

**VACCINE HESITANCY ACROSS TIME: LEGAL AND POLICY  
INTERVENTIONS FROM THE DAWN OF THE ANTI-VACCINATION  
MOVEMENT TO THE ERA OF SOCIAL MEDIA**

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*This Article explores the intertwined topics of hesitancy and trust towards vaccines. The Article traces the evolution of anti-vaccine sentiments, their consolidation into organized movements, and their recent evolution, as vaccine misinformation and disinformation circulate with unprecedented ease through digital channels. The Article then examines selected legal and policy interventions that have been used to counter vaccine hesitancy—sometimes through top-down or mandatory frameworks, other times, through voluntary ones. In particular, this Article examines vaccination mandates, as well as rules imposing or promoting vaccination; mechanisms designed to increase the flow of information about vaccines; and nudges to vaccination, such as lotteries and other prize-like mechanisms.*

**TABLE OF CONTENTS**

<b>I. INTRODUCTION .....</b>	<b>841</b>
<b>II. VACCINES AS PRODUCTS OF BIOTECHNOLOGY: FROM SCIENTIFIC COMPLEXITY TO VACCINE-QUESTIONING DISCOURSES.....</b>	<b>843</b>
<b>III. THE HISTORICAL ARC OF VACCINE HESITANCY .....</b>	<b>847</b>
<i>A. The Dawn of Anti-Vaccine Movements .....</i>	<i>847</i>

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<i>B. Vaccine Hesitancy in the Era of Social Media</i> .....	853
<b>IV. LEGAL AND POLICY INTERVENTIONS ADDRESSING VACCINE HESITANCY</b> .....	<b>863</b>
<i>A. Top-Down Approaches: Laws and Regulations Promoting         Vaccination</i> .....	863
<i>B. Informational Approaches</i> .....	869
<i>C. The Role of Nudges in Vaccination Policy</i> .....	875
<b>V. CONCLUSION</b> .....	<b>881</b>

## I. INTRODUCTION

In 2019, the World Health Organization (“WHO”) defined vaccine hesitancy as “the reluctance or refusal to vaccinate despite the availability of vaccines” and added it to the list of the top ten threats to global health.<sup>1</sup> Pronounced increases in the number of individuals foregoing or unduly delaying vaccination result in significant detrimental effects on public and individual health.<sup>2</sup> In recent years, diseases that had long been prevented by the broad administration of vaccines have resurfaced across the world. For instance, in 2019, the United States experienced several outbreaks of measles, a vaccine-preventable disease. These outbreaks were

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<sup>1</sup> TEN THREATS TO GLOBAL HEALTH IN 2019, WORLD HEALTH ORG. (2019), <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019> [<https://perma.cc/MG67-TYQB>]. There are several other definitions of vaccine hesitancy, and the concept has long defied universal characterization. *See, e.g.*, Eve Dubé et al., *Vaccine Hesitancy: An Overview*, 9 HUM. VACCINES & IMMUNOTHERAPEUTICS 1763, 1763–64 (2013); Noni E. MacDonald & The SAGE Working Group on Vaccine Hesitancy, *Vaccine Hesitancy: Definition, Scope and Determinants*, 33 VACCINE 4161, 4163 (2015).

<sup>2</sup> *See, e.g.*, Saad B. Omer et al., *Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases*, 360 NEW ENG. J. MED. 1981, 1986–87 (2009); Denis G. Gill, *Vaccine Refusal and the Risks of Vaccine-Preventable Diseases*, 360 NEW ENG. J. MED. 723, 723 (2009); Daniel A. Salmon et al., *Vaccine Hesitancy: Causes, Consequences, and a Call to Action*, 49 AM. J. PREVENTIVE MED. S391, S395 (2015); Eve Dubé et al., *Vaccine Hesitancy, Vaccine Refusal and the Anti-Vaccine Movement: Influence, Impact and Implications*, 14 EXPERT REV. VACCINES 99, 99 (2015); Varun K. Phadke et al., *Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis*, 315 J. AM. MED. ASS’N 1149, 1150 (2016).

later connected to escalating rates of vaccine hesitancy in the affected communities.<sup>3</sup> By opening the door to the propagation of communicable diseases, low and declining levels of vaccination also contribute to the straining of health systems, as more people are likely to require medical attention, leading to both short- and long-term productivity and economic losses.<sup>4</sup>

Levels of vaccine hesitancy rose in many countries throughout the 2010s,<sup>5</sup> and the COVID-19 pandemic has so far been similarly marked by worrisome levels of vaccine hesitancy.<sup>6</sup> The debates surrounding the development, allocation, and administration of COVID-19 vaccines have further exacerbated the polarized nature of vaccine-related discourses.<sup>7</sup> As such, the question of how best to

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<sup>3</sup> See, e.g., David A. Broniatowski et al., *Facebook Pages, the “Disneyland” Measles Outbreak, and Promotion of Vaccine Refusal as a Civil Right, 2009–2019*, 110 AM. J. PUB. HEALTH S312, S316–18 (2020); see also Phadke, *supra* note 2, at 1155.

<sup>4</sup> See, e.g., Fangjun Zhou et al., *Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009*, 133 PEDIATRICS 577, 580 (2014).

<sup>5</sup> See Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 388–89 (2004). See generally Sarah Lane et al., *Vaccine Hesitancy Around the Globe: Analysis of Three Years of WHO/UNICEF Joint Reporting Form Data-2015–2017*, 36 VACCINE 3861 (2018); Heidi J. Larson et al., *Understanding Vaccine Hesitancy Around Vaccines and Vaccination from a Global Perspective: A Systematic Review of Published Literature, 2007–2012*, 32 VACCINE 2150 (2014).

<sup>6</sup> See, e.g., Matilde de Albuquerque Veloso Machado et al., *The Relationship Between the COVID-19 Pandemic and Vaccine Hesitancy: A Scoping Review of Literature Until August 2021*, 9 FRONTIERS PUB. HEALTH 747, 787 (2021); Shingai Machingaidze & Charles Shey Wiysonge, *Understanding COVID-19 Vaccine Hesitancy*, 27 NATURE MED. 1338, 1338 (2021); Corrina Moucheraud et al., *Trust in Governments and Health Workers Low Globally, Influencing Attitudes Toward Health Information, Vaccines*, 40 HEALTH AFFS. 1215, 1222 (2021).

<sup>7</sup> See generally Neha Puri et al., *Social Media and Vaccine Hesitancy: New Updates for the Era of COVID-19 and Globalized Infectious Diseases*, 16 HUM. VACCINES & IMMUNOTHERAPEUTICS 2586 (2020); Federico Germani & Nikola Biller-Andorno, *The Anti-Vaccination Infodemic on Social Media: A Behavioral Analysis*, 16 PLOS ONE e0247642 (2021); Ali Haif Abbas, *Politicizing COVID-19 Vaccines in the Press: A Critical Discourse Analysis*, INT’L J. FOR SEMIOTICS L.

promote trust in vaccines and vaccination has attracted unprecedented attention well beyond the traditional fora for public health law and policy.

Neither the phenomenon of vaccine hesitancy nor the proliferation of legal and policy interventions to promote vaccine trust is new.<sup>8</sup> This Article places ongoing discussions on the intertwined topics of hesitancy and trust towards vaccines against a larger historical backdrop. Part II sets the stage by framing vaccines as complex technological products. Part III describes the origins of vaccine hesitancy and contrasts those origins with emerging forms of vaccine hesitancy fueled by the spread of vaccine misinformation in the online environment. In so doing, it underscores the idea that, albeit highly idiosyncratic at any given point in time, this phenomenon should be understood as part of a long continuum of both individual and societal responses to the development of new biomedical technologies. Part IV examines different types of legal and policy interventions that have been used to counter vaccine hesitancy by promoting vaccine uptake—sometimes through top-down, mandatory frameworks, other times, through voluntary ones. Additionally, Part IV offers selected examples of these interventions, ranging in policy strength—from mandates, to informational duties placed on different actors in the public health ecosystem, to “nudges” in the form of prize-like mechanisms. A brief conclusion underscores the continued need for a plurality of legal and policy interventions aimed at promoting greater trust in vaccines.

## II. VACCINES AS PRODUCTS OF BIOTECHNOLOGY: FROM SCIENTIFIC COMPLEXITY TO VACCINE-QUESTIONING DISCOURSES

In previous work, this Author has highlighted the importance of considering vaccines as forms of technology.<sup>9</sup> The result of

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1 (2021); Joshua M. Sharfstein et al., *Uncoupling Vaccination from Politics: A Call to Action*, 398 LANCET 1211 (2021).

<sup>8</sup> See, e.g., Dubé et al., *supra* note 2.

<sup>9</sup> See generally ANA SANTOS RUTSCHMAN, VACCINES AS TECHNOLOGY: INNOVATION, BARRIERS, AND THE PUBLIC HEALTH (2022).

biotechnology processes, vaccines are artificial products made by combining a wide array of components, ranging from antigens<sup>10</sup>—the substances used to elicit an immune response from the human body—to sugars and other stabilizers,<sup>11</sup> salts that help create a stronger immune response,<sup>12</sup> and residual materials from the cells' cultures in which viruses or bacteria were grown.<sup>13</sup> Modern vaccines are complex products, whose inner workings are not readily apparent to or easily understandable by the lay people who receive them. As such, vaccines and vaccination have long been subjected to intense scrutiny and debate in non-scientific fora.<sup>14</sup>

To be sure, vaccines are not the only complex products routinely used in modern medicine. To give but one example, the world's best-selling drug,<sup>15</sup> adalimumab,<sup>16</sup> is a biologic (the same type of drug as a vaccine) with a large molecular structure that is vastly larger and more complex than that of many vaccines. Moreover, whether a product is simple as opposed to complex, or easily understood by the public as opposed to opaque, is immaterial to the safety and efficacy of the product itself and should not, in principle, hinder its widespread use in indicated patients. Drug regulators, as well as the scientific community at large, play pivotal roles in evaluating new drugs and vaccines and serve as informational mediators by conveying to the public that a drug or vaccine entering

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<sup>10</sup> *How Do Vaccines Work?*, WORLD HEALTH ORG. (Dec. 8, 2020), <https://www.who.int/news-room/feature-stories/detail/how-do-vaccines-work> [<https://perma.cc/B9WQ-WQAE>].

<sup>11</sup> *What's in Vaccines*, CDC (Aug. 5, 2019), <https://www.cdc.gov/vaccines/vac-gen/additives.htm> [<https://perma.cc/E574-BCGT>].

<sup>12</sup> *Id.*; see also *What Is an Adjuvant and Why Is It Added to a Vaccine?*, CDC (Aug. 14, 2020), <https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html> [<https://perma.cc/4UDJ-K2KE>].

<sup>13</sup> See WORLD HEALTH ORG., *supra* note 10.

<sup>14</sup> See *infra* Part III.

<sup>15</sup> See Eric Sagonowsky, *The Top 20 Drugs by Worldwide Sales in 2020*, FIERCE PHARMA (May 3, 2021, 3:00 AM), <https://www.fiercepharma.com/special-report/top-20-drugs-by-2020-sales> [<https://perma.cc/BL7W-V5Z7>].

<sup>16</sup> See U.S. FOOD & DRUG ADMIN., *Humira: Highlights of Prescribing Information* (2008), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2008/125057s0110lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/125057s0110lbl.pdf) [<https://perma.cc/9TU7-YANK>] (explaining that Adalimumab is sold in the United States under the brand name Humira).

the market has been vetted as safe and effective according to the best available data and scientific knowledge.

Even so, the use of vaccines has historically elicited especially visceral reactions from the public at large, as well as from specific groups. These groups include parental communities, which understandably have a particular interest in vaccine-related debates, as children typically receive more vaccines during a concentrated period of time than older individuals.<sup>17</sup> More recently, as seen in Part III, the number and typology of groups involved in intensive vaccine debates have expanded to include actors that are extraneous to scientific discussions, operating instead in the pursuit of geopolitical goals.<sup>18</sup>

The formation of organized or semi-organized movements contesting the use of vaccines—even their public health value—dates back to at least the nineteenth century.<sup>19</sup> In illustrating the earliest forms of these movements and their evolution to the present, this Article employs the terms “anti-vaccine” and “anti-vaccination” to denote opposition to vaccination in ways that conflict with current scientific parameters and with public health precepts—that is, behaviors that negate scientific pronouncements about the safety and efficacy of a vaccine that have been properly vetted by a drug regulator, or that generally contest the endorsement of vaccination by public health authorities.<sup>20</sup>

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<sup>17</sup> *Recommended Vaccines Needed by Age*, CDC (Nov. 22, 2016), <https://www.cdc.gov/vaccines/vpd/vaccines-age.html> [<https://perma.cc/QVW9-GKE6>].

<sup>18</sup> See *infra* Part III.B.

<sup>19</sup> See *infra* Part III.A.

<sup>20</sup> The concepts of “anti-vaccine” and “anti-vaccination” are often used interchangeably with “vaccine hesitancy.” A growing body of literature has questioned the porousness, imprecision, and conceptual appropriateness of “vaccine hesitancy.” See, e.g., Ana Santos Rutschman & Timothy L. Wiemken, *Vaccine Hesitancy: Experimentalism as Regulatory Opportunity*, 4 BUS. ENTREPRENEURSHIP & TAX L. REV. 227, 233–36 (2020); see also E. Allison Hagood & Stacy Mintzer Herlihy, *Addressing Heterogeneous Parental Concerns About Vaccination with a Multiple-Source Model: A Parent and Educator Perspective*, 9 HUM. VACCINES & IMMUNOTHERAPEUTICS 1790, 1790–91 (2013) (proposing that parental hesitancy towards vaccination be characterized in a more granular way by the adoption of the categories of parents who are “vaccine rejectors,” “vaccine resisters,” and “vaccine hesitant”).

This Article does not mean to suggest that the way vaccines are discovered and developed, vetted by regulators, allocated, and distributed, should not be scrutinized.<sup>21</sup> Nor does this Article mean to suggest that individuals or groups experiencing concerns about vaccine-related issues should be dismissed. As anthropologist Heidi Larson—one of the leading voices in vaccine trust-building policymaking—has repeatedly argued, most people labeled as “anti-vaxxers” are not “uneducated, science-denying individualists but . . . people with genuine questions and doubts in search of guidance.”<sup>22</sup> Several other commentators in this field have shown that the way messages about the safety and efficacy emanate from experts and public health authorities often fail to account for the need for dialectic, non-polarizing approaches.<sup>23</sup> As such, this Article references the names by which vaccine-questioning movements are commonly known in a merely descriptive fashion.

Part III now turns to the evolution of these movements as a setup to the question of how law and policy can be better designed in the future to respond to the manifold, heterogenous concerns that many

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<sup>21</sup> See, e.g., Dorit R. Reiss, *The COVID-19 Vaccine Dilemma*, 6 ADMIN. L. REV. ACCORD 49, 51–52 (2020) (discussing successes and failures of bringing vaccines to market in the specific case of COVID-19); Sam F. Halabi & Ana Santos Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, EMORY INT’L L. REV. (forthcoming 2022) (discussing problems in the transnational allocation of COVID-19 vaccines).

<sup>22</sup> See Jenny Anderson, *She Hunts Viral Rumors About Real Viruses*, N.Y. TIMES (Mar. 26, 2021), <https://www.nytimes.com/2020/10/13/health/coronavirus-vaccine-hesitancy-larson.html> [<https://perma.cc/UF2H-EGAF>]; see also HEIDI J. LARSON, STUCK: HOW VACCINE RUMORS START — AND WHY THEY DON’T GO AWAY (2020); BERNICE L. HAUSMAN, ANTI/VAX: REFRAMING THE VACCINATION CONTROVERSY (2019).

<sup>23</sup> See generally Brendan Nyhan et al., *Effective Messages in Vaccine Promotion: A Randomized Trial*, 133 PEDIATRICS e835 (2014); Jessica Nihlén Fahlquist, *Vaccine Hesitancy and Trust. Ethical Aspects of Risk Communication*, 46 SCANDINAVIAN J. PUB. HEALTH 182 (2018); Annabelle de St. Maurice & Kathryn Edwards, *Rethinking Flu Vaccine Messaging*, 146 PEDIATRICS e20201770 (2020); NAT’L ACADS. SCIS., ENG’G, & MED., THE CRITICAL PUBLIC HEALTH VALUE OF VACCINES: TACKLING ISSUES OF ACCESS AND HESITANCY: PROCEEDINGS OF A WORKSHOP (2021).

individuals experience when facing the prospect of receiving a vaccine.

### III. THE HISTORICAL ARC OF VACCINE HESITANCY

This Part traces the historical evolution of resistance to vaccination, focusing on how vaccine-questioning discourses evolved into organized movements.

#### A. *The Dawn of Anti-Vaccine Movements*

Anti-vaccine movements can be traced back to late eighteenth-century and early nineteenth-century Europe,<sup>24</sup> beginning as scattered opposition to the then-new practice of vaccination, voiced by a small number of actors for varying reasons.<sup>25</sup> At a time in which both the practice of medicine and the development of medical technologies were still underregulated, there was widespread distrust of the medical profession.<sup>26</sup> Some members of the clergy took issue with vaccines specifically because of the animal provenance of some of their content.<sup>27</sup> Parents feared subjecting

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<sup>24</sup> See *History of Anti-Vaccination Movements*, COLL. PHYSICIANS PHILA. (Jan. 10, 2018), <https://www.historyofvaccines.org/index.php/content/articles/history-anti-vaccination-movements> [<https://perma.cc/7U3L-58PB>]; *The Anti-Vaccination Movement*, AM. RED CROSS, <https://measlesrubellainitiative.org/anti-vaccination-movement/> [<https://perma.cc/Y5PD-FLF7>] (last visited Apr. 2, 2022); see also Dale L. Ross, *Leicester and the Anti-Vaccination Movement, 1853–1889*, 43 LEICESTERSHIRE ARCHAEOLOGICAL & HIST. SOC'Y 35, 35 (1967); Pierre Darmon, *The Beginning of Vaccinations Against Small-Pox in France (1800–1850)*, 185 BULL. ACAD. NAT'L MED. 767 (2001); José Luis Duro Torrijos & José Tuells, *Vaccine Hesitancy in Spain (1801)*, 94 REV. ESP. SALUD PUB. e1 (2020) (discussing the emergence of the earliest anti-vaccination movements in several European countries). See generally JONATHAN M. BERMAN, ANTI-VAXXERS: HOW TO CHALLENGE A MISINFORMED MOVEMENT (2020).

<sup>25</sup> See COLL. PHYSICIANS PHILA., *supra* note 24.

<sup>26</sup> *Id.*; see also Dorothy Porter & Roy Porter, *The Politics of Prevention: Anti-Vaccinationism and Public Health in Nineteenth-Century England*, 32 MED. HIST. 231, 236 (1988). See generally ROY PORTER, THE CAMBRIDGE HISTORY OF MEDICINE, (1st ed. 2006); Simar Singh Bajaj & Fatima Cody Stanford, *Beyond Tuskegee—Vaccine Distrust and Everyday Racism*, 384 NEW ENG. J. MED. e12(1) (2021).

<sup>27</sup> COLL. PHYSICIANS PHILA., *supra* note 24; see also Nadja Durbach, 'They Might As Well Brand Us': Working-Class Resistance to Compulsory Vaccination in Victorian England, 13 SOC. HIST. MED. 45, 47 (2000).

their children to a recently developed process<sup>28</sup> that was outwardly anything but reassuring (early forms of immunization against smallpox, for example, involved applying matter harvested from infected sores to incisions made on a person's arm).<sup>29</sup>

These scattered strands of criticism soon permeated popular debates. Consider the following cartoon published in 1802 by English caricaturist James Gillray, entitled *The Cow Pock*.



Figure 1: *The Cow Pock*, a cartoon published in 1802 by James Gillray.<sup>30</sup>

The cartoon appeared shortly after British physician Edward Jenner—often regarded as the founder of modern vaccine

<sup>28</sup> COLL. PHYSICIANS PHILA., *supra* note 24.

<sup>29</sup> See, e.g., Kendall A. Smith, *Edward Jenner and the Small Pox Vaccine*, 2 FRONTIERS IMMUNOLOGY (ARTICLE 21) 1, 2–3 (2011).

<sup>30</sup> James Gillray, *The Cow Pock or the Wonderful Effects of the New Inoculation* (illustration), in *Edward Jenner vaccinating patients in the Smallpox and Inoculation Hospital at St. Pancras: the patients develop features of cows. Coloured etching, 1803, after J. Gillray, 1802*, WELLCOME IMAGES, <https://wellcomecollection.org/works/jh8pftqz/images?id=h66cbv9g> [https://perma.cc/6RZD-CQUV] (last visited Jan. 26, 2022).

science<sup>31</sup>—published *On the Origin of Vaccine Inoculation*, one of the first scientific papers on vaccines.<sup>32</sup> In Gillray’s cartoon, Jenner is seen at the center of the image, administering a dose of the smallpox vaccine to an apprehensive patient. Around Jenner and the patient, other individuals (who are implied to have received the vaccine) have grown horns and cow-like shapes throughout their bodies.

This cartoon is but one of several surviving artifacts denoting how vaccine-specific discourses became popular outside scientific circles. This quick expansion of societal debates about vaccines would soon also be fueled by contestation of the first laws designed to promote the widespread adoption of vaccination.<sup>33</sup>

In the United Kingdom, the passage of the Vaccination Act of 1853 (“1853 Act”), which mandated the vaccination of newborns against smallpox, led to widespread opposition—even riots in several towns.<sup>34</sup> As part of a growing movement viewing compulsory vaccination as an unwarranted intrusion on individual liberties, several anti-vaccine leagues were created across the United Kingdom.<sup>35</sup> Opposition to compulsory vaccination also led to the publication of specialized literature. The journal *Anti-Vaccinator* was founded in 1869, followed by the *National Anti-Compulsory Vaccination Reporter* in 1874, as well as multiple other publications in the United Kingdom alone.<sup>36</sup> In addition to longer pieces of written work, anti-vaccine leagues also sponsored the distribution of pamphlets and other promotional materials conveying anti-vaccination messages. One of the images that became popular in the

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<sup>31</sup> Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 BAYLOR U. MED. CTR. PROC. 21, 25 (2005).

<sup>32</sup> Edward Jenner, *On the Origin of the Vaccine Inoculation*, 5 MED. PHYSICAL J. 505 (1801); see also Edward Jenner, *History of the Inoculation of the Cow-Pox: Further Observations on the Variolæ Vaccinæ, or Cow-Pox*, 4 MED. PHYSICAL J. 313 (1799); Stanley Plotkin, *History of Vaccination*, 111 PROC. NAT’L ACAD. SCI. U.S. 12283, 12283 (2014).

<sup>33</sup> See COLL. PHYSICIANS PHILA., *supra* note 24.

<sup>34</sup> See Robert M. Wolfe & Lisa K. Sharp, *Anti-Vaccinationists Past and Present*, 325 BMJ 430, 430–32 (2002).

<sup>35</sup> See Stanley Williamson, *Anti-Vaccination Leagues*, 59 ARCHIVES OF DISEASES IN CHILDHOOD, 1195, 1195–96 (1984).

<sup>36</sup> Wolfe & Sharp, *supra* note 34, at 431.

nineteenth century and was quickly adopted by many of the anti-vaccine leagues created in direct response to the 1853 Act was that of *Death, the Vaccinator*.<sup>37</sup> The image depicted a mother and child surrounded by a policeman (symbolizing the state) and a skeleton (symbolizing death) who administered the vaccine. The image, which appeared in anti-vaccine journals, was rapidly adapted to appear on envelopes, pamphlets, and other materials meant for mass-distribution.<sup>38</sup>



Figure 2: Death the Vaccinator, a cartoon published in the late 1800s.<sup>39</sup>

The image contains clear and deliberate references to a recently enacted law (the papers held by the policeman with the caption reading “Compulsory Vaccination Act”). Unlike *The Cow-Pock*,

<sup>37</sup> See Carley Roche, *Death, the Vaccinator*, HIST. VACCINES (Oct. 26, 2016), <https://www.historyofvaccines.org/Death-The-Vaccinator> [https://perma.cc/96MZ-GDQG].

<sup>38</sup> *Id.*

<sup>39</sup> *Death the Vaccinator* (illustration), in *Death the Vaccinator*, THE HIST. MED. LIBR. OF THE COLL. OF PHYSICIANS OF PHILA., <https://www.historyofvaccines.org/content/death-vaccinator> (last visited Jan. 26, 2022) [https://perma.cc/3UGX-AEJ3].

which fostered vaccine-questioning sentiments through humor, *Death, the Vaccinator* tied vaccine-questioning sentiments to a specific legal intervention being met with skepticism by some segments of the population. Early attempts to promote vaccination were thus hurriedly intertwined with countervailing efforts to undermine public health policies and the legal frameworks that supported them. These challenges to the first laws mandating vaccination also begat the filament of vaccine-questioning discourses that frame vaccination mandates as conflicting with individual freedoms<sup>40</sup>—discourses which have echoed throughout the COVID-19 pandemic.<sup>41</sup>

The adversarial reactions elicited by the popularization of vaccination techniques in the early nineteenth century soon expanded within and beyond Europe.<sup>42</sup> In the United States, during a New York sojourn in 1879, one of the most well-known British anti-vaccination figures, William Tebb, contributed to the formation of the Anti-Vaccination Society of America.<sup>43</sup> Tebb was one of the most active opponents of compulsory vaccination legislation passed in the United Kingdom; he would go on to co-found the London Society for the Abolition of Compulsory Vaccination in 1880.<sup>44</sup>

The roots of the anti-vaccine movement in the United States are also linked to the enactment of the first laws designed to promote vaccination. In 1809, Massachusetts passed the first law requiring

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<sup>40</sup> See, e.g., Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in *LAW IN PUBLIC HEALTH PRACTICE* 338 (Richard A. Goodman et al. eds., 2d ed. 2007); see also *infra* Part IV (discussing *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)).

<sup>41</sup> See, e.g., Tara C. Smith & Dorit Rubinstein Reiss, *Digging the Rabbit Hole, COVID-19 Edition: Anti-Vaccine Themes and the Discourse Around COVID-19*, 22 *MICROBES & INFECTION* 608, 608 (2020); Mark Landler, *Vaccine Mandates Rekindle Fierce Debate Over Civil Liberties*, *N.Y. TIMES* (Dec. 10, 2021), <https://www.nytimes.com/2021/12/10/world/europe/vaccine-mandates-civil-liberties.html> [<https://perma.cc/Q3H3-75RH>]; Lawrence O. Gostin, *COVID-19 Vaccine Mandates—A Wider Freedom*, 2 *JAMA HEALTH F.* 1, 1 (2021), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785024> [<https://perma.cc/D9A3-XM73>].

<sup>42</sup> See Wolfe & Sharp, *supra* note 34, at 431.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

mandatory vaccination, in this case, against smallpox.<sup>45</sup> The first federal law designed to bolster vaccination efforts appeared in 1813 when Congress passed An Act to Encourage Vaccination, which created a federal agent charged with monitoring and coordinating functions in the distribution of the American vaccine supply.<sup>46</sup> The Act also enabled vaccines to be shipped free of charge through the U.S. Postal Service.<sup>47</sup> Although repealed in 1822, the Act marked the beginning of the process that would embed a pro-vaccine approach into America's laws and policies related to public health, consumer protection, and pharmaceuticals.<sup>48</sup> This legal action mirrored the growing acceptance of vaccination across the country.<sup>49</sup>

However, the increasing acceptance of vaccines as credible medical technologies and as public health instruments was challenged by the appearance and consolidation of pockets of resistance to vaccination. In his account of the history of the anti-vaccine movement in the United States, historian Martin Kaufman characterized the early stages of the movement as the byproduct of the actions of a limited number of individuals holding anti-vaccine views who were highly motivated to propagate their message: “[I]one wolves, doing their best to convince others of the danger of vaccination.”<sup>50</sup> These individuals became increasingly more active in the 1850s and 1860s.<sup>51</sup>

The reemergence of smallpox in the 1870s prompted several states to consider—and, in some cases, enforce—vaccination mandates, which had the same catalytic effect that similar legislation elicited in the United Kingdom. Shortly after the Anti-Vaccination Society of America was formed in the wake of William Tebb's visit, several others were founded in multiple states.<sup>52</sup> These societies

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<sup>45</sup> See Philip J. Smith et al., *Highlights of Historical Events Leading to National Surveillance of Vaccination Coverage in the United States*, 126 PUB. HEALTH REPS. 3, 4 (2011).

<sup>46</sup> An Act to Encourage Vaccination, ch. 37, 2 Stat. 806 (1813) (repealed 1822).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> Martin Kaufman, *The American Anti-Vaccinationists and Their Arguments*, 41 BULL. HIST. MED. 463, 463 (1967).

<sup>50</sup> *Id.* at 464.

<sup>51</sup> *Id.*

<sup>52</sup> Wolfe & Sharp, *supra* note 34, at 431.

were instrumental in popularizing anti-vaccine messages and in pressuring states to abandon compulsory vaccination policies, through both legal challenges and activism—which at least on two separate occasions degenerated into riots (Milwaukee, Wisconsin in 1884 and Montreal, Canada in 1885), again, much like what happened in the United Kingdom.<sup>53</sup> Eventually, a considerable number of states—California, Illinois, Indiana, Minnesota, Utah, West Virginia, and Wisconsin—repealed legislation imposing compulsory vaccination.<sup>54</sup> While the legality of state-enacted vaccination mandates would not be settled until the early twentieth century,<sup>55</sup> the roots of the anti-vaccine movement were firmly planted.<sup>56</sup>

### *B. Vaccine Hesitancy in the Era of Social Media*

While anti-vaccine sentiments never completely died down,<sup>57</sup> there were periods in the history of medicine and public health in which the collective sentiment towards vaccines and vaccination in the United States was, on balance, largely positive<sup>58</sup>—even though it is worth remembering that the development of vaccines during some of these periods was far less regulated than today and riddled with ethical violations.<sup>59</sup> The most emblematic example of an age of heightened collective enthusiasm surrounding vaccines is perhaps

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<sup>53</sup> *Id.*

<sup>54</sup> Kaufman, *supra* note 49, at 464.

<sup>55</sup> See HAUSMAN, *supra* note 22 and accompanying text.

<sup>56</sup> Kaufman, *supra* note 49, at 478.

<sup>57</sup> See, e.g., HAUSMAN, *supra* note 22.

<sup>58</sup> See *infra* note 61 and accompanying text; see also Alan R. Hinman, *Mass Vaccination Against Polio*, 251 JAMA 2994, 2994 (1984); DAVID M. OSHINSKY, *POLIO: AN AMERICAN STORY* (2006); Emma Goldberg, *Vaccine Memories of Another Time and Place*, N.Y. TIMES (Oct. 28, 2021), <https://www.nytimes.com/2020/12/25/health/covid-vaccine-polio.html> [<https://perma.cc/CSP2-W4PR>].

<sup>59</sup> See Ana Santos Rutschman, *Vaccine Clinical Trials and Data Infrastructure*, 2021 UTAH L. REV. 771, 779–84 (2021) [hereinafter Rutschman, *Vaccine Clinical Trials*]; see also Stephen Goldby, *Experiments at the Willowbrook State School*, 297 LANCET 749 (1971); Leah Rosenbaum, *The Hideous Truths of Testing Vaccines on Humans*, FORBES, <https://www.forbes.com/sites/leahrosenbaum/2020/06/12/willowbrook-scandal-hepatitis-experiments-hideous-truths-of-testing-vaccines-on-humans/?sh=4a6a344d279c> [<https://perma.cc/W3DR-XWUD>].

that of the rollout of the first polio vaccines in the 1950s in the United States.<sup>60</sup> As medical historian David Oshinsky noted:

If you had to pick a moment as the high point of respect for scientific discovery, it would have been then . . . . After World War II, you had antibiotics rolling off the production line for the first time. People believed infectious disease was [being] conquered. And then this amazing vaccine is announced. People couldn't get it fast enough.<sup>61</sup>

For decades, the number of vaccines recommended by public health authorities (or mandated for large numbers of individuals, such as pediatric populations) has steadily increased.<sup>62</sup> As a result, the prevalence of several vaccine-preventable diseases, such as mumps or tetanus, declined.<sup>63</sup> In some cases, diseases were eradicated, as was the case with polio and measles in the United States, as well as smallpox worldwide.<sup>64</sup>

Most recently, growing sentiments of hesitancy towards vaccination have caused some of these vaccine-preventable diseases to resurface and cause significant outbreaks.<sup>65</sup> The COVID-19 pandemic epitomized this change in collective vaccine sentiments,

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<sup>60</sup> See generally OSHINSKY, *supra* note 58.

<sup>61</sup> See Susan Brink, *Can't Help Falling in Love with A Vaccine: How Polio Campaign Beat Vaccine Hesitancy*, NPR (May 3, 2021, 9:00 AM), <https://www.npr.org/sections/health-shots/2021/05/03/988756973/cant-help-falling-in-love-with-a-vaccine-how-polio-campaign-beat-vaccine-hesitant> [<https://perma.cc/9NDJ-XNMB>].

<sup>62</sup> See, e.g., *Routine Vaccines*, CDC (2019), <https://wwwnc.cdc.gov/travel/page/routine-vaccines> [<https://perma.cc/8TYQ-C353>] (listing currently recommended vaccines in the United States).

<sup>63</sup> See Sandra W. Roush & Trudy V. Murphy, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2155 (2007) (describing a decline greater than ninety percent for diphtheria, mumps, pertussis and tetanus after vaccines against these diseases were developed in the United States).

<sup>64</sup> *Id.*; see also *History of Smallpox*, CDC (2021) <https://www.cdc.gov/smallpox/history/history.html> [<https://perma.cc/638K-DH3F>] (describing the eradication of smallpox in 1979).

<sup>65</sup> See Broniatowski, *supra* note 3, at S316–18; see also Peter Hotez, *America and Europe's New Normal: The Return of Vaccine-Preventable Diseases*, 85 PEDIATRIC RES. 912, 912–13 (2019); Alexandre de Figueiredo et al., *Mapping Global Trends in Vaccine Confidence and Investigating Barriers to Vaccine Uptake: A Large-Scale Retrospective Temporal Modelling Study*, 396 LANCET 898, 904–07 (2021).

particularly (although not exclusively)<sup>66</sup> in the United States, where the pendulum swung between individuals highly eager to be vaccinated as soon as possible and those who elected not to receive a single dose, albeit indicated for the vaccine.<sup>67</sup>

The behaviors of members of the latter group fall under most commonly used definitions of “vaccine hesitancy.”<sup>68</sup> The reasons invoked by vaccine-hesitant individuals for foregoing vaccination are highly heterogenous and remain understudied.<sup>69</sup> Moreover, they vary from vaccine to vaccine. For instance, hesitancy towards COVID-19 vaccines was colored by perceptions of how quickly these vaccines were developed,<sup>70</sup> as well as by the enmeshing of vaccine-related topics into high-profile political debates and controversies, including the reverberations of the 2016 presidential election in the United States.<sup>71</sup>

At their core, though, the reasons that lead individuals or communities to mistrust vaccines in the twenty-first century are not fundamentally different from those that motivated the first anti-vaccination movements. These reasons include, what public health researchers Cindy Shen and Vinita Dubey have labeled a “lack of confidence” in multiple features and actors in the vaccine ecosystem: the safety and effectiveness of a vaccine in itself; the “system” utilized to bring vaccines to market and promote

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<sup>66</sup> See, e.g., Amiel A. Dror et al., *Vaccine Hesitancy: The Next Challenge in the Fight Against COVID-19*, 35 EUR. J. EPIDEMIOL. 775, 776–79 (2020); Alfonso J. Rodriguez-Morales & Oscar H. Franco, *Public Trust, Misinformation and COVID-19 Vaccination Willingness in Latin America and the Caribbean: Today’s Key Challenges*, 3 LANCET REG. HEALTH AM. 1, 1–2 (2021).

<sup>67</sup> See Machingaidze & Wiysonge, *supra* note 6, at 1338.

<sup>68</sup> See Dubé, *supra* note 1, at 1763–64.

<sup>69</sup> See Rutschman & Wiemken, *supra* note 20, at 243; Shixin (Cindy) Shen & Vinita Dubey, *Addressing Vaccine Hesitancy: Clinical Guidance for Primary Care Physicians Working with Parents*, 65 CAN. FAM. PHYSICIAN 175, 176 (2019); Julio S. Solís Arce et al., *COVID-19 Vaccine Acceptance and Hesitancy in Low- and Middle-Income Countries*, 27 NATURE MED. 1385, 1386–88 (2021).

<sup>70</sup> Machingaidze & Wiysonge, *supra* note 6, at 1338–39.

<sup>71</sup> See, e.g., Sharfstein, *supra* note 7, at 1211; Smith & Reiss, *supra* note 41, at 609; Jennifer Kates et al., *The Red/Blue Divide in COVID-19 Vaccination Rates*, KAISER FAM. FOUND. (Sept. 14, 2021), <https://www.kff.org/policy-watch/the-red-blue-divide-in-covid-19-vaccination-rates/> [<https://perma.cc/UBD2-URQ7>].

vaccination uptake; and, policymakers.<sup>72</sup> Additional reasons invoked by vaccine-hesitant individuals—not related to trust in vaccines per se, or in the way vaccines come to market—include a “perceived low risk” of contracting a vaccine-preventable disease, as well as the “lack of convenience” associated with getting a specific vaccine or dealing with the aftermath of vaccination.<sup>73</sup>

Twenty-first century hesitancy, attributable to factors linked to a “lack of confidence” in vaccines, echoes the embryonic reasons for vaccine hesitancy that formed in the nineteenth century.<sup>74</sup> As discussed above, the earliest sentiments of mistrust regarding vaccines were largely due to concerns about an emerging form of technology; a desire to protect children from potential harm; apprehensions surrounding the practice of medicine in general; and, as the first laws designed to promote vaccination were introduced, the pitting of these public health-driven laws against arguments anchored on individual rights and civil liberties.<sup>75</sup> Although the precise formulation of each one of these concerns has changed over time, they retain their essence. These general, twenty-first century sentiments mirror those surrounding the COVID-19 vaccines—for instance, the questions surrounding the use of a newly developed form of vaccine technology, mRNA vaccines, during the COVID-19 pandemic;<sup>76</sup> the concern that many parents experienced in having those or other types of vaccines administered to their children;<sup>77</sup> the legacy of the profoundly checkered history of medical research that causes many individuals or communities to place lower levels of

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<sup>72</sup> Shen & Dubey, *supra* note 69, at 176.

<sup>73</sup> *Id.* (categorizing these reasons under the brackets of “complacency” and “lack of convenience,” as opposed to being related to “lack of confidence”).

<sup>74</sup> See *supra* notes 25–29 and accompanying text.

<sup>75</sup> *Id.*

<sup>76</sup> See, e.g., Elissa R. Weitzman et al., *SARS-CoV-2 mRNA Vaccine Attitudes as Expressed in U.S. FDA Public Commentary: Need for a Public-Private Partnership in a Learning Immunization System*, 9 FRONTIERS PUB. HEALTH 1, 2 (July 2021), <https://www.frontiersin.org/articles/10.3389/fpubh.2021.695807/full> [<https://perma.cc/L9F6-TVA6>].

<sup>77</sup> See, e.g., Nina L. Alfieri et al., *Parental COVID-19 Vaccine Hesitancy for Children: Vulnerability in an Urban Hotspot*, 21 BMC PUB. HEALTH 1, 4 (2021); Melissa Suran, *Why Parents Still Hesitate to Vaccinate Their Children Against COVID-19*, 327 J. AM. MED. ASS’N 23, 23–25 (2021).

trust in science and medicine;<sup>78</sup> and, the ongoing fierce debate about vaccination mandates and other policies.<sup>79</sup>

While there has been both continuity and evolution of the reasons behind vaccine hesitancy, early twenty-first century vaccine hesitancy is nonetheless being fueled in significantly different ways from before. An especially complicated piece of the puzzle of contemporary hesitancy derives from the widespread use of online channels as super-propagators of anti-vaccine messages.<sup>80</sup> Even though anti-vaccination movements have had a powerful impact on the history of vaccines, these movements have always represented the views of a relatively limited number of individuals.<sup>81</sup> Today, these minority views—and the inaccurate messages they often convey—travel exponentially faster and reach far more targets than ever.<sup>82</sup> This effect, in turn, poses new challenges for the law and for policymakers seeking to promote trust in vaccines, vaccination uptake, or both.

Increased usage of online fora, especially of social media, has long been documented as contributing to the increasingly unfettered

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<sup>78</sup> See generally Brian Dolan & George Rutherford, *How History of Medicine Helps Us Understand COVID-19 Challenges*, 135 PUB. HEALTH REP. 717 (2020); HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* (2006); Ruqaiyah Yearby, *Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study*, 67 CASE W. RES. L. REV. 1171 (2017); Rutschman, *Vaccine Clinical Trials*, *supra* note 59, at 779–84.

<sup>79</sup> See, e.g., Mark C. Navin & Katie Attwell, *Vaccine Mandates, Value Pluralism, and Policy Diversity*, 33 BIOETHICS 1042, 1043–44 (2019); Christopher Buccafusco & Daniel J. Hemel, *Framing Vaccine Mandates: Messenger and Message Effects 1–2* (Univ. Chi., Working Paper No. 793) (available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3964812](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3964812) [<https://perma.cc/PR63-57RU>]); *Na'l Fed'n Indep. Bus., et al. v. Dep't Labor, Occupational Safety and Health Admin.*, 142 S. Ct. 661, 664–67 (2022).

<sup>80</sup> See, e.g., Anna Kata, *Anti-Vaccine Activists, Web 2.0, and the Postmodern Paradigm--An Overview of Tactics and Tropes Used Online by the Anti-Vaccination Movement*, 30 VACCINE 3778, 3779 (2012).

<sup>81</sup> See HAUSMAN, *supra* note 22, at 16; Federico Germani & Nikola Biller-Andorno, *The Anti-Vaccination Infodemic on Social Media: A Behavioral Analysis*, 16 PLOS ONE 1, 2 (2021); Neil F. Johnson et al., *The Online Competition Between Pro- and Anti-Vaccination Views*, 582 NATURE 230, 231 (2020).

<sup>82</sup> See, e.g., Anna Kata, *A Postmodern Pandora's Box: Anti-Vaccination Misinformation on the Internet*, 28 VACCINE 1709, 1713 (2010).

proliferation of inaccurate information.<sup>83</sup> In this context, researchers and commentators often use the term “misinformation” to denote information that is false or misleading,<sup>84</sup> while the term “disinformation” refers to cases in which there is an *intentional* spread of false or misleading information.<sup>85</sup>

Both phenomena pre-date the digital age.<sup>86</sup> Yet, digital technologies have rendered the adoption of misinformation and disinformation strategies so pervasive that some commentators now speak of a “misinformation age,” ushered in by the widespread use of social media and other online platforms able to reach both popular and niche audiences in nearly instantaneous ways.<sup>87</sup>

Health- and vaccine-specific misinformation and disinformation are also not new. For instance, researchers now frame the messages promoted by the anti-vaccination leagues of the nineteenth century as misinformation.<sup>88</sup> And while available online, the now-retracted paper that ignited the debate about an alleged (albeit non-existent)

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<sup>83</sup> See, e.g., Michela Del Vicario et al., *The Spreading of Misinformation Online*, 113 PROC. NAT'L ACAD. SCI. 554, 554–58 (2016).

<sup>84</sup> See, e.g., Gordon Pennycook et al., *Shifting Attention to Accuracy Can Reduce Misinformation Online*, 592 NATURE 590, 590 (2021).

<sup>85</sup> See Don Fallis, *The Varieties of Disinformation*, in THE PHILOSOPHY OF INFORMATION QUALITY, at 358 (Luciano Floridi & Phyllis Illari eds., 2014) (defining disinformation as “intentionally misleading information”).

<sup>86</sup> See generally Julie Posetti & Alice Matthews, *A Short Guide to the History of 'Fake News' and Disinformation*, INT'L CTR. JOURNALISTS (2018), [https://www.icfj.org/sites/default/files/2018-07/A%20Short%20Guide%20to%20History%20of%20Fake%20News%20and%20Disinformation\\_ICFJ%20Final.pdf](https://www.icfj.org/sites/default/files/2018-07/A%20Short%20Guide%20to%20History%20of%20Fake%20News%20and%20Disinformation_ICFJ%20Final.pdf) [<https://perma.cc/VZ78-7WRE>]; MICHAEL GRANT, GREEK AND ROMAN HISTORIANS: INFORMATION AND MISINFORMATION (1995); CAILIN O'CONNOR & JAMES OWEN WEATHERALL, THE MISINFORMATION AGE: HOW FALSE BELIEFS SPREAD 1–3 (2019).

<sup>87</sup> O'CONNOR & WEATHERALL, *supra* note 86.

<sup>88</sup> Elizabeth Dohms-Harter, *History Shows Anti-Vaccination, Misinformation Campaigns Are Nothing New*, WISC. PUB. RADIO (Mar. 30, 2021), <https://www.wpr.org/history-shows-anti-vaccination-misinformation-campaigns-are-nothing-new> [<https://perma.cc/XG4W-G2PG>].

link between the administration of vaccines and autism pre-dated the age of social media proper.<sup>89</sup>

Vaccine misinformation and disinformation have nonetheless grown exponentially since the popularization of social media use, particularly throughout the 2010s.<sup>90</sup> To be sure, social media have also played an important role in the circulation and amplification of *accurate* information about vaccines, providing experts and public health authorities with new avenues to communicate with the public at large.<sup>91</sup> At the same time, these platforms have become hubs for disseminating vaccine-specific misinformation and one of the primary grounds for the organization and operation of groups spreading vaccine disinformation.<sup>92</sup>

The use of social media by prominent anti-vaccination individuals and organized movements, as a means to promote vaccine misinformation and disinformation has increased at a worrisome pace in recent years. Studies show that part of this increase is attributable to the use of automated programs designed to spread anti-vaccine content.<sup>93</sup> For instance, research by Professor David Broniatowski and colleagues on vaccine disinformation on Twitter revealed that, in addition to human-operated programs, two different types of automated programs—which they distinguished

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<sup>89</sup> See Fiona Godlee & Jane Smith, *Wakefield's Article Linking MMR Vaccine and Autism Was Fraudulent*, 342 BRIT. MED. J. 64, 64–66 (2011) (describing the fraudulent Wakefield study implying a nexus between the administration of the MMR vaccine (against measles, mumps and rubella) and the development of autism in children).

<sup>90</sup> See, e.g., CTR. COUNTER DIGIT. HATE, *The Anti-Vaxx Industry: How Big Tech Powers and Profits from Vaccine Misinformation* (2020), [https://252f2edd-1c8b-49f5-9bb2-cb57bb47e4ba.filesusr.com/ugd/f4d9b9\\_6910f8ab94a241cfa088953dd5e60968.pdf](https://252f2edd-1c8b-49f5-9bb2-cb57bb47e4ba.filesusr.com/ugd/f4d9b9_6910f8ab94a241cfa088953dd5e60968.pdf) [<https://perma.cc/H6WX-EQVD>].

<sup>91</sup> See Mark Dredze et al., *Understanding Vaccine Refusal: Why We Need Social Media Now*, 50 AM. J. PREV. MED. 550, 551 (2016).

<sup>92</sup> See Kata, *supra* note 80, at 3779; Steven Lloyd Wilson & Charles Wiysonge, *Social Media and Vaccine Hesitancy*, 5 BRIT. MED. J. GLOBAL HEALTH 1, 2 (2020); David A. Broniatowski et al., *Weaponized Health Communication: Twitter Bots and Russian Trolls Amplify the Vaccine Debate*, 108 AM. J. PUB. HEALTH 1378, 1378–79 (2018).

<sup>93</sup> Broniatowski et al., *supra* note 92, at 1378.

as “content pollutants”<sup>94</sup> versus “bots”<sup>95</sup>—were releasing content about vaccines at higher rates than accounts operated by humans.<sup>96</sup> Malicious programs labeled as “content polluters” propagated vaccine misinformation or disinformation at rates that were seventy-five percent higher than those programs associated with non-automated accounts.<sup>97</sup>

Other studies have shown that, although the majority of social media users hold favorable views towards vaccination, anti-vaccination groups are more connected, more efficient, and more successful in spreading their vaccine-related messages than groups holding pro-vaccine views.<sup>98</sup> For instance, in their study of vaccine misinformation and disinformation on Facebook, Neil Johnson and colleagues found that anti-vaccination groups had become “robust and resilient” and were much better than public health authorities at operating Facebook to reach users with undecided views on vaccination.<sup>99</sup>

Moreover, anti-vaccination actors on social media routinely succeed in using automated programs to simulate “buy-in” regarding anti-vaccine discussions, giving users a false sense that anti-vaccine threads are going viral or otherwise becoming popular.<sup>100</sup> One of these techniques is known as “flooding the discourse,” which reflects the practice of saturating a given social media platform with multiple entries on one topic (e.g., the safety—or lack thereof—of a vaccine) in order to bolster statistics and become more noticeable in searches and social media traffic.<sup>101</sup> Additionally, automated programs have been deployed to mislead

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<sup>94</sup> Content polluters were described as “malicious accounts identified as promoting commercial content and malware.” *Id.* at 1382.

<sup>95</sup> Bots were described as “accounts that automate content promotion.” *Id.* at 1387.

<sup>96</sup> *Id.* at 1378, 1382.

<sup>97</sup> *Id.* at 1382.

<sup>98</sup> See Johnson, *supra* note 81, at 230–31.

<sup>99</sup> *Id.*

<sup>100</sup> Broniatowski et al., *supra* note 92, at 1380.

<sup>101</sup> *Id.*

social media users as to the provenance of anti-vaccination content, feigning grassroots support for anti-vaccination views.<sup>102</sup>

A noteworthy development in the recent history of organized movements promoting vaccine disinformation is the emergence of a set of communication strategies described by Broniatowski and colleagues as the “weaponization” of vaccine-related communication.<sup>103</sup> This weaponization has occurred via the use of automated programs on popular social media by actors linked to Russia and other post-Soviet countries to spread vaccine disinformation in Western countries—especially to the United States.<sup>104</sup> In some cases, these programs were used to share both anti- and pro-vaccine content, in a bid to increase societal divisiveness and discord.<sup>105</sup>

Collectively, recent studies suggest an acceleration and expansion of the circulation of inaccurate content about vaccines, with a significant portion of this content being deliberately promoted for instrumental purposes. One of the consequences of this pervasiveness is that online misinformation and disinformation about vaccines is now recognized as one of the major contributors to increasing rates of vaccine hesitancy.<sup>106</sup>

Against this backdrop, questions of how law and policy should be used to curb vaccine hesitancy and promote vaccine trust are, once again, at the forefront of both legal and popular debates. Accordingly, Part IV considers existing legal and policy interventions that could be devised to accomplish these goals.

Nevertheless, in addition to asking what law has done, or should do, to address the renewed challenges posed by vaccine hesitancy, it is equally important to understand what law and policymakers have *not* done so far. One example is the crucial role played by, and

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<sup>102</sup> *Id.* at 1382. This practice is known as “astroturfing.” See generally Derek Weber & Frank Neumann, *Amplifying Influence Through Coordinated Behavior in Social Networks, Now*, 11 SOC’Y NETW. ANALYSIS & MINING 1 (2021).

<sup>103</sup> Broniatowski et al., *supra* note 92, at 1379.

<sup>104</sup> *Id.* at 1382.

<sup>105</sup> *Id.* On the topic of divisiveness within the United States, see, for example, Erwin Chemerinsky, *The Non-United States of America*, 21 J. APP. PRAC. & PROCESS 259, 259–76 (2021).

<sup>106</sup> See Wilson & Wiysonge, *supra* note 9292, at 6.

the instrumentality of, social media in contemporary modes of propagation of vaccine disinformation. The proliferation of vaccine disinformation across social media is partly rooted in a legal vacuum.<sup>107</sup> Content moderation on social media occurs primarily through self-regulatory modes, with each platform adopting its own policies, if any, on vaccine misinformation and disinformation.<sup>108</sup> Thus, left to determine and apply their own content moderation policies, social media platforms have been largely permissive of inaccurate content about vaccines;<sup>109</sup> have failed to remove content qualifying as vaccine misinformation, even when required by their own policies;<sup>110</sup> have enabled the monetization of content qualifying as vaccine misinformation;<sup>111</sup> and, have allowed for the migration of misinformation and disinformation from the more-regulated to the lesser-regulated platforms.<sup>112</sup>

Ultimately, the limitations of current approaches to deal with online vaccine misinformation and disinformation have detrimental consequences from a public health perspective.<sup>113</sup> Yet, the heart of this problem can scarcely be framed as one of classic health law and policy, with discussions on social media regulation occupying primarily constitutionalists, technologists, and experts in related fields.<sup>114</sup> This suggests that a holistic approach to the problem of vaccine hesitancy must, from now on, draw from a constellation of legal and policy regimes.

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<sup>107</sup> Ana Santos Rutschman, *Social Media Self-Regulation and the Rise of Vaccine Misinformation*, 4 J.L. & INNOVATION 25, 46 (2022) [hereinafter Rutschman, *Social Media*].

<sup>108</sup> *Id.* at 43–59; see also Dawn Carla Nunziato, *Misinformation Mayhem: Social Media Platforms' Efforts to Combat Medical and Political Misinformation*, 19 FIRST AMEND. L. REV. 32, 35–36 (2020) (noting that the content moderation approaches employed by social media are consistent with the (limited) reach of the First Amendment regarding private actors).

<sup>109</sup> Rutschman, *Social Media*, *supra* note 107, at 47–51.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*; see generally *The Anti-Vaxx Industry*, *supra* note 90, at 33.

<sup>112</sup> Rutschman, *Social Media*, *supra* note 107, at 47–59.

<sup>113</sup> See Weber & Neumann, *supra* note 106, at 111.

<sup>114</sup> See, e.g., Kate Klonick, *The New Governors: The People, Rules, and Processes Governing Online Speech*, 131 HARV. L. REV. 1598, 1668 (2017); Mark A. Lemley, *The Contradictions of Platform Regulation*, 1 J. FREE SPEECH L. 303, 325–26 (2021).

#### IV. LEGAL AND POLICY INTERVENTIONS ADDRESSING VACCINE HESITANCY

As discussed below, most interventions adopted so far to promote vaccination have primarily been lifted from the playbook of traditional public health law. Part A illustrates this phenomenon by surveying “top-down” approaches in the form of laws and regulations designed to increase vaccination levels, while Part B focuses on approaches aimed at increasing the informational flow in the vaccination ecosystem. Even though these interventions were instrumental in promoting widespread vaccination from the early nineteenth century onwards, they face renewed pressures with the rise in vaccine hesitancy in the early decades of the twenty-first century. Part C thus turns to emerging approaches to nudge individuals and communities to receive a vaccine they are indicated for, particularly during a large-scale public health crisis.

##### *A. Top-Down Approaches: Laws and Regulations Promoting Vaccination*

In some cases, the law has been used in ways that impose the adoption of a specific behavior—such as receiving one or multiple doses of a vaccine. These laws, as outlined below, often carry penalties for failing to comply with their requirements. However, laws mandating vaccination of indicated individuals do not address hesitancy problems directly, seeking instead to promote vaccination uptake and, indirectly, reduce the number of vaccine-hesitant individuals.<sup>115</sup>

After Edward Jenner popularized the first modern vaccine, the United Kingdom enacted its first comprehensive law designed to promote vaccination on a large scale, the Vaccination Act of 1840, which provided free vaccination to the poor.<sup>116</sup> This Act was followed by a string of legislation expanding the scope of mandatory vaccination over the coming decades. The Vaccination Act of 1853 mandated the vaccination of newborns against smallpox within the

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<sup>115</sup> See Malone & Hinman, *supra* note 40, at 3.

<sup>116</sup> See DEBORAH BRUNTON, *THE POLITICS OF VACCINATION: PRACTICE AND POLICY IN ENGLAND, WALES, IRELAND AND SCOTLAND, 1800–74* (2008); see also *supra* Part III.A.

first three months of life, subjecting parents who did not have their infants vaccinated to fines and potential imprisonment, while the Act of 1867 extended compulsory vaccination frameworks to children aged fourteen.<sup>117</sup>

In the United States, it has long been settled law that the states—not the federal government—have the authority to impose vaccination mandates for public health reasons. The Supreme Court first spoke on this issue in 1905 in *Jacobson v. Massachusetts*.<sup>118</sup> The case concerned a Massachusetts law authorizing the board of health of a city or town to mandate vaccinations for public health or safety reasons, and establishing that, in such cases, vaccinations should be provided by the city or town for free.<sup>119</sup> Moreover, the state law established that adults who did not comply with the mandate incurred a penalty of five dollars, approximately the equivalent of one-hundred dollars today, adjusted for inflation.<sup>120</sup>

The City of Cambridge relied on this legal framework to enact a regulation during a smallpox outbreak in 1902, imposing the vaccination or revaccination of the City's inhabitants.<sup>121</sup> Henning Jacobson, an adult who did not fall into any of the exceptions enumerated in the City's mandatory law, refused to comply with the board of health's regulation.<sup>122</sup> Jacobson argued that the regulations unduly curtailed his liberty by subjecting him to the payment of a fine for having refused vaccination.<sup>123</sup> He also argued that a law mandating vaccination was in itself unreasonable and arbitrary, depriving individuals of their freedom.<sup>124</sup>

In addressing the question of restrictions imposed by states on individuals, the Supreme Court started broadly by noting that “the

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<sup>117</sup> BRUNTON, *supra* note 116, at 1800–74.

<sup>118</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 25–26 (1905).

<sup>119</sup> The Revised Laws of the Commonwealth of Massachusetts, ch. 75 § 137. The law also created an exception for “children who present a certificate, signed by a registered physician that they are unfit subjects for vaccination.” *Id.* § 139.

<sup>120</sup> Wendy K. Mariner et al., *Jacobson v Massachusetts: It's Not Your Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581, 582 (2005).

<sup>121</sup> *Jacobson*, 197 U.S. at 12.

<sup>122</sup> *Id.* at 13.

<sup>123</sup> *Id.* at 26.

<sup>124</sup> *Id.*

liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.”<sup>125</sup> The Court went on to note that an absolute view of individual rights and freedoms, or “[r]eal liberty for all,” would undermine life in an organized society.<sup>126</sup> The Court then reiterated the principle long upheld in Supreme Court jurisprudence that “persons and property are subjected to all kinds of restraints and burdens, in order to secure the general comfort, health, and prosperity of the State.”<sup>127</sup>

Even though *Jacobson* was decided in a very different context from the one we experience today<sup>128</sup> the principle that states can lawfully use their police powers to impose vaccination mandates to meet public health needs has remained good law ever since.<sup>129</sup> Having the decision of imposing vaccination to be made at the state or local levels allows, in principle, for states to work closely with their constituents, recognize and address the concerns of local communities, and cater to the idiosyncrasies in vaccine hesitancy that may not be captured by a unified mandate established at the federal level. Legal scholar Wendy Parmet has framed this relationship between the states and their citizens as one that develops in a more dialectic way than a federal mandate would, which, in turn, might help the case for state-based mandates:

This democratic process, which can occur more organically in the states, helps debunk anti-vaccination misinformation and educates the public about the value and safety of vaccines, as well as the utility of strong

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<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.* The caselaw on which the Supreme Court relied to articulate this principle included *Crowley v. Christensen*, 137 U.S. 86, 90–91 (1890) (examining state-based regulation of alcohol sales); *Railroad Co. v. Husen*, 95 U.S. 465, 469–70 (1877); and, *Missouri, Kansas & Texas Ry. Co. v. Haber*, 169 U.S. 613, 618–19 (1898) (collectively examining states’ ability to internally police regulations in the context of transportation restrictions).

<sup>128</sup> Mariner, *supra* note 120, at 581.

<sup>129</sup> *See Zucht v. King*, 260 U.S. 174, 176 (1922).

state mandates. This process can also provide mandates with the political support and democratic legitimacy they need to succeed.<sup>130</sup>

Yet, as coercive mechanisms, vaccination mandates are not without limitations and may, in some cases, fuel vaccine hesitancy.<sup>131</sup> In her study of the 2009 H1N1 pandemic (also known as the swine flu pandemic), Parmet argued that:

[B]y placing virtually all of the risks associated with vaccines on taxpayers and individuals who are vaccinated without providing for sufficient review or oversight of claims by independent decision makers, these pandemic vaccine laws may provide support for pre-existing populist distrust of government and erode the public's trust in vaccine safety. As a result, laws that are designed to facilitate the rapid, widespread distribution of vaccines may undermine the public's willingness to be vaccinated.<sup>132</sup>

It is worth noting that not all top-down approaches to imposing or promoting vaccination come from the states, nor do all coercive mechanisms take the form of a mandate. One example is the emergency temporary standard enacted by the Occupational Safety and Health Administration (“OSHA”) in late 2021.<sup>133</sup> The standard, which was enacted with the explicit goal of “protect[ing] unvaccinated employees of large employers” against COVID-19, gave employers a choice between implementing either a mandatory vaccination policy or a policy that would give employees the choice between producing valid proof of vaccination for COVID-19 or

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<sup>130</sup> Wendy E. Parmet, *Gottlieb's Threat of Federal Vaccine Mandates: Questionable Legality, Poor Policy*, STAT (Feb. 28, 2019), <https://www.statnews.com/2019/02/28/gottlieb-federal-action-vaccine-mandates/> [<https://perma.cc/9H55-YUJ2>].

<sup>131</sup> See, e.g., 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, 131–32 (2010).

<sup>132</sup> Wendy E. Parmet, Abstract, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, SSRN (Mar. 1, 2011), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1793203](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1793203) [<https://perma.cc/XV6P-EHR4>].

<sup>133</sup> *US Department of Labor Issues Emergency Temporary Standard to Protect Workers from Coronavirus*, U.S. DEP'T LAB. (Nov. 4, 2021), <https://www.osha.gov/news/newsreleases/national/11042021> [<https://perma.cc/YZ9R-VTVQ>].

being tested on a regular basis.<sup>134</sup> In this case, the legal mechanism used to promote vaccination was imposed by a federal agency seeking to exercise emergency powers; the resulting standard applied to a subset of the population indicated for vaccination against a pathogen causing a severe public health crisis (as enacted, the standard targeted employers of businesses with more than ninety-nine workers);<sup>135</sup> and it made vaccination an option among other possible behaviors, all of which were aimed at reducing the spread of COVID-19.

The standard was stayed almost immediately by the Court of Appeals for the Fifth Circuit<sup>136</sup> and faced challenges in several other jurisdictions. Litigation was consolidated in the Sixth Circuit, and, in December 2021, the court granted an emergency motion to dissolve the stay.<sup>137</sup> Against this backdrop, in early 2022, the Supreme Court considered two consolidated applications to stay the standard and decided, in a *per curiam* opinion, to uphold the stay.<sup>138</sup> Amidst several arguments, the court framed the imposition of the vaccination-or-test policy designed by OSHA as a “broad public health measure.”<sup>139</sup> The court then reasoned that the Occupational Safety and Health Act gave OSHA the authority to regulate

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<sup>134</sup> COVID-19 Vaccination and Testing: Emergency Temporary Standard, 86 Fed. Reg. 61402 (Nov. 5, 2021). In addition to imposing a requirement of regular testing, the latter option also required employees who did not produce valid proof of vaccination against COVID-19 to wear face coverings while at work. *Id.* The standard also imposed further obligations on employers, such as the provisions of paid time to employees who received a COVID-19 vaccine and the obligation to temporarily remove employees who tested positive or were diagnosed with COVID-19 from the workplace. *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> Petition for Review of Occupational Safety & Health Administration Emergency Temporary Standard at 2, *BST Holdings et al. v. OSHA*, No. 21-60845 (5th Cir., Nov. 6, 2021).

<sup>137</sup> Multi-Circuit Petitions for Review from an Order of the U.S. Department of Labor, Occupational Safety & Health Administration, No. OSHA-2001-0007, *In re MCP No. 165, Occupational Safety & Health Admin Rule on COVID-19 Vaccination and Testing*, 86 Fed. Reg. 61402, No. 21-7000 (6th Cir., Dec. 17, 2021).

<sup>138</sup> *Nat’l Fed’n Indep. Bus., et al. v. Dep’t Labor, Occupational Safety & Health Admin.*, 142 S. Ct. 661, 662–63 (2022).

<sup>139</sup> *Id.* at 665.

“workplace safety standards” but not public health more generally; and, thus the agency had exceeded its authority.<sup>140</sup>

In a piece recently co-authored with legal scholar Ruqaiijah Yearby, this Author analyzed the Supreme Court’s reading of both “public health” and the Occupational Safety and Health Act.<sup>141</sup> Here—in the specific context of legal tools used to advance policies furthering vaccination-related goals—two other aspects of the emergency standard are considered. The first is the highly divisive nature of top-down interventions seeking to promote vaccination (even when vaccination is but one component of a broader regulation). This is not to say that top-down approaches should not be considered and deployed, when appropriate from a public health perspective and within the boundaries of the law—both criteria that Professor Yearby and this Author argued were satisfied by the OSHA standard.<sup>142</sup> But the fact that the application of a particular legal tool may be desirable from a public health perspective, or that it may be legal, does not necessarily insulate it from extraneous challenges. At a time of heightened social and political divisiveness, top-down approaches in as combustible a field as vaccination are bound to face strong pushback—which, as seen in the case of the OSHA standard, may preclude their implementation altogether.

Secondly, in spite of the contested legality of the OSHA standard, data suggest that many employers were mandating vaccination, or other measures that the standard sought to impose, well before the standard was enacted.<sup>143</sup> This does not mean that

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<sup>140</sup> *Id.*

<sup>141</sup> Ana Santos Rutschman & Ruqaiijah Yearby, *Public Health Law and Policy in the Wake of NFIB v. OSHA: Probing Emerging Divides in the Supreme Court’s View of Public Health*, N.Y.U. J. LEG. & PUB. POL’Y QUORUM (Mar. 24, 2022), <https://nyujlpp.org/quorum/rutschman-yearby-public-health-law/> [<https://perma.cc/D6TV-MQQW>] (making the case that the Supreme Court erred in both its reading of the law and its narrow view of “public health” as separate from “occupational health”).

<sup>142</sup> *Id.*

<sup>143</sup> See, e.g., Kylie Ora Lobell, *Employers Enforce Vaccine Mandates Even Though Some Workers Quit*, SHRM (Oct. 19, 2021), <https://www.shrm.org/resourcesandtools/hr-topics/employee-relations/pages/employers-enforce-vaccine-mandates-even-though-some-workers-quit.aspx> [<https://perma.cc/L2PB-69YP>].

modes of voluntary regulation are or should be viewed as preferable to top-down approaches in public health (specifically, in the case of vaccination policy), but it underscores the sometimes uneasy co-existence of actors and behavioral approaches at play in the response to outbreaks of vaccine-preventable diseases.

In addition to top-down approaches (and, as just noted, the possibility of voluntary regulation by some actors), vaccination policy has also historically relied and continues to rely on other, non-coercive approaches designed to counter vaccine hesitancy. This Article now turns to these approaches, exploring first the informational aspects of the vaccine delivery ecosystem and then the creation of nudges to vaccination through prizes or prize-like tools.

### *B. Informational Approaches*

The importance of conveying accurate *and* persuasive information as a way to promote trust in vaccines has been well understood since the early days of modern vaccination—even before modern vaccines existed. For instance, in 1767, Italian physician Angelo Gatti published *New Reflections on the Practice of Inoculation*, which called attention to the idea that it would be very difficult to popularize inoculation (a precursor to modern vaccination) if the practice was not widely perceived as safe.<sup>144</sup> Gatti further pointed out that reliance on the opinion of experts alone would likely not sufficiently persuade individuals harboring doubts about inoculation to change their views.<sup>145</sup> At the time, this category of experts was largely comprised of medical professionals, as drug regulators did not yet exist and public health systems were in their infancy.<sup>146</sup> Gatti noted that, although in line with the scientific

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<sup>144</sup> ANGELO GATTI, NOUVELLES RÉFLEXIONS SUR LA PRATIQUE DE L'INOCULATION (Brussels, Chez Musier Fils 1768); see also Elise Lipkowitz, *The Physicians' Dilemma in the 18th-Century French Smallpox Debate*, 290 J. AM. MED. ASS'N 2329, 2329–30 (2003).

<sup>145</sup> GATTI, *supra* note 144, at 160–61.

<sup>146</sup> See, e.g., Lembit Rägo & Budiono Santoso, *Drug Regulation: History, Present and Future*, in DRUG BENEFITS AND RISKS: INTERNATIONAL TEXTBOOK OF CLINICAL PHARMACOLOGY (C.J. van Boxtel, B. Santoso & I.R. Edwards eds., 2008); COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, NAT'L ACAD. SCI., *A History of the Public Health System*, in THE FUTURE OF PUBLIC HEALTH 57–58 (1988).

knowledge of the day, unidirectional communications from the expert community were insufficient to dispel the personal concerns experienced by individuals.<sup>147</sup> Gatti's remarks, which were published at a time when the first statistical methods for assessing risks posed by medical products were being deployed,<sup>148</sup> underscored the gap between expert-generated information about risk and how that information is subjectively processed and acted upon at the individual level. This gap has never ceased to exist.

Within this context, the law has been used for persuasive reasons: to promote the disclosure of information by different types of experts in the vaccine ecosystem to the public in general. The history of the "information sheets" made available with many of the vaccines administered in the United States illustrates this type of legal intervention.

The Centers for Disease Control and Prevention ("CDC") produces information sheets about vaccines, which have become known as Vaccine Information Statements (or "VISs").<sup>149</sup> The first of these informational products was published in 1976, in the wake of judicial decisions in which courts tightened the requirements around vaccine manufacturers' duty to warn consumers about the risks associated with the administration of their products.<sup>150</sup>

The remote antecedent of VIS was *Davis v. Wyeth Laboratories*, a case decided in 1968 by the Court of Appeals for the Ninth Circuit involving a polio vaccine that came to market a few years after physician Jonas Salk's vaccine, known as a Sabin-type vaccine (after Albert Sabin, the lead scientist behind its development).<sup>151</sup> Unlike the Salk vaccine, which required an injection, Sabin developed an oral vaccine, which became widely administered after

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<sup>147</sup> GATTI, *supra* note 144; Lipkowitz, *supra* note 144, at 2329–30; *see also* Matthew Hornsey et al., *The Psychological Roots of Anti-Vaccination Attitudes: A 24-Nation Investigation*, 37 HEALTH PSYCHOL. 307, 308–10 (2018) (exploring contemporary applications of this idea).

<sup>148</sup> Lipkowitz, *supra* note 144, at 2329.

<sup>149</sup> *History of Vaccine Information Statements*, CDC (2016), <https://www.cdc.gov/vaccines/hcp/vis/downloads/vis-history.pdf> [<https://perma.cc/M2VJ-A5P9>].

<sup>150</sup> *Id.*

<sup>151</sup> *Davis v. Wyeth Lab'ys, Inc.*, 399 F.2d 121, 122 (9th Cir. 1968).

receiving approval from the Food and Drug Administration (“FDA”) in 1960 due to ease of administration and its strong ability to elicit a protective immune response.<sup>152</sup> The Sabin oral vaccine eventually replaced the Salk vaccine in the United States market in the late 1960s.<sup>153</sup>

In 1963, the plaintiff in *Davis* had received the Sabin polio vaccine at a mass vaccination clinic in West Yellowstone, Montana.<sup>154</sup> The clinic was part of a national strategy to eliminate polio and was sponsored by the local medical society.<sup>155</sup> Wyeth Laboratories had manufactured the vaccine, which was commercialized with a package insert alerting consumers to the risks associated with its administration.<sup>156</sup> Neither the medical society nor the Wyeth salesman who assisted in setting up the clinic informed the clinic pharmacist of the risk.<sup>157</sup> Similarly, the promotional materials disseminated in connection with the vaccination campaign were silent on the matter of risk.<sup>158</sup> Glynn Davis received the vaccine in March 1963 and, within thirty days, experienced lower-body paralysis and other symptoms associated with polio.<sup>159</sup> While the package insert provided by Wyeth disclosed the risks associated with the administration of the vaccine, including excerpts of a report issued by the U.S. Surgeon General, neither the clinic pharmacist nor Davis read the insert.<sup>160</sup> Davis, who later testified that he had no knowledge of the risk, sued the vaccine manufacturer, alleging that the vaccine manufacturer had breached its duty to warn the ultimate consumers of its product.<sup>161</sup>

The Restatement (Second) of Torts, published in 1965, had bolstered product liability law by subjecting manufacturers to strict

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<sup>152</sup> Anda Baicus, *History of Polio Vaccination*, 1 WORLD J. VIROLOGY 108, 110–11 (2012).

<sup>153</sup> Lee Hampton, *Albert Sabin and the Coalition to Eliminate Polio from the Americas*, 99 AM. J. PUB. HEALTH 34, 35 (2009).

<sup>154</sup> *Davis*, 399 F.2d at 122.

<sup>155</sup> *Id.* at 123.

<sup>156</sup> *Id.* at 125.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 122.

<sup>160</sup> *Id.* at 125.

<sup>161</sup> *Id.* at 121.

liability for harms caused by the use of their products;<sup>162</sup> however, the Restatement also established that manufacturers were not responsible for harms resulting from the use of properly prepared products known to be inherently dangerous or risky.<sup>163</sup> The Restatement expressly cited pharmaceutical products as the quintessential types of goods that fit into that category, noting that, as long as drugs and vaccines are “properly prepared . . . and accompanied by proper directions and warning,” pharmaceuticals cannot be considered “defective” or “unreasonably dangerous.”<sup>164</sup>

The Ninth Circuit reasoned that, in the case of most prescription drugs, providing a warning directed at prescribing physicians is enough to fulfill the manufacturer’s duty.<sup>165</sup> But, in the case of the vaccine given to Davis was provided as a prescription drug without the intermediation of a physician.<sup>166</sup> Vaccine doses were provided to the clinic, which in turn distributed them to all-comers.<sup>167</sup> The court thus held that, when drugs or vaccines are provided at mass clinics, the duty to warn is not fulfilled if the manufacturer only provides a warning to the immediate purchaser (the clinic) and that, “it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning.”<sup>168</sup>

The court noted that this reading of the duty to warn would not impose an unreasonable burden on manufacturers of drugs and vaccines.<sup>169</sup> In most cases, a sufficient warning can be provided through labels attached to the product. And, in the case of vaccines (often dispensed in containers never seen by consumers), there are several alternative methods to provide a warning, including via release forms and oral warnings.<sup>170</sup>

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<sup>162</sup> RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965).

<sup>163</sup> *Id.* § 402A, cmt. k.

<sup>164</sup> *Id.*

<sup>165</sup> *Davis v. Wyeth Lab’ys, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968).

<sup>166</sup> *Id.* at 131.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

The decision in *Davis* was not unanimous. Judge Hamlin dissented, arguing that the vaccine manufacturer had satisfied the duty to warn by providing printed inserts that accompanied each bottle sold to the clinic. The majority's line of reasoning, however, prevailed in the long run.<sup>171</sup>

In *Reyes v. Wyeth Laboratories*, decided by the Court of Appeals for the Fifth Circuit in 1974, the plaintiff filed suit on behalf of his infant daughter, who received the Sabin-type oral polio vaccine in 1970.<sup>172</sup> The vaccine was administered by a nurse at a Texas clinic.<sup>173</sup> Within two weeks, the infant was diagnosed with paralytic polio.<sup>174</sup> Reyes sued the vaccine manufacturer, alleging a breach of the duty to warn.<sup>175</sup> The mother, whose primary language was Spanish, testified that she was not aware of any danger associated with administering the vaccine.<sup>176</sup> The mother, whose primary language was Spanish, had signed a form in English that released Texas from "all liability in connection with immunization."<sup>177</sup> The release form contained no warning, and it soon became apparent that the mother had likely not understood the implications of signing the release.<sup>178</sup>

Among several claims, the Complaint alleged that the vaccine manufacturer had failed to warn the parents of the risk of contracting the disease.<sup>179</sup> Wyeth Laboratories had provided a warning circular with each vial of vaccine.<sup>180</sup> The nurse had read the warning circular but had not informed the mother of the potential risks to her child.<sup>181</sup> A representative of the vaccine manufacturer testified that it was "common knowledge" that a significant amount of the vaccine was being administered at mass clinics like the one visited by the Reyes family in Texas—or Glynn Davis in Montana—where no physician-

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<sup>171</sup> *Id.*

<sup>172</sup> *Reyes v. Wyeth Lab'ys*, 498. F.2d 1264, 1270 (5th Cir. 1974).

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.* at 1269.

<sup>176</sup> *Id.* at 1270.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

patient relationship was established before or during the administration of the vaccine.<sup>182</sup>

The Fifth Circuit thus took a similar approach to the one adopted by the *Davis* court, holding that Wyeth Laboratories had not met its duty to provide a warning directly to the recipient of the vaccine, or the recipient's parents or legal representatives.<sup>183</sup> The court went even further than the *Davis* court, making it clear that, unlike physicians, nurses are not considered "learned intermediar[ies]" for the purposes of applying the doctrine of duty to warn.<sup>184</sup> As such, absent the intervention of a physician, vaccine manufacturers are required to warn the ultimate recipient of a vaccine, and failure to do so will render them strictly liable for injuries that occur in connection with the administration of their products.<sup>185</sup>

The *Reyes* case caused upheaval in the pharmaceutical community. Anticipating a surge in litigation, vaccine manufacturers began increasing their prices to offset their expected litigation-related expenses.<sup>186</sup> At that point, the CDC intervened and effectively assumed responsibility of the informational function that is at the core of the duty to warn.<sup>187</sup> The CDC negotiated with vaccine manufacturers and committed to insert a "duty to warn clause" in its vaccine purchase agreements.<sup>188</sup> The Agency then developed the first Important Information Statement ("ISS"), which was issued in 1976 for a vaccine against both swine flu and A/Victoria flu;<sup>189</sup> the ISS evolved into the Vaccine Information Statement ("VIS") in 1994.<sup>190</sup> Through the National Childhood Vaccine Injury Act of 1986, federal law now requires healthcare providers to provide a VIS whenever they administer any of the most

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<sup>182</sup> *Id.* at 1277.

<sup>183</sup> *Id.* at 1277–78.

<sup>184</sup> *Id.* at 1276–77.

<sup>185</sup> *Id.* at 1276.

<sup>186</sup> CDC, *supra* note 149.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 2.

common vaccines to any adult or child.<sup>191</sup> In the case of children, the VIS should be provided to their parents or legal representatives.<sup>192</sup> Healthcare providers must record both the administration of the vaccine and the provision of a VIS.<sup>193</sup>

The history of the VIS illustrates how different actors in the vaccination ecosystem—the CDC, an institutional actor, and healthcare professionals—play separate but complementary roles in disseminating information about vaccines. In this context, the law has been used to impose informational duties on these actors, in furtherance of transparency and educational goals. The informational function of these and other actors in the public health system is also meant to play a persuasive role in countering vaccine hesitancy.<sup>194</sup> Similar to other interventions induced by law, both the duty to warn and the production and distribution of VISs are mandatory when specified by statute or developed through caselaw. This Article now turns to sets of measures that rely on voluntary frameworks to counter vaccine hesitancy.

### *C. The Role of Nudges in Vaccination Policy*

The previous Parts surveyed interventions aimed at implementing markedly different requirements that nonetheless share a common trait: They result in the *mandatory* adoption of some type of measure deemed instrumental in promoting vaccination uptake. Some of these interventions are inherently coercive and directly aimed at increasing vaccination rates—as is the case with mandates—while others operate as tools to increase the flow of information about the risks and benefits of vaccines—as

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<sup>191</sup> 42 U.S.C. § 300aa-26. The full list, as of 2021, includes the vaccines against diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox). See *Instructions for Using VISs*, CDC, <https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html> [<https://perma.cc/36CD-RE6V>] (last visited Apr. 1, 2022).

<sup>192</sup> CDC, *supra* note 191.

<sup>193</sup> *Id.*

<sup>194</sup> See, e.g., Shen & Dubey, *supra* note 69, at 176–77 (discussing the role of family physicians in countering vaccine hesitancy).

is the case with obligations imposed on a wide range of actors— from federal agencies to healthcare providers.

In addition to modalities resulting in the imposition of varying behaviors, another option available to policymakers rests on the adoption of *non-mandatory* measures designed to nudge individuals (or communities) to elect to receive a vaccine.<sup>195</sup> While the idea of utilizing nudges to promote certain behaviors in the context of healthcare is not new,<sup>196</sup> the COVID-19 pandemic provided fertile ground for the development of vaccination-specific nudges.<sup>197</sup>

In the United States, an unprecedented number of varying incentives for COVID-19 vaccination were offered at the state level.<sup>198</sup> Many of these nudges consisted of offers of small tokens, such as food items or gift vouchers. Indiana, for instance, offered a box of Girl Scout cookies to individuals receiving a COVID-19

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<sup>195</sup> See generally RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* (2009); Matteo M. Galizzi, *Label, Nudge or Tax? A Review of Health Policies for Risky Behaviors*, 1 J. PUB. HEALTH RSCH. 14 (2012) (discussing nudging policies in the context of healthcare). See also Ronald F. White, *An Introduction to “Nudge Science”*, 37 POL. & LIFE SCIS. 114 (2018); Jacob Goldin, *Which Way to Nudge? Uncovering Preferences in the Behavioral Age*, 125 YALE L.J. 226 (2015); Cass R. Sunstein, *The Ethics of Nudging*, 32 YALE J. ON REG. 413 (2015); Brian Galle, *Tax, Command—or Nudge?: Evaluating the New Regulation*, 92 TEX. L. REV. 837 (2014); Ryan Calo, *Code, Nudge, or Notice?*, 99 IOWA L. REV. 773 (2014) (discussing nudging policies outside the context of healthcare). But see Lauren E. Willis, *When Nudges Fail: Slippery Defaults*, 80 U. CHI. L. REV. 1155 (2013) (focusing on shortcoming of nudging approaches).

<sup>196</sup> See generally Thaler & Sunstein, *supra* note 195; Wendy Netter Epstein, *Nudging Patient Decision-Making*, 92 WASH. L. REV. 1255 (2017); J. S. Blumenthal-Barby & Hadley Burroughs, *Seeking Better Health Care Outcomes: The Ethics of Using the “Nudge”*, 12 AM. J. BIOETHICS 1 (2013).

<sup>197</sup> See generally Mark Donald C. Reñosa et al., *Nudging Toward Vaccination: A Systematic Review*, 6 BRIT. MED. J. GLOB. HEALTH 1,1 (2021); Serena Tinari & Catherine Riva, *Donuts, Drugs, Booze, and Guns: What Governments Are Offering People to Take Covid-19 Vaccines*, 374 BRIT. MED. J. n1737 (2021).

<sup>198</sup> *COVID-19 Vaccine Incentives*, NAT’L GOVERNORS ASS’N. (Oct. 19, 2021), <https://www.nga.org/center/publications/covid-19-vaccine-incentives/> [https://perma.cc/2D9L-UJ8U].

vaccine at designated vaccination sites.<sup>199</sup> Maine provided numerous incentives to residents eighteen years of age and older to get their first COVID-19 vaccine dose.<sup>200</sup> These incentives included fishing licenses, hunting licenses, and Maine Wildlife Park Passes.<sup>201</sup> North Carolina, which initially set a \$25 reward for COVID-19 vaccination, upped the amount during summer 2021, offering a gift card worth \$100 to individuals eighteen years of age and older who received a first dose of a COVID-19 vaccine at designated sites.<sup>202</sup> A study published in late 2021 suggested that the \$25 reward had been effective in promoting vaccination uptake (no study on the \$100 reward was available at the time of writing this Article).<sup>203</sup>

Other nudges were tied to the possibility of entering contests for significantly large monetary rewards. The most well-known nudge was the lottery program established by Ohio, which became known as the “Ohio Vax-a-Million.”<sup>204</sup> The lottery ran for five weeks, offering permanent Ohio adult residents the chance to enter a lottery for \$1 million each week, on the condition that the entrant received

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<sup>199</sup> See Shari Rudavsky, *Sweet Shot: Some Indiana Clinics to Give Girl Scouts Cookies Along With COVID-19 Vaccine*, INDIANAPOLIS STAR (May 10, 2021), <https://www.indystar.com/story/news/health/2021/05/10/indiana-covid-19-vaccine-clinics-girl-scout-cookies-near-me/5026809001/> [<https://perma.cc/SQ89-E2Y8>].

<sup>200</sup> *Your Shot to Get Outdoors!: Maine’s COVID-19 Vaccine Incentive Program*, ME. OFF. GOV. (2021), <https://www.maine.gov/covid19/vaccines/get-outdoors> [<https://perma.cc/YA9J-8MA7>].

<sup>201</sup> *Id.*

<sup>202</sup> *North Carolina Offers \$100 Cards for First-time COVID-19 Vaccinations, and \$25 Cards for Drivers*, N.C. DEP’T HEALTH & HUM. SERVICES (Aug. 3, 2021), <https://www.ncdhhs.gov/news/press-releases/2021/08/03/north-carolina-offers-100-cards-first-time-covid-19-vaccinations-and-25-cards-drivers> [<https://perma.cc/TCW9-YJ9L>].

<sup>203</sup> See Charlene A. Wong et al., *Guaranteed Financial Incentives for COVID-19 Vaccination: A Pilot Program in North Carolina*, 182 J. AM. MED. ASS’N INTERNAL MED. 78, 78–80 (2021).

<sup>204</sup> See, e.g., *Ohio’s COVID Vaccine Lottery Registration Opens: How Vax-a-Million Drawings Will Work*, ASSOCIATED PRESS (May 13, 2021), <https://www.10tv.com/article/news/health/coronavirus/vaccine/how-ohios-vax-a-million-lottery-will-work/530-00a5cf8b-d7fe-4794-83c7-72d5d803aaa5> [<https://perma.cc/E6K2-N8AW>]; Sarah Mervosh, *Who Wants to Be a Millionaire? In Ohio, You Just Need Luck, and a Covid Vaccine*, N.Y. TIMES (May 26, 2021), <https://www.nytimes.com/2021/05/26/us/coronavirus-ohio-lottery-vax-a-million.html> [<https://perma.cc/XA3A-PFNP>].

a dose of a COVID-19 vaccine.<sup>205</sup> Some researchers have questioned the effectiveness of Ohio's lottery in nudging individuals to get vaccinated against COVID-19, pointing out that the State's uptake in COVID-19 vaccination "closely coincided" with the FDA's authorization of the Pfizer-BioNTech vaccine to be administered to adolescents between the ages of twelve and fifteen.<sup>206</sup> Others have concluded that Ohio's lottery was successful, estimating that it increased the rate of the vaccinated population in the State by 1.5%.<sup>207</sup> Since the publication of these initial studies, research has yielded mixed results. Several studies that focused on Ohio's specific lottery model have argued that the program likely had a positive impact in nudging vaccination against COVID-19.<sup>208</sup> A broader study, surveying eleven states with lottery programs and twenty-eight without, suggested that "lottery programs *may* be associated with decreased COVID-19 vaccine hesitancy, but that success might differ across states."<sup>209</sup> Other studies found no association between lottery programs and vaccination uptake. A study surveying nineteen states with lottery programs, for example, found no statistically relevant association between the launch of state lotteries and increases in COVID-19 vaccination rates.<sup>210</sup> These mixed results suggest that further research is necessary to assess the viability of lotteries as potential policy levers during large-scale public health crises.

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<sup>205</sup> ASSOCIATED PRESS, *supra* note 204. Permanent Ohio residents between the ages of twelve and seventeen were eligible for a full scholarship at a four-year program at a university in Ohio. *Id.*

<sup>206</sup> Allan J. Walkey et al., *Lottery-Based Incentive in Ohio and COVID-19 Vaccination Rates*, 326 J. AM. MED. ASS'N 766, 766 (2021).

<sup>207</sup> Andrew Barber & Jeremy West, *Conditional Cash Lotteries Increase COVID-19 Vaccination Rates*, 81 J. HEALTH ECON. 1, 12 (2021).

<sup>208</sup> See Neil K. R. Sehgal, *Impact of Vax-a-Million Lottery on COVID-19 Vaccination Rates in Ohio*, 134 AM. J. MED. 1424, 1424–26 (2021); Peter J. Mallow et al., *COVID-19 Financial Lottery Effect on Vaccine Hesitant Areas: Results from Ohio's Vax-a-Million Program*, AM. J. EMERGENCY MED. 1, 1–2 (2021).

<sup>209</sup> Binod Acharya & Chandra Dhakal, *Implementation of State Vaccine Incentive Lottery Programs and Uptake of COVID-19 Vaccinations in the United States*, 2 J. AM. MED. ASS'N NETWORK OPEN 9–11 (2021) (emphasis added).

<sup>210</sup> Dhaval Dave et al., *Association Between Statewide COVID-19 Lottery Announcements and Vaccinations*, 4 J. AM. MED. ASS'N HEALTH F. 1, 3 (2021).

Incentives aimed at nudging COVID-19 vaccination uptake were also utilized in several other countries. For instance, Serbia was one of the earliest countries to offer a monetary reward (3,000 dinars, or approximately 30 USD, according to May 2021 conversion rates) to citizens who received their first dose of a COVID-19 vaccine.<sup>211</sup> And the district of Mae Chaem in Northern Thailand implemented a raffle campaign offering a cow a week for twenty-four weeks.<sup>212</sup> Each cow was worth approximately 10,000 baht (just over 300 USD, as of May 2021), prompting the number of vaccinated people in a town of 43,000 inhabitants to climb from hundreds to thousands in a matter of days.<sup>213</sup>

The popularity of initiatives like the ones surveyed above suggest that incentives designed to nudge vaccination warrant greater study beyond the COVID-19 pandemic; nonetheless, a few caveats are in order. In separate work, this Author has addressed the problems surrounding some types of incentives for vaccination.<sup>214</sup> This Author has argued that, as a rule, monetary approaches are unlikely to be the best policy tool and should be closely scrutinized.<sup>215</sup> This Author made this argument in connection with

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<sup>211</sup> Serbia in 'World First' as Citizens Offered €25 to Have COVID Vaccine, EURONEWS (May 5, 2021), <https://www.euronews.com/2021/05/05/serbia-in-world-first-as-citizens-offered-25-to-have-covid-vaccine> [<https://perma.cc/KPL4-X53A>].

<sup>212</sup> Panarat Thepgumpanat, *Cattle for Raffle Gets Thai Town in Mood for Vaccines*, REUTERS (May 20, 2021), <https://www.reuters.com/world/asia-pacific/thai-town-offers-free-cows-boost-vaccine-campaign-2021-05-20/> [<https://perma.cc/W9DD-BRDN>].

<sup>213</sup> *Id.*

<sup>214</sup> See Ana Santos Rutschman, *Why the Government Shouldn't Pay People to Get Vaccinated Against COVID-19*, Bill of Health (Dec. 1, 2020), <https://blog.petrieflom.law.harvard.edu/2020/12/01/payment-covid-vaccine-incentive/> [<https://perma.cc/2JV9-7PUF>] [hereinafter Rutschman, *Why the Government*]; Ana Santos Rutschman & Timothy L. Wiemken, *The Case Against Monetary Behavioral Incentives in the Context of COVID-19 Vaccination*, 27 HARV. PUB. HEALTH REV. (manuscript at 2–4) (2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3830769](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3830769) [<https://perma.cc/5YFX-XQ2U>]. See generally Ivo Vlaev et al., *Changing Health Behaviors Using Financial Incentives: A Review from Behavioral Economics*, 19 BMC PUB. HEALTH 1059 (2019).

<sup>215</sup> Rutschman, *Why the Government*, *supra* note 214; Rutschman & Wiemken, *supra* note 214, at 1–4.

some proposals put forth early in the COVID-19 pandemic in the United States that suggested the federal government pay around \$1,000 to those vaccinated against COVID-19.<sup>216</sup> These proposals—which were never implemented—differ from the types of incentives surveyed in this Part. On the one hand, the monetary value is significantly higher than the value of gift cards and similar incentive mechanisms. On the other hand, it sets a reward that is certain, while the incentives surveyed above that entailed large cash prizes (e.g., lotteries) offered an uncertain, low-probability reward.<sup>217</sup> This distinction is relevant from a policy perspective, as a certain cash reward is likely to have a greater impact on (and potentially constrain) decisions about vaccination made by lower-income individuals, families, or communities.<sup>218</sup> Moreover, recent empirical work in the context of COVID-19 vaccination by legal scholar Christopher Robertson and colleagues suggests that the use of monetary incentives, while potentially beneficial in some situations, may in some circumstances disfavor certain racial and ethnic minorities.<sup>219</sup>

On balance, the COVID-19 experience with nudges to vaccination suggests that these various types of incentives warrant greater study ahead of future outbreaks of vaccine-preventable

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<sup>216</sup> See Robert E. Litan, *Want Herd Immunity? Pay People to Take the Vaccine*, BROOKINGS (Aug. 18, 2020), <https://www.brookings.edu/opinions/want-herd-immunity-pay-people-to-take-the-vaccine/> [<https://perma.cc/ZQ5B-JQZH>] (suggesting that payment could attach to either the first shot or to a booster shot). See also John K. Delaney, *Pay Americans to Take a Coronavirus Vaccine*, WASH. POST (Nov. 23, 2020), <https://www.washingtonpost.com/opinions/2020/11/23/pay-americans-coronavirus-vaccine-john-delaney/> [<https://perma.cc/8NTZ-4JXS>] (proposing a payment of around \$1,500).

<sup>217</sup> Rutschman, *Why the Government*, *supra* note 214; Rutschman & Wiemken, *supra* note 214, at 2–4.

<sup>218</sup> *Id.* (noting further, collectively, that these communities have also systematically experienced racial and ethnic discrimination throughout the history of medical research and development and calling for greater study on the potentially coercive effects of setting certain and relatively large cash prizes in the context of vaccination policy).

<sup>219</sup> See Christopher Robertson et al., *Paying Americans to Take the Vaccine—Would It Help or Backfire?*, 8 J.L. & BIOSCIS. 1, 16 (2021) (“For Black and Latino Americans especially, very large financial incentives may be counter-productive.”).

diseases. At the same time, if deployed by policymakers, some incentives—particularly those setting a cash reward that is relatively large and certain—should be closely scrutinized as they may have disparate effects across vaccine-eligible populations. At yet a broader level, the relative popularity of nudges to vaccination adopted by policymakers during the COVID-19 pandemic further underscores the need for pluralistic legal and policy approaches in an area of ever-growing behavioral complexity.

#### V. CONCLUSION

Vaccine hesitancy is not a new phenomenon. This Article has traced its evolution from the late eighteenth and early nineteenth centuries to the digital era of today. As debates about vaccines and vaccination become increasingly polarized, it is timely to explore the role(s) of law and policy in promoting trust in vaccines as instruments of public health. By surveying selected, heterogenous legal and policy tools, this Article has sought to contribute to ongoing discussions in this area, which will continue to require pluralistic approaches, particularly at a time in which outbreaks of vaccine-preventable diseases are projected to occur at a greater pace.