://perma.cc/TE78-YMJR].

[301] Florian Krammer, *SARS-CoV-2 Vaccines in Development*, 586 NATURE 516, 518 (2020).

[302] *Preventive Vaccines Market Trends and Analysis Research Report 2027 | Impact of COVID-19 Pandemic*, MARKETWATCH (Oct. 15, 2020, 2:33 AM), https://www.marketwatch.com/press-release/preventive-vaccines-market-trends-and-analysis-research-report-2027-impact-of-covid-19-pandemic-2020-10-15 [https://perma.cc/4KGA-GN5Q] (emphasis added).

[303] Mark Blaxill & Dan Olmstead, *A License to Kill?*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 175, 176–78.

[304] *History of the Immunization Schedule*, HIST. VACCINES, https://www.historyofvaccines.org/content/history-immunization-schedule [https://perma.cc/SJQ8-5TL3].

[305] *Id.*

Act, doctors injected twenty-four vaccine doses into children; today, it is recommended that doctors inject children with seventy vaccine doses.[306] The Injury Act encourages the production of new vaccines, since drug companies do not have to bear the litigation risks and costs connected with adverse reactions.[307] Additionally, drug companies do not need to invest in vaccine advertising to persuade people to use their product, since the government effectively requires individuals to get vaccinated.

Critics of U.S. vaccine policy suggest that the Injury Act was only the government's first step in insulating the industry from legal and financial liability for vaccine injuries. In 2002, Congress enacted section 304 of the Homeland Security Act (Section 304) to create a compensation system related to smallpox vaccine injuries.[308] Smallpox was eradicated in 1979, but the Bush Administration initiated a partial mandate for the smallpox vaccination in 2002, deeming it a prudent precaution against potential terrorist attacks.[309] Section 304 was a fault-based compensation system that required the injured party to prove not only that a vaccine caused the injury, but also that the drug company had been negligent in producing it.[310] In 2003, Congress enacted the Smallpox Emergency Personnel Protection Act (SEPPA), which barred *any* appellate review regarding smallpox vaccine injuries.[311] Other legislation, passed in 2005 and renewed in 2020 in the midst of the COVID-19 pandemic, limits emergency vaccine liability to cases in which a vaccine producer engages in "willful misconduct" that results in injury (this may become relevant in the next few years as COVID-19 vaccines are approved and distributed).[312]

Vaccine producers were reluctant to develop vaccines to be administered to pregnant mothers due to potential tort liability for fetal injury and death.[313] However, in 2016, Congress responded to these industry concerns with the 21st Century

---

[306] *See* Tenpenny, *supra* note 104.

[307] *See* Parasidis, *supra* note 13, at 2161.

[308] Homeland Security Act, Pub. L. No. 107-296, § 304, 116 Stat. 2135, 2167–68 (2002).

[309] Suzanne Malveaux, *Bush Gets Smallpox Vaccine*, CNN (Dec. 21, 2002, 10:13 PM), http://www.cnn.com/2002/US/12/21/bush.smallpox/index.html [https://perma.cc/V4CS-EQK8].

[310] *See* Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 18 (2005).

[311] 42 U.S.C. § 239a(f)(2).

[312] 42 U.S.C. §§ 247d-6d(a)(1), (d)(1).

[313] BIOTECHNOLOGY INDUSTRY ORG., MATERNAL IMMUNIZATION CHALLENGES & OPPORTUNITIES: PERSPECTIVE OF VACCINE DEVELOPERS & MANUFACTURERS 5 (2014), www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2014/bio_maternalimmunization_septnvac2014.pdf. [https://perma.cc/52SE-VMBK].

Cures Act (Cures Act).[314] The Cures Act insulates vaccine producers from civil liability if their vaccines injure or kill a fetus *in utero*.[315] In doing so, the Cures Act encourages healthcare providers to "vaccinate pregnant women" and creates "opportunities for pregnant women to be vaccinated at higher rates."[316] It likewise creates additional opportunities for the pharmaceutical industry to profit free from financial and legal liability related to vaccine injuries.

Vaccine critics believe that these liability protections go too far.[317] Vaccine proponents, however, believe they do not go far enough. Indeed, some vaccine advocates call for imposing financial and legal liability on vaccine-hesitant parents. These advocates argue that vaccine-hesitant parents should be financially liable in the event of a disease outbreak in order to hold "antivaccine parents responsible for their decisions."[318] That is, when a vaccine-preventable disease infects a vaccinated child (or a child who cannot be vaccinated), the parents of those children should be allowed to sue parents who sought legal vaccine exemptions for their children.[319] To some vaccine critics, this call for "accountability" might strike a discordant note given the industry's blanket limited liability in the profitable (and compulsory) vaccine market. As Wendy Parmet observes: "Suspicion and doubt can grow when vaccination laws put all of the risk on ordinary individuals and remove all of the risk from health officials and pharmaceutical makers."[320] The government's seemingly counterproductive insulation of vaccine manufacturers from normal market conditions and legal liability is, perhaps to some observers, a curious policy choice. As such, the government's liability-transferring measures serve as the third legal structure that breeds parental distrust and, subsequently, promotes vaccine hesitancy.

---

[314] 21st Century Cures Act, Pub. L. No. 114-255, § 3093(c), 130 Stat. 1151–52 (amending provisions of the National Childhood Vaccine Injury Act of 1986, codified as amended at 42 U.S.C. § 300aa-14(e)).

[315] *Id.*

[316] *See* Levine & Davey, *supra* note 206, at 49.

[317] *See* Holland, *supra* note 213, at 421–22.

[318] Tucker Levis, Note, *Vaccines and the Tragedy of the Commons: An Argument for an Alternative Liability Tort Remedy*, 65 DRAKE L. REV. 1059, 1061, 1078 (2017); *see also* Dorit Rubinstein Reiss, *Compensating the Victims of Failure to Vaccinate: What are the Options?*, 23 CORNELL J. L & PUB. POL'Y 595, 595 (2014) (making the case for holding vaccine-hesitant parents financially responsible in tort for outbreaks of vaccine-preventable diseases).

[319] *See* Reiss, *supra* note 318, at 595–97.

[320] *See* Parmet, *supra* note 107, at 149.

IV. THE LEGAL STRUCTURE OF DOUBT

These legal structures—compulsory immunization, financial conflicts of interest, and limited industry liability—lay the foundation for vaccine hesitancy. For some parents, a close examination of U.S. vaccine legislation might produce a certain degree of skepticism related to the nation's immunization policies. That is, the United States compels parents to immunize healthy children against an ever-expanding list of diseases, while peer nations with superior public health outcomes impose less extensive mandates.[321] Meanwhile, pharmaceutical industry executives and others who stand to profit from these vaccine mandates play a role in the vaccine approval process.[322] These same executives and the companies they represent enjoy blanket immunity from lawsuits when vaccines harm American children.[323] For some parents, this confluence of factors breeds systemic doubt about vaccines. Further, given the proven and undeniable importance of immunization, that doubt—and the hesitancy it produces—endangers the public health. Though vaccines unquestionably produce more benefits than harm, vaccine-hesitant critics point to incidents where these legal structures converge as "proof" that the pharmaceutical industry aims to profit at their children's expense. Two paradigmatic examples demonstrate this phenomenon: the 2009 H1N1 (swine flu) pandemic and the autism omnibus proceeding.

A. The 1976 and 2009 Swine Flu Immunization Programs

The swine flu controversy begins in 1976. The threat of pandemic influenza (flu) recurs each year with the arrival of flu season.[324] Fear about the flu is not unfounded, as estimates suggest that the 1918 flu pandemic killed as many as 50 million people worldwide.[325] The U.S. government warns that a flu

---

[321] *See supra* Part I.

[322] *See supra* Part II.

[323] *See supra* Part III.

[324] Renae Reints, *Another Flu Pandemic Is Inevitable, World Health Organization Says*, FORTUNE (Mar. 11, 2019, 3:08 PM), http://fortune.com/2019/03/11/flu-pandemic-influenza-who/[https://perma.cc/99UE-6QYK]; *see also* Peter A. Patriarca & Nancy J. Cox, *Influenza Pandemic Preparedness Plan for the United States*, 176 J. INFECTIOUS DISEASES S4, S4 (1997) (predicting that another influenza pandemic is inevitable in the future).

[325] *1918 Pandemic (H1N1 Virus)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html#:~:text=It%20is%20estimated%20that%20about,occurring%20in%20the%20United%20States [https://perma.cc/S4ZG-GNS3].

pandemic could kill up to 2 million Americans.[326] Indeed, as the United States grapples with the ongoing and tragic COVID-19 pandemic, contemporary Americans now fully realize the importance of public health vigilance in pandemic preparedness.[327] Pandemic warnings circulated in 1976, and the government took action after several Army soldiers in New Jersey contracted the swine flu virus.[328] Based on these isolated cases, the government created a nationwide swine flu immunization program aiming to vaccinate 95 percent of the U.S. population.[329] However, the drug companies that produced the swine flu vaccine refused to sell it to the government unless the government indemnified them against vaccine injuries.[330] In response, Congress passed the Swine Flu Act.[331] The Swine Flu Act was the direct legislative predecessor to the Injury Act: it provided vaccine producers with immunity from liability and initiated a taxpayer-funded compensation program for injuries.[332] The CDC Director in 1976 later stated that, in hindsight, the industry demand for indemnification should have served as a strong indication that there was "something wrong with this vaccine."[333]

As it turned out, there was something wrong with the swine flu vaccine. Almost immediately after the government initiated the mass-vaccination program, immunized individuals fell sick and some died.[334] The vaccine caused Guillain-Barre syndrome at an unexpectedly high rate.[335] Guillain-Barre syndrome is a rare disorder that can cause paralysis and even death as a result of triggering the body's immune system to attack the nervous system.[336] The government suspended the swine flu immunization program after ten weeks and after only

---

[326] HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA: IMPLEMENTATION PLAN 15 (2006), https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf [https://perma.cc/3KZC-VVM4].

[327] Chun Han Wong, *U.S. Coronavirus Cases Near 84,000 for Second Day in a Row*, WALL STREET J. (Oct. 25, 2020, 8:27 AM), https://www.wsj.com/articles/u-s-coronavirus-cases-near-84-000-for-second-day-in-a-row-11603621961 [https://perma.cc/539L-2TSE].

[328] RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE 5–6, 24–30 (1978).

[329] *See id.* at 31; *see also* David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 29–30 (2006).

[330] *See* Sencer & Millar, *supra* note 329, at 31.

[331] National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (1976).

[332] *See* Greenberger, *supra* note 310, at 11–12.

[333] *See* Sencer & Millar, *supra* note 329, at 31.

[334] *See* Parasidis, *supra* note 13, at 2198–99.

[335] *See id.*

[336] *Guillain-Barre Syndrome*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/guillain-barre-syndrome/symptoms-causes/syc-20362793 [https://perma.cc/WXJ9-KJC7].

40 million Americans had been vaccinated.[337] Officials spent $137 million of taxpayer money to purchase the vaccine and an additional $90 million in tax funds to compensate vaccine-injured victims.[338] No swine flu pandemic arrived in 1976. Government estimates suggest that "[o]nly about 200 cases of swine flu and one death were ultimately reported in the U.S."[339] The CDC determined that during the swine flu vaccine surveillance period, Americans reported 532 serious injuries and 58 fatalities.[340] As a result of the swine flu "debacle," the nation's public health suffered (and continues to suffer), because

> [s]ome of the American public's hesitance to embrace vaccines—the flu vaccine in particular—can be attributed to the long-lasting effects of a failed 1976 political campaign to mass-vaccinate the public against a strain of the swine flu virus. This government-led campaign was widely viewed as a debacle and put an irreparable dent in future public health initiatives, as well as negatively influenced the public's perception of both the flu and the flu shot in this country.[341]

The confluence of government mandates, adverse side effects from an unsafe vaccine, and blanket immunity from liability for vaccine manufacturers produced cynicism among the public and planted the seeds of widespread doubts about vaccines. That said, the 1976 swine flu vaccination program taught the government an important lesson about pandemic preparedness.[342] Congress passed the Public Readiness and Emergency Preparedness Act (PREPA) in 2005.[343] PREPA allows the HHS Secretary, if she perceives a credible risk, to unilaterally declare a disease-related "public health emergency."[344] Once the HHS Secretary declares an emergency, the PREPA declaration insulates covered vaccine producers

---

[337] Shari Roan, *Swine Flu 'Debacle' of 1976 is Recalled*, L.A. TIMES (Apr. 27, 2009, 12:00 AM), https://www.latimes.com/archives/la-xpm-2009-apr-27-sci-swine-history27-story.html [https://perma.cc/6DKG-ZDEK] (observing that "[w]aiting in long lines at schools and clinics, more than 40 million Americans—almost 25% of the population—received the swine flu vaccine before the program was halted in December after 10 weeks").

[338] *See* Parasidis, *supra* note 13, at 2199 (observing that "[b]y April 1985, compensation judgments and awards totaled approximately $90 million, which nearly matched the $ 100 million that the government had earmarked for purchase of the vaccine itself"); *see also* Sencer & Millar, *supra* note 329, at 32 ("The direct cost of the 1976 program was $137 million.").

[339] *See* Roan, *supra* note 337.

[340] Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. ENVTL. AFF. L. REV. 169, 183–84 (1986).

[341] Rebecca Kreston, The Public Health Legacy of the 1976 Swine Flu Outbreak, Discover (Sept. 30, 2013, 9:30 AM), http://blogs.discovermagazine.com/bodyhorrors/2013/09/30/public-health-legacy-1976-swine-flu/#.XJ0jK5hKi72 [https://perma.cc/B445-9GEN].

[342] *See* Parmet, *supra* note 107, at 132.

[343] *Id.* at 136; 42 U.S.C. § 247d-6d.

[344] 42 U.S.C. § 247d-6d(b)(1).

from civil liability (barring "willful misconduct") for vaccine-related injuries.[345] In addition, the declaration of a "public health emergency" permits HHS to issue an "emergency use authorization," empowering the government to purchase and administer unlicensed vaccines and drugs.[346] PREPA was in place to address the nation's next swine flu pandemic, which arrived in 2009.

On June 11, 2009, shortly after the first cases of H1N1 were identified in the United States, HHS Secretary Kathleen Sebelius issued a PREPA declaration stating that the swine flu outbreak constituted a "public health emergency."[347] After the PREPA declaration, the government spent $6.15 billion to combat the pandemic.[348] Of those expenditures, $1.72 billion went toward "vaccines, adjuvants, and ancillary supplies" and the "government bought 190 million doses of pandemic vaccine from five manufacturers."[349] The government spent an additional $1.3 billion on antiviral drugs, including Tamiflu.[350] The accompanying "emergency use authorization" allowed the government to administer the vaccines and Tamiflu for uses and to individuals for which and whom the FDA had not approved them.[351] Investigations later revealed that Tamiflu is mostly ineffective at treating the flu and may in fact cause fatal heart attacks.[352] Tamiflu researchers had engaged in clinical bias that ignored failed drug trials, and the company then paid a "ghostwriter" to draft and publish medical journal articles with a company-controlled message to establish the drug's safety and efficacy.[353]

---

345 42 U.S.C. §§ 247d-6d(a)(1), (d)(1).

346 21 U.S.C. § 360bbb-3a(d)–(e); *see also* Parmet, *supra* note 107, at 120–22 (explaining the nature and extent of "Emergency Use Authorizations" under PREPA).

347 Pandemic Influenza Antivirals—Amendment, 74 Fed. Reg. 29213, 29213–14 (June 19, 2009) (amendment pursuant to Public Health Services Act § 319F-3 (42 U.S.C. § 247d-6d)).

348 Robert Roos, *GAO Details Spending On, Lessons From 2009 Pandemic*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (June 28, 2011), http://www.cidrap.umn.edu/news-perspective/2011/06/gao-details-spending-lessons-2009-pandemic [https://perma.cc/FMH8-SYRD].

349 *Id.*

350 U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-632, INFLUENZA PANDEMIC: LESSONS FROM THE H1N1 PANDEMIC SHOULD BE INCORPORATED INTO FUTURE PLANNING 7 (2011), https://www.gao.gov/new.items/d11632.pdf [https://perma.cc/D756-PB5Z].

351 Susan E. Sherman et al., *Emergency Use Authority and 2009 H1N1 Influenza*, 7 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 245, 249 (2009).

352 Shannon Brownlee & Jeanne Lenzer, *The Truth About Tamiflu*, ATLANTIC (Dec. 2009), https://www.theatlantic.com/magazine/archive/2009/12/the-truth-about-tamiflu/307801/ [https://perma.cc/P8VT-4NQE]; *see also* Tom Jefferson et al., *Neuraminidase Inhibitors for Preventing and Treating Influenza in Healthy Adults: Systematic Review and Meta-Analysis*, 339 BRIT. MED. J. 1, 1 (2009) ("Neuraminidase inhibitors have modest effectiveness against the symptoms of influenza in otherwise healthy adults. The drugs are effective postexposure against laboratory confirmed influenza, but this is a small component of influenza-like illness, so for this outcome neuraminidase inhibitors are not effective.").

353 *See* Brownlee & Lenzer, *supra* note 352.

Despite industry claims about Tamiflu's effectiveness, the FDA required the manufacturer to disclose that "Tamiflu has not been proven to have a positive impact on the potential consequences (such as hospitalizations, mortality, or economic impact) of seasonal, avian, or pandemic influenza."[354]

Critics of the government's response also grew suspicious over perceived financial conflicts of interest between the government and industry with regard to Tamiflu. Gilead Sciences, Inc. developed Tamiflu and licenses it to Roche Pharmaceuticals for a 10 percent royalty.[355] Former Secretary of Defense Donald Rumsfeld was previously chairman of Gilead, and held between $5 and $25 million in Gilead stock when the government began to stockpile the drug in preparation for a pandemic.[356] Other individuals with government ties (including former Secretary of State George Shultz) sat on the Gilead board of directors, some of whom earned millions of dollars from Gilead stock—a stock price that rose approximately 50 percent in the wake of government Tamiflu purchases.[357]

U.S. government entities continued implementing an aggressive approach to the swine flu "public health emergency." New York State mandated the swine flu vaccine for certain populations, including healthcare workers.[358] New York issued its mandate before the vaccine was approved, a decision which "was met with fear and anger by health care workers, many of whom resented the state's imposition on their liberty and feared the not-yet-licensed vaccine."[359] Similar to the 1976 pandemic, the 2009 swine flu pandemic never fully materialized. In fact, the seasonal flu proved more dangerous than swine flu that year—and 2009 was a mild flu season.[360] Americans reported 11,209 adverse swine flu vaccine reactions and fifty-six deaths to the government's VAERS database.[361] However, since these individuals received the vaccine under a PREPA "public health emergency" declaration, those victims could not utilize the

---

[354] Shannon Brownlee & Jeanne Lenzer, *Does the Vaccine Matter*?, ATLANTIC (Nov. 2009), https://www.theatlantic.com/magazine/archive/2009/11/does-the-vaccine-matter/307723/ [https://perma.cc/86UG-W8ZA].

[355] Nelson D. Schwartz, *Rumsfeld's Growing Stake in Tamiflu: Defense Secretary, Ex-Chairman of Flu Treatment Rights Holder, Sees Portfolio Value Growing*, CNN (Oct. 31, 2005, 10:55 AM), https://money.cnn.com/2005/10/31/news/newsmakers/fortune_rumsfeld/ [https://perma.cc/NQF8-54JH].

[356] *Id.*

[357] *Id.*

[358] N.Y. COMP. CODES R. & REGS. tit. 10, § 66-3 (expired Nov. 10, 2009).

[359] *See* Parmet, *supra* note 107, at 141–42.

[360] *Id.* at 119.

[361] *Id.* at 123 (observing that "[f]ifty-six deaths were reported and were being investigated, but preliminary findings did not 'suggest' any association with the vaccine").

Injury Act's no-fault compensation program and therefore had no immediate recourse against the government or industry.[362]

The government's legal response to the 2009 swine flu pandemic may have proven as destructive to U.S. public health as its misguided 1976 response. The confluence of compulsion (or fear-based coercion), financial conflicts of interest, and limited liability again reinforced widespread vaccine doubt. Indeed, the government's legal response

> during the 2009 outbreak may have reaffirmed populist suspicions about the intentions of government, public health officials, and vaccine makers. At the least, the laws fit comfortably within the populist, antigovernment narrative, thereby providing, however unintentionally, support for suspicions about the actions of health officials and the safety of vaccines.[363]

The legal framework and the government's response to the swine flu pandemics in both 1976 and 2009 have undoubtedly contributed to the rise of vaccine hesitancy in the United States. The swine flu pandemics also demonstrate how misguided vaccine legislation instills widespread and lasting public doubt about immunizations. Indeed, a majority of Americans still forgo the flu shot each year.[364] In addition, these government missteps may help explain why polls indicated that 44 percent of Americans will decline a COVID-19 vaccine, despite living in the midst of a deadly global pandemic.[365]

B. The Autism Omnibus Proceeding

The autism omnibus proceeding has played an even more significant role in the regulatory production of vaccine hesitancy. Autism diagnoses are on the rise in the United States.[366] In 1989, doctors diagnosed 1 in 2500 children with autism; in 2014, 1 in 68 children were diagnosed with autism.[367]

---

[362] Robert Roos, *HHS Preparing to Handle Claims of Harm From H1N1 Vaccine*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Mar. 12, 2010), http://www.cidrap.umn.edu/news-perspective/2010/03/hhs-preparing-handle-claims-harm-h1n1-vaccine [https://perma.cc/R97W-F9MK].

[363] *See* Parmet, *supra* note 107, at 144.

[364] Rachel Bergman, *CDC: Fewer than Half of Americans Get Flu Vaccine*, NATION'S HEALTH (Dec. 2017), http://thenationshealth.aphapublications.org/content/47/9/E45 [https://perma.cc/KE89-8RN6].

[365] *See* Santhanam, *supra* note 16.

[366] *Data & Statistics on Autism Spectrum Disorder*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/ncbddd/autism/data.html [https://perma.cc/BRN5-ZMMG].

[367] Claire Laurier Decoteau & Kelly Underman, *Adjudicating Non-Knowledge in the Omnibus Autism Proceedings*, 45 SOC. STUD. SCI. 471, 471–72 (2015); *see also Data & Statistics on Autism Spectrum Disorder*, *supra* note 366 (concluding that in 2016 "[a]bout 1 in 54 children has been identified with autism spectrum disorder (ASD) according to estimates from CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network").

Some doctors claimed that vaccines caused neurological complications as early as the 1970s, but the perceived vaccine-autism "link" emerged in the late 1990s.[368] In 1998, Andrew Wakefield and other researchers at the British Royal Free Hospital published a (now discredited) study in the *Lancet* medical journal, suggesting a possible link between autism and the combined measles, mumps, and rubella (MMR) vaccine.[369] Twelve years later (but after unfounded fear of the MMR vaccine insinuated itself across the globe) the *Lancet* retracted the article, concluding that Wakefield had engaged in clinical bias and had a financial conflict of interest (a potential third-party beneficiary funded the MMR study).[370] Moreover, citing additional ethics violations, Britain's General Medical Council subsequently revoked Wakefield's license to practice medicine.[371]

Public health advocates observe that individuals who continue promoting the debunked vaccine-autism link confuse a "coincidental temporal relationship" between vaccination and childhood autism.[372] People who associate autism with vaccines, they say, fall prey to the logical fallacy of "*post hoc ergo propter hoc*" ("after this, therefore because of this").[373] A brief statistical explanation of this phenomenon is illuminating. The law endorses that nearly all 74 million U.S. children should receive the MMR vaccine at 12–15 months of age.[374] *Some* of these 74 million children will inevitably get sick (unrelated to vaccines)

---

[368] *See* Henson, *supra* note 69, at 67; Donna Hilts, *TV Report On Vaccine Stirs Bitter Controversy*, WASH. POST (Apr. 28, 1982), https://www.washingtonpost.com/archive/local/1982/04/28/tv-report-on-vaccine-stirs-bitter-controversy/80d1fc8a-1012-4732-a517-7976c86ab52d/ [https://perma.cc/X3R3-3RE5] (reporting on the national outcry in response to a "television report on the dangers of the whooping cough vaccine"); A. J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637, 637 (1998).

[369] *See* Wakefield et al., *supra* note 368.

[370] Laura Eggertson, *Lancet Retracts 12-Year-Old Article Linking Autism to MMR Vaccines*, 182 CANADIAN MED. ASS'N J. E199, E199 (2010).

[371] Jim Edwards, *Autism Doctor Loses His Medical License; Now Let's Talk About How False Vaccine Beliefs Hurt Kids*, CBS NEWS (May 24, 2010, 12:45 PM), https://www.cbsnews.com/news/autism-doctor-loses-his-medical-license-now-lets-talk-about-how-false-vaccine-beliefs-hurt-kids/ [https://perma.cc/2H5M-Z62W].

[372] *See* Salmon et al., *supra* note 9.

[373] *Id.* (emphasis added).

[374] *Id.*; *The Majority of Children Live With Two Parents, Census Bureau Reports*, U.S. CENSUS BUREAU (Nov. 17, 2016), https://www.census.gov/newsroom/press-releases/2016/cb16-192.html [https://perma.cc/GT9F-U4J2] (The U.S. Census Bureau estimated that "[t]he majority of America's 73.7 million children under age 18 live in families with two parents (69 percent)"); *Measles, Mumps, and Rubella (MMR) Vaccination: What Everyone Should Know*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/vpd/mmr/public/index.html [https://perma.cc/ZZ3K-2VPP] ("[The] CDC recommends all children get two doses of MMR (measles-mumps-rubella) vaccine, starting with the first dose at 12 through 15 months of age, and the second dose at 4 through 6 years of age. Children can receive the second dose earlier as long as it is at least 28 days after the first dose.").

between 12–15 months of age. Of *those* children who get sick, some will—by the law of averages—get sick subsequently (but coincidentally) after vaccination. The fact that autism often emerges in children at 12–18 months of age only heightens the danger that people will succumb to the logical fallacy that vaccines cause autism.[375] As scholars have noted: "Unfortunately, illnesses or medical conditions of uncertain etiology unrelated to vaccines will certainly be experienced by some subset of children within the first two years of life. It is problematic to assume an event is caused by a vaccine based on a temporal connection alone."[376] Echoing this conclusion, public health advocates confirm that "there is absolutely no support" for the vaccine-autism link, which has "been thoroughly debunked by the scientific community."[377] So why, then, do claims about the vaccine-autism link continue to circulate?

Several legal anomalies related to thimerosal (a vaccine additive) unfortunately perpetuated the unfounded vaccine-autism nexus claims that Wakefield falsely initiated in 1998.[378] Thimerosal is a mercury-based preservative added to some vaccines to prevent bacterial growth during storage.[379] The government has repeatedly assured the public that thimerosal is safe.[380] Despite these government assurances, the CDC and American Pediatrics Association recommended in 1999 that manufacturers stop adding thimerosal to childhood vaccines.[381] In their joint statement, they advised the public that

---

[375] *See When Do Children Usually Show Symptoms of Autism?*, NAT'L INST. CHILD HEALTH & HUM. DEV., https://www.nichd.nih.gov/health/topics/autism/conditioninfo/symptoms-appear [https://perma.cc/FCS6-ATJ6].

[376] *See* Reiss & Weithorn, *supra* note 25, at 939.

[377] *Id.* at 891; *see also Autism and Vaccines*, AUTISM SCI. FOUND., https://autismsciencefoundation.org/what-is-autism/autism-and-vaccines/ [https://perma.cc/86D3-JLV5] ("A decade ago most researchers agreed that we needed to study vaccines in relation to autism. We had to reconcile the fact that the number of vaccines children were receiving was increasing, and at the same time, the number of children who were being diagnosed with autism also was on the rise. Fortunately this was a question that could be studied—and answered—by science. We looked at children who received vaccines and those who didn't, or who received them on a different, slower schedule. There was no difference in their neurological outcomes. Multiple studies have been completed which investigated the measles, mumps and rubella vaccination in relation to autism. Researchers have also studied thimerosal, a mercury-based preservative, to see if it had any relation to autism. The results of studies are very clear; the data show no relationship between vaccines and autism.").

[378] *See Autism and Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccinesafety/concerns/autism.html [https://perma.cc/7633-968C].

[379] *Thimerosal and Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccinesafety/concerns/thimerosal/index.html [https://perma.cc/3BV6-GZWQ].

[380] *Id.*

[381] *Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, CTRS. FOR DISEASE CONTROL &

> [o]n the one hand, there is the known serious risk of diseases and deaths caused by failure to immunize our infants against vaccine-preventable infectious diseases; on the other, there is the unknown and *probably* much smaller risk, if any, of neurodevelopmental effects posed by exposure to thimerosal. The large risks of not vaccinating children far outweigh the unknown and *probably* much smaller risk, if any, of cumulative exposure to thimerosal-containing vaccines over the first 6 months of life.[382]

The perhaps too carefully worded statement only heightened the public's concerns about the vaccine-autism link.[383] Families began filing suit in state and federal courts alleging that thimerosal caused their children to develop autism.[384] Parents could sue in court (as opposed to Vaccine Court) because thimerosal was not a vaccine, but rather a preservative drug companies *added* to vaccines.[385] Eli Lilly is the sole producer of thimerosal.[386] As such, lawmakers did not ease suspicions when they inserted the now-infamous Eli Lilly rider in the Homeland Security Act of 2002 (Security Act).[387] During a holiday weekend, a still-unknown individual inserted language in the Security Act that barred any thimerosal lawsuits in state or federal courts.[388] The amendments required that individuals file all thimerosal claims (even though the preservative was distinct from the vaccine) through the Injury Act's taxpayer-funded compensation program.[389] The amendments would "result in the dismissal of thousands of cases filed by parents who contend that mercury in thimerosal has poisoned their

---

PREVENTION (July 9, 1999), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4826a3.htm [https://perma.cc/2C6F-B5XP].

382 *Id.* (emphasis added).

383 *See* Larson et al., *supra* note 64, at 528.

384 Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480, 496 (2011).

385 *See* Currier, *supra* note 255, at 236.

386 Sheryl Gay Stolberg, *A Capitol Hill Mystery: Who Aided Drug Maker?*, N.Y. TIMES (Nov. 29, 2002), https://www.nytimes.com/2002/11/29/us/a-capitol-hill-mystery-who-aided-drug-maker.html [https://perma.cc/MK23-LMC5].

387 *Id.*; *see also* Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 1714–15, 116 Stat. 2135, 2320 (2002) (amending the definition of vaccine "Manufacturer" and "Vaccine-Related Injury of Death" for purposes of the Injury Act).

388 Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 1714–15, 116 Stat. 2135, 2320 (2002) ("42 U.S.C. [§] 300aa-33(3) is amended—(1) in the first sentence, by striking 'under its label any vaccine set forth in the Vaccine Injury Table' and inserting 'any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine'; and (2) in the second sentence, by inserting 'including any component or ingredient of any such vaccine' before the period . . . .42 U.S.C. [§] 300aa-33(5) is amended by adding at the end the following: 'For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.'").

389 *See* Stolberg, *supra* note 386.

children, causing autism and other neurological ailments."[390] Eli Lilly, cynics observe, contributed $1.6 million to political campaigns during the 2002 election cycle, more than any other pharmaceutical company.[391] As the *New York Times* reported, Eli Lilly also had close ties to the Bush Administration in 2002.[392] President George H. W. Bush previously sat on the Eli Lilly board of directors, the White House budget director was a former Eli Lilly executive, and President Bush had recently appointed Eli Lilly's chief executive to serve on his presidential advisory council.[393] When asked for comment about the rider's sudden appearance in the Security Act, an Eli Lilly spokesperson responded that "[i]t's a mystery to us how it got in there."[394] The rider's appearance was not a mystery to vaccine critics, who simply saw another reason to doubt vaccine safety and to be suspicious about government claims regarding U.S. vaccine policy more generally.

The Vaccine Court simultaneously moved to reinforce the Eli Lilly rider in its decision *Leroy v. HHS*.[395] The special master in *Leroy* determined that the preservative thimerosal was now a part of the vaccine, meaning that the Injury Act preempted all thimerosal suits and that the government would use tax funds to compensate thimerosal-related injuries.[396] Also in 2002, the Justice Department ordered the Vaccine Court to immediately seal all records related to thimerosal's potential role in autism-related cases.[397] Cynical observers believed that the "government was trying to prevent families from obtaining damaging information about the preservative, which could later be used against drug companies" in pending lawsuits.[398] At the same time, and in a still singular departure from Vaccine Court procedure, the government filed *Autism General Order #1*, which consolidated all vaccine-injury autism claims into a single

---

[390] *Id.*

[391] *Id.*

[392] *Id.*

[393] *Id.*

[394] *Id.*

[395] *See generally* Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02–392V, 2002 WL 31730680 (Fed. Cl. Oct. 11, 2002).

[396] *Id.* at *3, *17.

[397] Bartholomew C. Wacek, Comment, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DEPAUL J. HEALTH CARE L. 305, 320–21 (2004); *see also* Sheryl Gay Stolberg, *Justice Dept. Seeks to Seal Vaccine Papers*, N.Y. TIMES (Nov. 27, 2002), https://www.nytimes.com/2002/11/27/us/justice-dept-seeks-to-seal-vaccine-papers.html [https://perma.cc/HY7F-XTDW] ("The Bush administration asked a federal claims court today to seal documents relating to hundreds of claims that a mercury-based preservative in vaccines, thimerosal, has caused autism and other neurological disorders in children.").

[398] *See* Stolberg, *supra* note 386.

proceeding.[399] The Autism Omnibus Proceeding (AOP) designated six test cases that would resolve the nearly 5,600 Injury Act petitions in which parents claimed that the MMR vaccine (and thimerosal) caused autism in their children.[400] The six cases tested two biological theories: 1) that the MMR vaccine (coupled with thimerosal) manifested as autism, and 2) that the MMR vaccine alone resulted in autism.[401]

In all six test cases, the special master found no causal link between the MMR vaccine, thimerosal, and autism.[402] The government awarded no compensation and appeared finally to put the spurious vaccine-autism correlation theory to rest.[403] However, news soon leaked that the government had surreptitiously settled one of the slated test cases.[404] In the settlement and subsequent court filings, the government conceded that the MMR vaccine caused encephalopathy (brain damage) in a child, which "eventually manifested as a chronic encephalopathy with features of autism spectrum disorder."[405] The special master awarded the family over $1.5 million in damages.[406] When pressed about the leaked settlement, the government responded that

> [t]he government has never compensated, nor has it ever been ordered to compensate, any case based on a determination that autism was actually caused by vaccines. We have compensated cases in which children exhibited an encephalopathy, or general brain disease. Encephalopathy may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures. Some children who have been compensated for vaccine injuries may have shown signs of autism before the decision to compensate, or may

---

399 *See In re* Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2002 WL 31696785, at *3 (Fed. Cl. July 3, 2002) (Autism General Order #1).

400 *See* Decoteau & Underman, *supra* note 367, at 471–72, 481–82.

401 *See* Jennifer Keelan & Kumanan Wilson, *Balancing Vaccine Science and National Policy Objectives: Lessons From the National Vaccine Injury Compensation Program Omnibus Autism Proceedings*, 101 AM. J. PUB. HEALTH 2016, 2017 (2011) ("The cases fell into 3 broad biological theories: (1) the combination of the measles-mumps-rubella vaccine and an ethylmercury preservative, thimerosal, was responsible for neurologic damage in infancy and early childhood, manifested as autism; (2) thimerosal alone was responsible for the development of autism; and (3) the measles-mumps-rubella vaccine was solely responsible for autism. The petitioners agreed to identify 3 test cases for each of these hypotheses, although they subsequently dropped the third hypothesis because most of the evidentiary material addressing it would be covered in the first set of test cases.").

402 *See* Decoteau & Underman, *supra* note 367, at 471.

403 *Id.*

404 *See* Holland et al., *supra* note 384, at 500.

405 Poling *ex rel.* Poling v. Sec'y of Health and Human Servs., No. 02–1466V, 2011 WL 678559, at *1 (Fed. Cl. Jan. 28, 2011); *see also* Holland et al., *supra* note 384, at 500 (explaining the details of the leaked Poling family settlement with the government).

406 *See* Holland et al., *supra* note 384, at 500–01.

> ultimately end up with autism or autistic symptoms, but we do not track cases on this basis.[407]

The government later admitted that the MMR vaccine "resulted" in the child's autism, but did not "cause" it.[408] Media reports following the leaked settlement declared that "there's no denying that the court's decision to award damages to the Poling family puts a chink—a question mark—in what had been an unqualified defense of vaccine safety with regard to autism."[409]

For the vaccine-hesitant, the leaked settlement and the government's qualified response only fed fears about the unfounded vaccine-autism link.[410] Indeed, for many vaccine critics, the vaccine-autism link is not "debunked." Legal researchers have identified eighty-three other Vaccine Court decisions in which special masters awarded damages in vaccine-related autism claims under the Injury Act.[411] Vaccine critics note that there are also "approximately sixty [published scientific] studies that support the autism-vaccine causation theory."[412] For these vaccine critics, this evidence "calls into question" the government's assertions on the topic of vaccine safety.[413] In any event, the swine flu immunization programs and the AOP demonstrate how three legal structures (legal compulsion, conflicts of interest in vaccine testing and approval, and limited liability for drug companies) lay the foundation for widespread and dangerous vaccine hesitancy in the United States.

V. PROPOSED SOLUTIONS TO THE VACCINE HESITANCY PHENOMENON

The *Journal of Law, Medicine, and Ethics* recently published an article that advocated for the public to begin shaming vaccine-hesitant parents.[414] The authors highlighted media

---

[407] *Id.* at 502.

[408] Sharyl Attkisson, *Family to Receive $1.5M+ in First-Ever Vaccine-Autism Court Award*, CBS NEWS (Sept. 10, 2010, 10:44 AM), https://www.cbsnews.com/news/family-to-receive-15m-plus-in-first-ever-vaccine-autism-court-award/ [https://perma.cc/ZY7J-SUF3].

[409] Claudia Wallis, *Case Study: Autism and Vaccines*, TIME (Mar. 10, 2008), http://content.time.com/time/health/article/0,8599,1721109,00.html [https://perma.cc/PQ3M-RZCQ].

[410] Jennifer Keelan & Kumanan Wilson, *Balancing Vaccine Science and National Policy Objectives: Lessons from the National Vaccine Injury Compensation Program Omnibus Autism Proceedings*, 101 AM. J. OF PUB. HEALTH 2016, 2019 (2011) ("After the Poling concession, advocates of the link between autism and vaccines hailed it as a vindication of their viewpoint.").

[411] *See* Holland et al., *supra* note 384, at 522.

[412] Ginger Taylor, *The Role of Government and Media*, *in* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 10, at 206, 219.

[413] *See* Holland et al., *supra* note 384, at 523.

[414] *See generally* Ross D. Silverman & Lindsay F. Wiley, *Shaming Vaccine Refusal*, 45 J.L. MED. & ETHICS 569 (2017).

headlines that declared "stupid parents are driving the vaccination crisis" and "[a]nti-vaxxers are stupid and contagious."[415] They suggested that "shaming vaccine-refusing parents by attaching a negative social meaning to their choice to refuse vaccines might influence vaccine-hesitant parents who are on the fence."[416] This article attempts to dissuade these kinds of solutions. Vaccine-hesitant parents are not "stupid," but instead tend to be among the most highly educated, financially secure, and experienced caregivers in the United States.[417] In fact, the vaccine-hesitant constitute a *majority* of American parents.[418] The perils of vaccine hesitancy are today more pronounced than ever before, as polling suggests that more than 40 percent of Americans would be unwilling to take a COVID-19 vaccine.[419] Many of these individuals unfortunately question whether factors beyond science and health may have contributed to some U.S. vaccine policy decisions.[420]

As this article demonstrates, *vaccines* are not the source of vaccine hesitancy—indeed, vaccines are among the great achievements of modern medicine.[421] Instead, the public health crisis of vaccine hesitancy exists because U.S. vaccine policy employs three legal structures that lay the foundations for doubt, distrust, and even accusations of government-industry collusion. While other developed nations do mandate some vaccines, the strictness and breadth of compulsory vaccination laws in the United States are unique. Meanwhile, America's public health outcomes trail peer nations that impose less stringent vaccine mandates. The government-sanctioned revolving door and the financial conflicts of interest it produces undermines vaccine testing and approval procedures. And, the blanket immunity from liability that the government affords vaccine producers creates the appearance of industry protectionism. Together, these legal structures produce vaccine hesitancy. To improve public confidence in U.S. vaccine policy and help reduce vaccine hesitancy, the government should consider amending (or eliminating) one or more of these three legal structures.

First, the government could simply terminate compulsory vaccine mandates. Global comparisons demonstrate that vaccine mandates are not necessary to produce excellent public health outcomes in developed nations. The nation's social

---

415 *Id.* at 572.
416 *Id.* at 571 (emphasis omitted).
417 *See* sources cited *supra* note 14.
418 *See* Habakus & Holland, *supra* note 10.
419 *See* Santhanam, *supra* note 16.
420 *Id.*
421 *See* Calandrillo, *supra* note 7, at 438.

fabric and U.S. public health will not disintegrate if the government reconsiders its policy. Great Britain, Germany, Australia, and other developed democratic nations that employ mostly voluntary vaccine policies boast superior public health outcomes compared to the United States.[422]

Alternatively, the government could simply begin enforcing the financial conflict of interest laws that are already on the books.[423] The law prohibits federal employees from acting on a matter in which they have a substantial financial conflict of interest.[424] However, the law allows agencies to grant waivers to conflicted employees.[425] Granting waivers to individuals who stand to profit from vaccine mandates breeds suspicion and raises ethical concerns. Many U.S. citizens distrust vaccines because the people who test, approve, recommend, and mandate vaccines too often stand to profit from them. The government can reduce vaccine hesitancy if it denies financial conflict of interest waivers in the vaccine approval process to individuals who, in at least one case, have reportedly earned millions of dollars from vaccine sales, according to estimates.[426] At the very least, the U.S. government might consider barring pharmaceutical industry executives from sitting on a committee that helps determine whether a new vaccine should be given to American children.[427]

Finally, and perhaps most importantly, the government could stop insulating the vaccine industry from civil liability for injuries that its products cause. European nations have adopted guidance that "affirms an individual's right to sue vaccine manufacturers for harms that she reasonably could not have expected based on the product warnings and on the 'particularly high level of safety' she is entitled to expect for vaccines."[428] The implementation of this policy has neither caused a vaccine market exodus nor an increase in vaccine prices in Europe.[429] Affording the public legal recourse against a for-profit vaccine industry would ameliorate doubt and distrust, even if the government continues to legally compel vaccination and grant conflict-of-interest waivers. As the erstwhile CDC Director conceded after

---

[422] *See supra* Section I.D.2.

[423] *See* 18 U.S.C. § 208; 5 C.F.R. §§ 2635.401–.403.

[424] *See* 5 C.F.R. § 2635.402.

[425] *See* 5 C.F.R § 2635.402(d).

[426] *See* Kroll, *supra* note 177.

[427] *See Roster of the Vaccines and Related Biological Products Advisory Committee*, *supra* note 173.

[428] *See* Holland, *supra* note 213, at 459 (quoting Case C-621/15, N.W. v. Sanofi Pasteur MSD SNC, ¶ 41 (June 21, 2017)).

[429] *See* Joshi, *supra* note 296.

the 1976 swine flu pandemic, pharmaceutical industry demands for vaccine-related limited liability suggested then that there was something wrong with the vaccines it was selling.[430] If the goal is to persuade more parents that vaccines are as safe as pharmaceutical companies and the government attest, then continuing to afford blanket limited liability to the industry seems entirely unnecessary and counterproductive from a public health (and trust) perspective.

CONCLUSION

Vaccine hesitancy has unfortunately been on the rise for decades in the United States.[431] The crisis has serious implications, as we are currently witnessing during the COVID-19 pandemic. This article argues that vaccine hesitancy is the direct byproduct of U.S. vaccine legislation. Mandatory vaccination laws, lax regulation, and limited liability for vaccine producers function together as a scaffolding upon which parental doubts about immunizations rest. As vaccine hesitancy amongst American parents continues to grow, federal and state governments respond by bolstering the very legal structures that produce and reinforce that doubt.[432] Vaccine-hesitant parents, in turn, respond to stronger vaccine legislation with renewed and seemingly redoubled opposition to vaccines.[433] This article proposes a different solution to the public health crisis of vaccine hesitancy. The government can destabilize the legal foundations upon which vaccine hesitancy rests if it simply amends or eliminates one or more of these legal structures. The U.S. government can alleviate vaccine hesitancy among parents simply by making more immunizations optional (as is the case in many peer nations across the globe), eliminating financial conflicts of interest in vaccine regulation, or allowing parents to sue vaccine manufacturers when mandatory immunizations harm their children. If the government amends one or more of these legal structures, it can help mitigate the dangers of vaccine hesitancy and restore trust in an indispensable public health tool.

---

[430] *See* Sencer & Millar, *supra* note 329, at 31.

[431] Jan Hoffman, *How Anti-Vaccine Sentiment Took Hold in the United States*, N.Y. TIMES (Sept. 23, 2019), https://www.nytimes.com/2019/09/23/health/anti-vaccination-movement-us.html [https://perma.cc/WM6K-5H2Z].

[432] *See* Parmet *supra* note 107, at 147.

[433] Michael Shepherd, *Maine Will Vote on Effort to Repeal New School Vaccine Requirement in March 2020*, BANGOR DAILY NEWS (Oct. 17, 2019), https://bangordailynews.com/2019/10/17/politics/maine-will-vote-on-effort-to-repeal-new-school-vaccine-requirement-in-march-2020/ [https://perma.cc/HB9T-6BFU].