

# Of Vaccine and Hesitancy

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## ABSTRACT

Vaccinated individuals—like Tolstoy’s happy families—are all alike; each unvaccinated individual is hesitant for her own reason. Irrational and unreasonable conspiracy theories about COVID-19 and its vaccine abound among the anti-vaxxers. Contrary to popular belief, however, conspiracy theories are not the main driver of vaccine hesitancy. Whether an individual remains hesitant about receiving a COVID-19 vaccine may depend on personal beliefs, informed by a background that is a totality of, for example, race (and its historical past), gender, education, life experience, and information consumption. This individualized background then forms a value system that informs the personal decision-making process as to whether to receive a COVID-19 vaccine.

## I. INTRODUCTION

Vaccine hesitancy is as old as vaccines themselves. For instance, Justice Jackson wrote in a 1938 letter to his mother, advising her of the benefits of the scarlet fever vaccine: “I am quite sure that they now have a pretty dependable vaccine which either prevents the development of the disease or at least reduces its severity.”<sup>1</sup> Reading the tea leaves,<sup>2</sup> Jackson’s loved one was uncertain of—and undoubtedly hesitant about—whether or not to receive the scarlet fever vaccine.<sup>3</sup> But that was just Jackson’s *ex ante* view.<sup>4</sup> To look at vaccines *ex post*,<sup>5</sup> the late Justice Scalia, writing for the majority in

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<sup>1</sup> Letter from Robert H. Jackson to his mother (Feb. 25, 1938), <https://thejacksonlist.com/wp-content/uploads/2021/09/20210729-Vaccination.pdf> [hereinafter Jackson’s Letter].

<sup>2</sup> See generally J.K. ROWLING, HARRY POTTER AND THE PRISONER OF AZKABAN (1999) (explaining tasseography, the practice of identifying symbols and interpreting messages found in the shapes and configurations of tea leaves).

<sup>3</sup> See Jackson’s Letter, *supra* note 1.

<sup>4</sup> See also, e.g., *Massachusetts v. Oakes*, 491 U.S. 576, 586 (1989) (explaining “ex post, that is, after the offending statute is enacted, but also ex ante, that is, when the legislature is contemplating what sort of statute to enact”); *City & Cnty. of San Francisco v. Sheehan*, 575 U.S. 600, 620 (2015) (explaining “ex post—after the Court has improvidently decided the uncertworthy question . . . Ex ante, however—before we considered and deliberated upon the second [question presented] but after petitioners’ principal brief made clear that they would not address the Circuit conflict presented by the first [question presented]”). See generally Barbara H. Fried, *Ex Ante/Ex Post*, 13 J. CONTEMP. LEGAL ISSUES 123 (2003); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 568–86 (1992).

<sup>5</sup> See sources cited *supra* note 4.

*Bruesewitz v. Wyeth LLC*, summed up what vaccination has accomplished in the last seventy-five years, that “the elimination of communicable diseases through vaccination became ‘one of the greatest achievements’ of public health in the 20th century.”<sup>6</sup> Nevertheless, since the 1970’s and 1980’s, vaccines have, ironically, writes Scalia, “been so effective in preventing infectious diseases that the public became much less alarmed at the threat of those diseases, and much more concerned with the risk of injury from the vaccines themselves.”<sup>7</sup> This has resulted in, to not put too fine a point on it, vaccines becoming what Scalia calls “victims of their own success,”<sup>8</sup> among which the recently available COVID-19 vaccine evidently bears no exception.<sup>9</sup>

The public began asking when a vaccine could be ready almost as soon as the pandemic began. But the better question one should have asked, as we now know, is how many people would actually receive the vaccine when it becomes available? Every dimension of the COVID-19 pandemic has been politicized, from lockdown measures, masking, to the very existence of the virus.<sup>10</sup> As with these issues, people were fractured over whether to be vaccinated, when, and with which vaccine. For instance, more than a third of Americans reported as of March 2021 that they remain hesitant about receiving a COVID-19 vaccine.<sup>11</sup> Such an alarming rate of vaccine hesitancy prompts the research for this Article, investigating what makes hesitancy to the COVID-19 vaccine so widespread. Of particular interest is why racial<sup>12</sup> disparities in COVID-19 vaccination rates have persisted.

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<sup>6</sup> 562 U.S. 223, 226 (2011) (quoting *Achievements in Public Health, 1900–1999: Impact of Vaccines Universally Recommended for Children—United States, 1990–1998*, 48 MORBIDITY & MORTALITY WKLY. REP. 243, 247 (Apr. 2, 1999)).

<sup>7</sup> *Bruesewitz v. Wyeth*, 562 U.S. 223, 226 (2011) (citing Edward A. Mortimer, Jr., *Immunization Against Infectious Disease*, 200 SCIENCE 902, 906 (1978); NATIONAL VACCINE ADVISORY COMMITTEE, A COMPREHENSIVE REVIEW OF FEDERAL VACCINE SAFETY PROGRAMS AND PUBLIC HEALTH ACTIVITIES 2–3 (Dec. 2008)); see also Eugene McCarthy, *The Regulatory Production of Vaccine Hesitancy*, 86 BROOK. L. REV. 81, 134 (2020) (“Vaccine hesitancy has unfortunately been on the rise for decades in the United States.”). It is perhaps human nature that we fail to appreciate what we have that is working and too often focus solely on the what-if.

<sup>8</sup> *Bruesewitz*, 562 U.S. at 226. But to read between the lines, the Court appears to be implying that the public, by virtue of confidently relying on America’s healthcare system for treatment and cure, has become so spoiled to the point that it can afford the luxury of no-prevention-necessary.

<sup>9</sup> People often—aptly—compared the COVID-19 pandemic to the 1918–1919 influenza pandemic that infected one-third of the world’s world population and claimed an estimated 50–100 million lives. See also, e.g., David Morens & Anthony Fauci, *The 1918 Influenza Pandemic: Insights for the 21st Century*, 195 J. INFECTIOUS DISEASES 1018 (2007) (noting the 1918–1919 H1N1 influenza pandemic as one of the deadliest events in recorded human history).

<sup>10</sup> See also *Whitney v. California*, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring) (“Those who won our independence believed that . . . public discussion is a political duty; and that this should be a fundamental principle of the American government.”). Yet, “experiment shows it’s surprisingly easy to change someone’s political views, revealing how flexible we are.” Philip Parnaments & Jay Van Bavel, *How Political Opinions Change*, SCI. AM. (Nov. 20, 2018), <https://www.scientificamerican.com/article/how-political-opinions-change/>.

<sup>11</sup> Michael Daly, Andrew Jones & Eric Robinson, *Public Trust and Willingness to Vaccinate Against COVID-19 in the US from October 14, 2020, to March 29, 2021*, 325 JAMA 2397, 2398 (May 24, 2021) (surveying 7,420 participants and finding 46% COVID-19 vaccine hesitancy rate in October 2020, declining to 35.2% in March 2021).

<sup>12</sup> While this Article acknowledges that “race” may factually be a “socially constructed and contingent system of meaning that is attached to aspects of physical characteristics and ancestry” that the Critical Race Theory (CRT) scholars have posited, its focus is to not distinguish the boundaries of “race” and who does, or does not, qualify to be within a certain “race.” Mantiangai Sirleaf, *Racial Valuation of*

As a preliminary matter, readers should be on the same page on the definition. Vaccine hesitancy generally means the reluctance toward vaccination. The World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) Working Group on Vaccine Hesitancy defines vaccine hesitancy as the "delay in acceptance or refusal of vaccination despite availability of vaccination services," which is "complex and context specific, varying across time, place and vaccines" and "is influenced by factors such as complacency, convenience and confidence."<sup>13</sup> Similarly, CDC defines a person as "hesitant" if she would probably not, or definitely not, receive a COVID-19 vaccine if one were available to her.<sup>14</sup> Put differently, vaccine hesitancy is split into two camps: the bona fide hesitancy v. the paranoid<sup>15</sup> (anti-vaccination or, colloquially, anti-vaxxers<sup>16</sup>). The distinguishing factor between the two camps is whether one can be persuaded, with logic and reason, to receive a vaccine. To tease out each individual's unique decision-making process of whether to receive a vaccine, this paper's focus is on the bona-fide-hesitancy camp, which includes vaccine skepticism, vaccine critics, and vaccine deliberation that involves a host of different responses to the decision-making process of whether to receive a vaccine.

Putting aside genuine religious beliefs,<sup>17</sup> irrational and unreasonable conspiracy theories about COVID-19 and its vaccine abound among the anti-vaxxers—a subgroup of science deniers.<sup>18</sup> These conspiracy theories include—to name just a few:

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*Diseases*, 67 UCLA L. REV. 1820, 1823 (2021). See generally, e.g., IAN HANEY LÓPEZ, WHITE BY LAW: THE LEGAL CONSTRUCTION OF RACE xxi, 10 (10th anniversary ed. 2006); MICHAEL OMI & HOWARD WINANT, RACIAL FORMATION IN THE UNITED STATES 111 (3d ed. 2015) (defining race). But see CHARLES MURRAY, HUMAN DIVERSITY: THE BIOLOGY OF GENDER, RACE, AND CLASS (2020) (contending that the dogma of race, in addition to gender and class, as a social construct is a half-truth that has stifled progress in understanding how richly biology has added to our knowledge of the social, political, and economic worlds we live in). Accordingly, the Article's usage of the terms "race" and "racial" is in their generic, popular meanings—not analyzed under the CRT line of thought.

<sup>13</sup> Noni E. MacDonald, *Vaccine Hesitancy: Definition, Scope and Determinants*, 33 VACCINE 4161, 4161 (2015); accord *Ten Threats to Global Health in 2019*, WORLD HEALTH ORG., <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019> (defining vaccine hesitancy as "the reluctance or refusal to vaccinate despite the availability of vaccines") (last visited Aug. 14, 2022).

<sup>14</sup> *Estimates of Vaccine Hesitancy for COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://data.cdc.gov/stories/s/Vaccine-Hesitancy-for-COVID-19/end2-a6zw/> (last visited Sept. 21, 2021). Measures of hesitancy were based on a household survey in which respondents were asked whether they would get a COVID-19 vaccine and could choose between the following options: "definitely get a vaccine"; "probably get a vaccine"; "unsure"; "probably not get a vaccine"; "definitely not get a vaccine."

<sup>15</sup> An example of the paranoid is the small group of people who still believe that putting fluoride in tap water is merely a government's plot to control people's minds, not to help with dental care. Note that the paranoid may still have a subjectively good faith belief (in conspiracy theories, for example) that is erroneous but genuinely held. That belief, however, may not be held with objectively good faith, upon considering scientific advances and evidence.

<sup>16</sup> See, e.g., McCarthy, *supra* note 7, at 81 n.3 (2020) (defining anti-vaxxers as "individuals who oppose government-mandated vaccination").

<sup>17</sup> See, e.g., Louiegi L. Garcia & John Federick C. Yap, *The Role of Religiosity in COVID-19 Vaccine Hesitancy*, 43 J. PUB. HEALTH e529 (June 3, 2021) (noting, for example, in "Islam, vaccines with pork derivatives are prohibited" and the Vatican's "stance toward vaccination . . . remain[ing] firm in their admonition toward use of cell lines from aborted fetuses in COVID-19 vaccines"). See generally Dorit Rubinstein Reiss, *Thou Shalt Not Take the Name of the Lord Thy God in Vain: Use and Abuse of Religious Exemptions from School Immunization Requirements*, 65 HASTINGS L.J. 1551 (2014).

<sup>18</sup> See generally Sarah Evanega, Mark Lynas, Jordan Adams & Karinne Smolenyak, *Coronavirus Misinformation: Quantifying Sources and Themes in the COVID-19 'Infodemic'*, J. MED. INTERNET RES. (Oct. 2020), available in preprint at <https://preprints.jmir.org/preprint/25143>.

- *Miracle Cures*: Former President Donald J. Trump promoted the anti-malarial drugs, hydroxychloroquine and chloroquine, as COVID-19 cures in March 2020.
- *Democratic Party Hoax*: Former President Trump's son, Eric Trump, commented on Fox News that COVID-19 will "magically all of a sudden go away and disappear and everybody will be able to reopen" after the 2020 presidential election.<sup>19</sup>
- *5G Technology*: 5G technology's alleged negative health impacts predate the COVID-19 pandemic. Rumors suggest that the emergence of the novel coronavirus was somehow related to the rollout of 5G mobile technology, especially in light of the installation of several 5G towers in Wuhan, China.<sup>20</sup>
- *Bill Gates' Surveillance Microchips*: This theory suggests that COVID-19 vaccines contain tracking microchips, which conspiracists link to Gates' long-standing interest in vaccination as a public health measure. People might have arrived at this belief due to a tenuous connection to a published paper on how "quantum dots" could be delivered to the skin to produce light and show whether an individual has been vaccinated.<sup>21</sup>
- *Fauci's Erroneous Predictions*: Dr. Anthony Fauci's<sup>22</sup> erroneous claims from early in the pandemic have been used to discredit his later statements; for example, he told Americans in March 2020 that "it will take at least a year to a year in a half to have a vaccine we can use"<sup>23</sup> and that "there's no reason to be walking around with a mask."<sup>24</sup>

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<sup>19</sup> Victor Garcia, *Eric Trump Says Democrats 'Trying to Milk' Coronavirus Shutdown, Media 'Stoking Fear'*, FOX NEWS (May 17, 2020), <https://www.foxnews.com/media/eric-trump-says-democrats-trying-to-milk-coronavirus-shutdown-media-stoking-fear>.

<sup>20</sup> See, e.g., Axel Bruns, Stephen Harrington & Edward Hurcombe, *'Corona? 5G? or Both?': The Dynamics of COVID-19/5G Conspiracy Theories on Facebook*, 177 MEDIA INT'L AUSTL. (Aug. 4, 2020), <https://journals.sagepub.com/doi/full/10.1177/1329878X20946113>.

<sup>21</sup> See, e.g., Brie D. Sherwin, *Anatomy of a Conspiracy Theory: Law, Politics, and Science Denialism in the Era of COVID-19*, 8 TEX. A&ML. REV. 537, 555 (2021); April Falcon Doss, *Data Privacy & National Security: A Rubik's Cube of Challenges and Opportunities That Are Inextricably Linked*, 59 DUQ. L. REV. 231, 247 (2021); John J. Chung, *Rethinking the Role of NGOs in an Era of Extreme Wealth Inequality: The Example of the Bill & Melinda Gates Foundation*, 26 ROGER WILLIAMS U. L. REV. 1, 7 (2021).

<sup>22</sup> See generally FAUCI (National Geographic Documentary Films et al. 2021).

<sup>23</sup> Stephanie Soucheray, *Fauci: Vaccine at Least Year Away, as COVID-19 Death Toll Rises to 9 in Seattle*, UNIV. OF MINN. CIDRAP NEWS (Mar. 3, 2020), <https://www.cidrap.umn.edu/news-perspective/2020/03/fauci-vaccine-least-year-away-covid-19-death-toll-rises-9-seattle>.

<sup>24</sup> Fire Fauci Act, H.R. 2316, 117th Cong. (2021), <https://www.govinfo.gov/content/pkg/BILLS-117hr2316ih/html/BILLS-117hr2316ih.htm>.

- *Plandemic*: The YouTube pseudo-documentaries titled “Plandemic” claim that vaccines are “a money-making enterprise that causes medical harm,” which would result in a loss of free speech and free choice.<sup>25</sup>
- *Wuhan Bioweapon*: This conspiracy suggests a secret bioweapon facility, Wuhan Institute of Virology, deliberately or accidentally released COVID-19.<sup>26</sup>
- *Population Control*: Conspiracists suggest that COVID-19 vaccines might be a population control effort within an intentional population control scheme that is COVID-19.<sup>27</sup>
- *Bat Soup*: This theory posits that COVID-19 originated from the bats in Wuhan that humans consumed.<sup>28</sup>
- *Antisemitic Theories*: COVID-19 pandemic drove anti-Jewish sentiment domestically and in Europe.<sup>29</sup>
- *New World Order / Deep State*: The secret “new world orders” or “deep state” government allegedly paid for the COVID-19 responses (including those by Fauci and Gates). This conspiracy is often linked to former President Trump’s “joke” that called the U.S. State Department a “Deep State Department” during a March 2020 coronavirus press briefing.<sup>30</sup>

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<sup>25</sup> See Sheera Frenkel, Ben Decker & Davey Alba, *How the ‘Plandemic’ Movie and Its Falsehoods Spread Widely Online*, N.Y. TIMES (May 20, 2020), <https://www.nytimes.com/2020/05/20/technology/plandemic-movie-youtube-facebook-coronavirus.html> (discussing the twenty-six-minute Plandemic pseudo-documentary as a major topic of conspiracy conversations shortly after its YouTube debut on May 4, 2020 by a film producer named Mikki Willis); see also Davey Alba, *Virus Conspiracists Elevate a New Champion*, N.Y. TIMES (May 9, 2020), <https://www.nytimes.com/2020/05/09/technology/plandemic-judy-mikovitz-coronavirus-disinformation.html> (profiling the Plandemic’s main interviewee, a disgraced former virologist named Judy Mikovits).

<sup>26</sup> See Michael H. Fuchs, *The US-China Coronavirus Blame Game Is Undermining Diplomacy*, THE GUARDIAN (Mar. 31, 2020, 5:00 PM EDT), <https://www.theguardian.com/commentisfree/2020/mar/31/us-china-coronavirus-diplomacy>; Mark Lynas, *Did COVID-19 Escape from a Lab?*, CORNELL ALL. FOR SCI. (Apr. 15, 2020), <https://allianceforscience.cornell.edu/blog/2020/04/did-covid-19-escape-from-a-lab/>.

<sup>27</sup> See, e.g., Ali Ghaddar, Sanaa Khandaqji, Zeinab Awad & Rawad Kansoun, *Conspiracy Beliefs and Vaccination Intent for COVID-19 in an Infodemic*, 17 PLOS ONE e0261559 (Jan. 12, 2022).

<sup>28</sup> See Josh Taylor, *Bat Soup, Dodgy Cures and ‘Diseasology’: The Spread of Coronavirus Misinformation*, THE GUARDIAN (Jan. 30, 2020, 10:23 PM EDT), <https://www.theguardian.com/world/2020/jan/31/bat-soup-dodgy-cures-and-diseasology-the-spread-of-coronavirus-bunkum>.

<sup>29</sup> Laurie Kellman, *Report: Pandemic Amped Up Anti-Semitism, Forced It Online*, ASSOCIATED PRESS NEWS (Apr. 7, 2021), <https://apnews.com/article/race-and-ethnicity-conspiracy-theories-israel-coronavirus-pandemic-financial-markets-32bc8c63d8759ded9c1f2cb8ca7301e0>.

<sup>30</sup> *Trump Makes ‘Deep State Department’ Joke*, WASH. POST. (Mar. 23, 2020, 10:06 AM PST), [https://www.washingtonpost.com/video/politics/trump-makes-deep-state-department-joke/2020/03/23/aaf8d7d3-53e7-4e77-83ff-964ee8ccff86\\_video.html](https://www.washingtonpost.com/video/politics/trump-makes-deep-state-department-joke/2020/03/23/aaf8d7d3-53e7-4e77-83ff-964ee8ccff86_video.html).

Contrary to popular belief,<sup>31</sup> conspiracy theories, however, are not the leading causes of vaccine hesitancy because people are often quite sensible and reasonable when it comes to matters of science.<sup>32</sup> Whether an individual remains hesitant about receiving a COVID-19 vaccine may depend on personal beliefs, informed by a background that is a totality of, for example, race (and its historical past), gender, education, life experience, and information consumption. This individualized background then forms a value system that informs the personal decision-making process as to whether to receive a COVID-19 vaccine.

This Article—part descriptive, part prescriptive, part normative, and featuring representative statistical studies on vaccine hesitancy<sup>33</sup>—aims to fill such an important gap in current scholarship by exploring, explaining, and expanding on the individualized decision-making process of whether to receive a COVID vaccine in four Parts. Part I describes the background information on the COVID-19 vaccine, including the timeline of its development and introduction to the American public, and how the vaccine is situated in FDA’s traditional and Emergency Use Authorization (EUA) processes when it comes to regulatory approval for public use.<sup>34</sup> Part II examines the reasons for COVID-19 vaccine hesitancy, with a particular focus on why racial disparities have continued to persist. Research reveals the leading cause<sup>35</sup> attributed primarily to government distrust,<sup>36</sup> whether it be rooted in historical trauma (from the now-infamous Tuskegee experiment, for example) or political affiliation (where vaccine willingness for several participants turns on which administration is promoting it). Further exacerbating this distrust and confusion are waves of misinformation promulgated on social media, including through “bot” accounts, that prey on the concerns and insecurities of an already vulnerable public. Thus, what

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<sup>31</sup> See, e.g., Zeynep Tufekci, *The Unvaccinated May Not Be Who You Think*, N.Y. TIMES (Oct. 15, 2021), <https://www.nytimes.com/2021/10/15/opinion/covid-vaccines-unvaccinated.html> (“[I]t seem[s] as if almost all the [vaccine] holdouts are conspiracy theorists and anti-science die-hards who think that Covid is a hoax, or that there is nothing we can do to reach more people. Real-life evidence, what there is, demonstrates that there’s much more to it.”).

<sup>32</sup> See Florence Momplaisir, Norrisa Haynes, Herve Nkwihoreze, Maria Nelson, Rachel M. Werner & John Jemmott, *Understanding Drivers of COVID-19 Vaccine Hesitancy Among Blacks*, CLINICAL INFECTIOUS DISEASES (Feb. 9, 2021), available in preprint at <https://pubmed.ncbi.nlm.nih.gov/33560346/>. People’s sensible and reasonable hesitancy is further explored in Part II *infra*.

<sup>33</sup> Needless to say, a *comprehensive* literature review paper of *all* statistical studies on COVID-19 vaccine hesitancy is certainly outside the scope of this law review Article written for the *Food and Drug Law Journal* Symposium. That topic, while unquestionably useful, is better fit for a paper in the *Nature* or *Science* magazine. See, e.g., Andy Tay, *How to Write a Superb Literature Review*, NATURE (Dec. 4, 2020), <https://www.nature.com/articles/d41586-020-03422-x>.

<sup>34</sup> See *infra* Part I.

<sup>35</sup> The Article uses the terms “reason(s)” and “cause(s)” interchangeably, in a general sense from an observational standpoint and not in the technical sense—like distinguishing “causation” from the statistical possibility of “correlation” (see generally Christian Borgelt & Rudolf Kruse, *Probabilistic Networks and Inferred Causation*, 18 CARDOZO L. REV. 2001, 2014–18 (1997)), or diving into the philosophy of “causation” that dates back to David Hume and Immanuel Kant.

<sup>36</sup> Relevant examples of this trust-deflected-into-distrust include J. Marion Sims’ unanesthetized fistula surgeries on enslaved Black women based on the stereotyped belief that Black people have a high tolerance for pain and the infamous Tuskegee Syphilis Study, the consequences of which we are still witnessing through the COVID-19 vaccine hesitancy. See, e.g., Keith Wailoo, *Opinion, Historical Aspects of Race and Medicine, The Case of J. Marion Sims*, 320 JAMA 1529, 1529 (2018); Durrenda Ojanuga, *The Medical Ethics of the ‘Father of Gynaecology’, Dr J Marion Sims*, 19 J. MED. ETHICS 28, 29 (1993); sources cited *infra* note 165.

makes COVID-19 different from earlier pandemics is the confluence of historical distrust of the government and government-recommended medical initiatives and the pervasive role of the Internet and social media in shaping public opinion.<sup>37</sup>

Part III explores *ex post* measures that have been employed to combat COVID-19 vaccine hesitancy (million-dollar lotteries for the vaccinated, for example) and how effective these methods have been. Part III also proposes other *ex ante* solutions that may work in light of the examined causes for vaccine hesitancy—trust-building messaging and addressing race-based distrust—including what governmental agencies like FDA and CDC can do to lessen the vaccine hesitancy.<sup>38</sup> Part IV, after having illuminated the vaccine hesitancy problem and possible solutions, briefly concludes with further thoughts for future avenues of research to shine a brighter light on the seemingly illusive shadow of vaccine hesitancy<sup>39</sup> and other related issues, such as treatment hesitancy.<sup>40</sup>

## II. VACCINE APPROVAL AND ROLLOUT

In order to supply COVID-19 vaccines to the general public, the vaccine companies must go through FDA, which essentially acts as what Justice Holmes would call “a brooding omnipresence in the sky.”<sup>41</sup> The urgency and severity of the COVID-19 pandemic necessitated expediting the usually lengthy vaccine testing, approval, and rollout process. In the United States, this meant utilizing FDA’s EUA system. This Part provides an overview of the EUA for the regulatory approval of the COVID-19 vaccine as compared to the traditional vaccine authorization process and a timeline of the key developmental milestones as they took place over the course of the pandemic. To put it another way, this Part, by nature, is mostly descriptive, with Part I.A discussing what the law is and Part I.B detailing what the facts (including dates) are.

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<sup>37</sup> See *infra* Part II.

<sup>38</sup> See *infra* Part III.

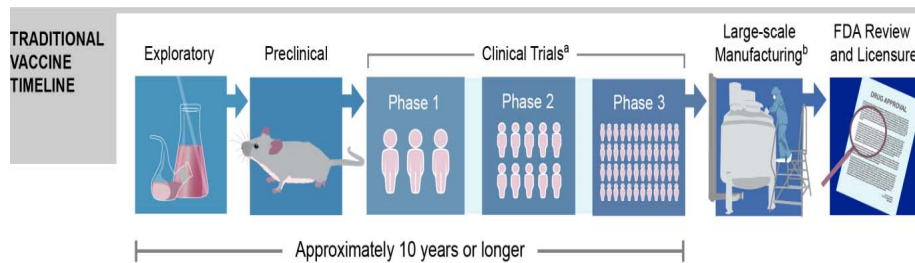
<sup>39</sup> See also, e.g., Vincent Blasi, *Reading Holmes Through the Lens of Schauer: The Abrams Dissent*, 72 NOTRE DAME L. REV. 1343, 1343 (1997) (“Even the best scholars rarely persuade. Mostly, they illuminate. They make us more discerning readers and interlocutors.”); Shari Motro, *Scholarship Against Desire*, 27 YALE J.L. & HUMAN. 115, 126 (2015) (Scholars “use their experience . . . in combination with the meta awareness we access through words to shine a light on truths that are knowable *and* to intimate something ineffable.”); Caprice L. Roberts, *Unpopular Opinions on Legal Scholarship*, 50 LOY. U. CHI. L.J. 365, 366 (2018) (“[S]cholars wish to shine a light on injustices and legal conundrums.”); cf. Robin West, *The Ethics of Normative Legal Scholarship*, 101 MARQ. L. REV. 981, 985 (2018) (“The goal or purpose of [Justice Cardozo’s and Professor Prosser’s] writing was not primarily to add to our store of knowledge about the world, or to shine a light on truth’s shadow, or to bring us closer to it, or to approximate it, or to claim it.”).

<sup>40</sup> See *infra* Part IV.

<sup>41</sup> *S. Pac. Co. v. Jensen*, 244 U.S. 205, 222 (1917) (Holmes, J., dissenting), *superseded by statute as stated in*, *Dir., Off. of Workers’ Comp. Programs v. Perini N. River Assocs.*, 459 U.S. 297, 306 (1983). See generally OLIVER WENDELL HOLMES JR., *THE COMMON LAW* 1 (1881) (recognizing the need for law to adapt to the “felt necessities of the time”). *But see*, e.g., H.L.A. HART, *THE CONCEPT OF LAW* 155–212 (2d ed. 1964) (criticizing Holmes’ predictive theory of law and arguing that judges use legal rules—not as data to predict but rather—to *guide* their decisions).

### A. *Traditional v. Emergency Use Authorization*

While the timeline to develop a vaccine from scratch can vary, it generally takes several years before a new vaccine will be administered to the general public.<sup>42</sup> As an initial matter, it typically takes over ten years to conduct exploratory, preclinical, and clinical trials of a new vaccine, as shown in the following Figure.<sup>43</sup>



A Phase 1 clinical trial typically includes fewer than 100 volunteers to test the basic safety profile of a new product, including by testing different dosage levels.<sup>44</sup> Phase 2 clinical trials might include between a few dozen and hundreds of volunteers to test the efficacy and short term side effects of a vaccine, to assess potential risks and benefits.<sup>45</sup> Phase 3 clinical trials are only performed when earlier trials suggest the product will be effective at its intended use. These later-stage trials typically involve several hundred to thousands of volunteers, including people with higher risk of infection, in order to determine more conclusively whether a product is safe and effective.<sup>46</sup>

In the United States, the Center for Biologics Evaluation and Research (CBER)—an arm of FDA—is responsible for regulating biological products, including vaccines, for use in humans. Under the federal Public Health Service Act (PHS), biological products must be licensed before they are introduced into interstate commerce.<sup>47</sup> PHS and specific provisions of the Federal Food, Drug, and Cosmetic Act give CBER the authority to issue biological licenses, suspend them when products present a danger to public health, procure and produce products in public health emergencies, and perform other regulatory and enforcement services under the gamut of biological products.<sup>48</sup> CBER defines a biological product as safe based on the assessment of “reasonable

<sup>42</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, THE JOURNEY OF YOUR CHILD’S VACCINE, <https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine-h.pdf> (“Before a new vaccine is ever given to people, extensive lab testing is done that can take several years. Once testing in people begins, it can take several more years before clinical studies are complete and the vaccine is licensed.”).

<sup>43</sup> U.S. GOV’T ACCOUNTABILITY OFF., GAO 21-319, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES 3 (Feb. 2021), <https://www.gao.gov/assets/gao-21-319.pdf> [hereinafter GAO, OPERATION WARP SPEED].

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

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> 42 U.S.C. § 262 (a)(1)(A).

<sup>48</sup> *Center for Biologics Evaluation and Research (CBER) Responsibilities Questions and Answers*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/center-biologics-evaluation-and-research-cber-responsibilities-questions-and-answers> (last visited Sept. 23, 2021).



risks, given the patient's condition, the magnitude of the benefit expected, and the alternatives available."<sup>49</sup> Under the traditional approval process, after clinical trials of a new vaccine are complete, FDA and CBER review an application for licensure to ensure safety and efficacy before final approval. However, because the safety of the manufacturing process is part of the licensure criteria, at least some manufacturing of a new product can begin before a product is officially approved.<sup>50</sup>

Statutorily, Emergency Use Authorization for a new product or treatment may only be issued if the product satisfies Section 564 of the Federal Food, Drug, and Cosmetic Act.<sup>51</sup> EUA gives the Secretary of Health and Human Services (HHS)—a political appointee<sup>52</sup>—the authority to authorize unapproved drugs and unapproved use of an approved drug. In short, the HHS Secretary declares the public health emergency, and circumstances exist justifying the EUA of drugs or biologics during the emergency; nevertheless, it is FDA that actually issues the authorization. Specifically, an EUA may be issued to treat a life-threatening disease or condition if, after consultation with various other officials, the Secretary concludes “(2) that, based on the *totality of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—(A) the product may be effective in diagnosing, treating, or preventing*” the condition, and (B) “*the known and potential benefits of the product . . . outweigh the known and potential risks of the product . . .*,” and (3) there are “*no adequate, approved, and available alternative[s]*.”<sup>53</sup> The evidentiary criteria, as highlighted here, might be considered relatively low.<sup>54</sup> They are based on a reasonable belief standard of a possibility of efficacy, and only a basic cost-benefit assessment of risk-to-benefit. The EUA process was incorporated into the Operation Warp Speed program—the Trump Administration's plan for expediting COVID-19 vaccine development.

Operation Warp Speed proposed modifying the standard, linear, vaccine approval process by both 1) expediting the duration of clinical trial phases, and 2) allowing for parallel processes to take place. Specifically, the plan proposed condensing the typical ten-year clinical trial phase to approximately ten months, as shown in the following Figure.<sup>55</sup> Large-scale manufacturing could take place during clinical trials, and at a potentially higher rate than with the traditional procedure, so that a significant number of doses would be ready for distribution upon EUA issuance.

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<sup>49</sup> *About CBER*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/about-cber> (last visited Sept. 23, 2021).

<sup>50</sup> GAO, OPERATION WARP SPEED, *supra* note 43, at 3 n.b.

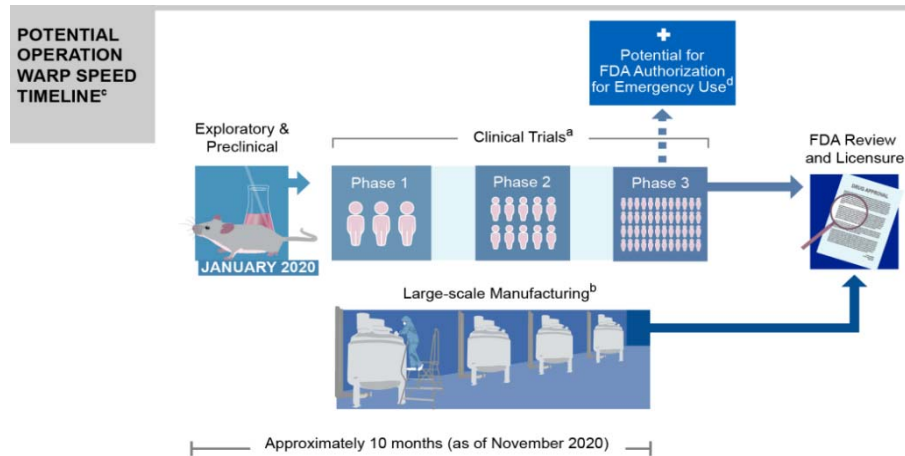
<sup>51</sup> 21 U.S.C. § 360bbb-3. *See generally, e.g.*, Mason M. Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 696–706 (2020).

<sup>52</sup> *See* Reorganization Plan No. 1 of 1953, 67 Stat. 631 (codified in 42 U.S.C. § 3501-1) (“There shall be at the head of the Department a Secretary of Health, Education, and Welfare . . . who shall be appointed by the President by and with the advice and consent of the Senate . . .”).

<sup>53</sup> 21 U.S.C. § 360bbb-3(c) (emphases added).

<sup>54</sup> Aris Angelis & Jonathan Darrow, *Safeguarding Evidence-Based Decision Making in the FDA for COVID-19 Vaccines*, 39 VACCINE 2328, 2328 (2021).

<sup>55</sup> GAO, OPERATION WARP SPEED, *supra* note 43, at 3 fig. 1; *see also* Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *Regulatory Reactivity: FDA and the Response to COVID-19*, 76 FOOD & DRUG L.J. 318 (2021) (describing FDA's adoption of EUAs for COVID-19 and the evolution of the Coronavirus Treatment Action Plan (CTAP), an emergency program for accelerating the development of therapeutics for COVID-19).



Further, the EUA could issue during Phase 3 clinical trials. FDA issued guidance on the proposed process in June 2020, containing its non-binding recommendations.<sup>56</sup> In it, FDA stated that, despite the need for an expedited process, “the goal of development programs should be to pursue traditional approval via direct evidence of vaccine efficacy,” but also outlined what it described as a more “seamless” approach, similar to that discussed above.<sup>57</sup> Also in this guidance, FDA “encourage[d],” but did not require, “the inclusion of diverse populations in all phases of vaccine clinical development.”<sup>58</sup> It emphasized, however, that safety considerations in the development of a COVID-19 vaccine “should be no different than for other preventive vaccines for infectious diseases.”<sup>59</sup>

FDA also issued guidance related to EUAs specifically in the context of COVID-19 vaccines.<sup>60</sup> In it, FDA moderately increased the evidentiary standard for EUA issuance. It specified that it would only issue an EUA based on data from “at least one well-designed Phase 3 clinical trial” showing that the vaccine’s benefits outweigh its risks, and demonstrating the vaccine’s safety and efficacy in a “clear and compelling

<sup>56</sup> U.S. FOOD & DRUG ADMIN., DEVELOPMENT AND LICENSURE OF VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY (June 2020), <https://www.fda.gov/media/139638/download> [hereinafter FDA, DEVELOPMENT AND LICENSURE]; see also Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA’s Role in America’s Covid-Testing Debacle*, 130 YALE L.J. F. 78, 78 (2020) (arguing that FDA lacks authority to require EUAs for COVID-related laboratory-developed tests and that FDA’s intervention, in key respects, just replicates protections that the Clinical Laboratory Improvement Amendments of 1988 has already provided); Paul D. Clement & Laurence H. Tribe, White Paper, *Laboratory Testing Services, as the Practice of Medicine, Cannot Be Regulated as Medical Devices*, AM. CLINICAL LAB. ASS’N (Jan. 6, 2015), <https://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf> (positing that FDA’s regulation of laboratory-developed tests—which are part of the practice of medicine—as medical devices interferes with the practice of medicine and its use of guidance documents circumvents the Administrative Procedure Act’s requirements). See generally Kevin Michael Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507 (2011).

<sup>57</sup> FDA, DEVELOPMENT AND LICENSURE, *supra* note 56, at 9.

<sup>58</sup> *Id.* at 11.

<sup>59</sup> *Id.* at 15.

<sup>60</sup> U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY (Mar. 31, 2022), <https://www.fda.gov/media/142749/download> [hereinafter FDA, EMERGENCY USE AUTHORIZATION].

manner.”<sup>61</sup> The guidance also outlined the specific categories of information that would be required for submission of an EUA application, including safety data, dosage, chemical, and manufacturing information.<sup>62</sup> It also emphasized the need for ongoing trials and efforts to file for full FDA approval through biologics licensure even after an EUA has issued.<sup>63</sup>

### B. Vaccine Development Timeline<sup>64</sup>

On March 11, 2020, the WHO officially declared the novel coronavirus that had begun spreading months before in late 2019 as a global pandemic. The first clinical trials of a COVID-19 vaccine were underway by the end of the month.<sup>65</sup> Given the global urgency of developing a vaccine, there was a high level of collaboration amongst scientists and institutions: for example, Chinese scientists in early January 2020 posted on an open-access site COVID-19’s genetic sequence, which showed an 89% similarity with SARS-related coronaviruses.<sup>66</sup> By December 2020, 214 vaccine projects were under development.<sup>67</sup> This timeline will focus on the four primary vaccines available for public use: Johnson & Johnson-Janssen (“J&J”), Moderna’s Spikevax, Pfizer-BioNTech’s (“Pfizer”) Comirnaty, and AstraZeneca—the last of which is the U.K.’s and not (yet) available in the United States. On May 15, 2020, the U.S. government announced Operation Warp Speed, a partnership between the Department of Defense (DoD) and HHS, which aimed to produce 300 million doses of COVID-19 vaccines by early 2021.<sup>68</sup> Six days later, the United States joined the effort that was already underway including the University of Oxford and AstraZeneca. By July 2020, AstraZeneca and another developer, CanSino Biologics, would release data revealing immune responses in volunteers injected with their products in early trials.

On July 22, 2020, the federal government announced its partnership with Pfizer to deliver 100 million doses of their vaccine by the end of the year. Moderna, Inc. was the first company to enter large-scale human trials for its vaccine, which had shown efficacy in its earliest trial phases in mid-July 2020 and entered Phase 3 clinical trials on July 27, 2020. The federal government also entered an agreement with Moderna on August 11, 2020 to deliver 100 million doses of its vaccine. Pfizer and J&J would follow Moderna into Phase 3 trials in late summer and early fall. On September 6, 2020, AstraZeneca halted its Phase 3 trials when a patient exhibited neurological

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<sup>61</sup> *Id.* at 4.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 12.

<sup>64</sup> Unless otherwise noted, dates and data in Part I.B are derived from the timelines of *The American Journal of Managed Care*, <https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020> and <https://www.ajmc.com/view/a-timeline-of-covid-19-vaccine-developments-in-2021>.

<sup>65</sup> GAO, OPERATION WARP SPEED, *supra* note 43, at 2.

<sup>66</sup> Jon Cohen, *Chinese Researchers Reveal Draft Genome of Virus Implicated in Wuhan Pneumonia Outbreak*, SCIENCEINSIDER (Jan. 11, 2020), <https://www.science.org/content/article/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak>.

<sup>67</sup> Hugo Garcia Tonioli Defendi, Luciana da Silva Madeira & Suzana Borschiver, *Analysis of the COVID-19 Vaccine Development Process: An Explanatory Study of Accelerating Factors and Innovative Environments*, 17 J. PHARM. INNOVATION 555 (2021); McCarthy, *supra* note 7, at 117.

<sup>68</sup> GAO, OPERATION WARP SPEED, *supra* note 43, at 2. The United States fell short of this goal. *Id.*

symptoms. J&J similarly paused its trials on October 11, 2020 due to safety concerns. Both companies restarted trials on October 23, 2020.

On November 9, 2020—just several days after the 2020 presidential election—Pfizer published data showing that its vaccination was more than 90% effective at preventing severe disease,<sup>69</sup> with Moderna following suit to say that its vaccine reduced risks of infection by 94.5% on November 16, 2020.<sup>70</sup> That same day, HHS Secretary Alex Azar stated that FDA would move “as quickly as possible” to authorize both vaccines under the EUA. Pfizer was the first to submit its EUA application, on November 20, 2020, and the FDA advisory panel recommended approval on December 10, 2020, formally approving it the next day.<sup>71</sup> Similarly, the FDA advisory panel recommended approval of Moderna’s vaccine on December 17, 2020, issuing its approval the next day.<sup>72</sup> Meanwhile, in early December 2020, U.K. doctors announced the first reported mutated strain of COVID-19.<sup>73</sup>

Throughout January 2021, states and the federal government struggled with the logistics of organizing the massive distribution campaign for the approved vaccines. There was confusion and inconsistency regarding eligibility, eligible individuals struggled to find a dose, and thousands of doses were going unused and to waste. At the same time, dangerous variants like B.1.1.7 out of the U.K. began circulating, and vaccines were tested for efficacy against the mutating virus. By January 26, 2021, Moderna had already begun to develop booster shots to combat COVID-19’s continuing mutations. With more and more people starting to be vaccinated, new cases of allergic reactions and, in the case of Moderna, anaphylactic reactions, began emerging, but remained minimal.

It was not until January 29, 2021 that J&J revealed that its one-shot vaccine was effective in preventing serious disease, but less so than Pfizer and Moderna; it submitted its EUA application on February 5, 2021. The FDA advisory panel recommended emergency authorization for the J&J vaccine on February 26, 2021, and

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<sup>69</sup> Press Release, Pfizer, Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study, Pfizer (Nov. 9, 2020, 6:45 AM), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against>.

<sup>70</sup> Press Release, Moderna, Moderna’s COVID-19 Vaccine Candidate Meets its Primary Efficacy Endpoint in the First Interim Analysis of the Phase 3 COVE Study, Moderna (Nov. 16, 2020, 6:56 AM), <https://investors.modernatx.com/news/news-details/2020/Modernas-COVID-19-Vaccine-Candidate-Meets-its-Primary-Efficacy-Endpoint-in-the-First-Interim-Analysis-of-the-Phase-3-COVE-Study/default.aspx>. Although AstraZeneca announced its vaccine as also being 90% effective on November 23, 2020, and despite early involvement in its development, FDA has yet to approve its use in the United States. The U.K. approved its use under emergency measures on December 30, 2020.

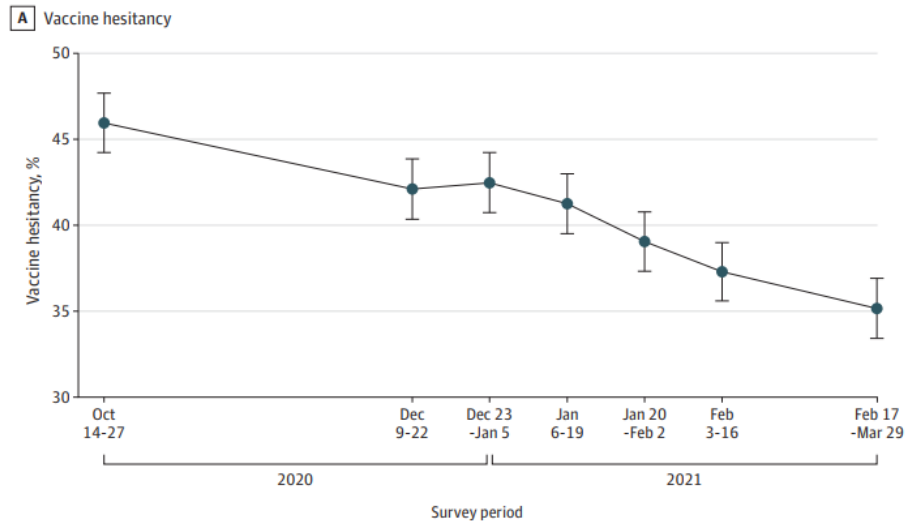
<sup>71</sup> News Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

<sup>72</sup> News Release, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>.

<sup>73</sup> Jacqui Wise, *COVID-19: New Coronavirus Variant Is Identified in UK*, 371 *BMJ* m4857, m4857 (2020).

as with the previous vaccines, it was authorized the next day.<sup>74</sup> The third vaccine with EUA began distribution just two days later.

After a staggered rollout, the new Biden Administration announced on March 3, 2021 that every U.S. adult would become eligible to receive a vaccine by the end of May at the latest. Despite rapidly expanding eligibility rules, distribution continued to be plagued by uneven access and ongoing resistance to vaccines. A survey found that the COVID-19 vaccine hesitancy rate was 46% in October 2020, which declined slowly to 35.2% in March 2021, as shown in the following Graph.<sup>75</sup>



There are quite a few ways to slice and dice these statistics and dive deeper into the numbers to better understand the hesitancy issue<sup>76</sup>: by race, by gender, by age, by political affiliation, and by education level.<sup>77</sup> Generally, higher rate of vaccine hesitancy is observed in people of color, especially Black Americans, as compared to white, in women as compared to men, in young adults as compared to elders, in Republicans as compared to Democrats, and in those with a lower level of education.<sup>78</sup> When two categories are combined together, however, the numbers may appear different. Take politics and gender together, for example: at least as early into the vaccine rollout as March 11, 2021, polling reported that 41% of Republicans—but 49% of Republican men—declared no intention to receive a COVID-19 vaccine.<sup>79</sup>

<sup>74</sup> News Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021), <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

<sup>75</sup> Daly et al., *supra* note 11, at 2398. The Graph was reproduced from Daly et al.'s article.

<sup>76</sup> See, e.g., *Flowers v. Mississippi*, 139 S. Ct. 2228, 2247 (2019) (“One can slice and dice the statistics . . . [b]ut any meaningful comparison yields the same basic assessment . . .”); see also *United States v. Members of Est. of Boothby*, 16 F.3d 19, 21 (1st Cir. 1994) (“There are, of course, several ways to skin a cat . . .”).

<sup>77</sup> The first three categories may be considered physical characteristics, whereas the latter two are non-physical characteristics, although there could be a small amount of overlap.

<sup>78</sup> See *infra* Part II.

<sup>79</sup> Laura Santhanam, *Politics Still Drives How Americans Feel About COVID Response, One Year in*, PBS (Mar. 11, 2021), <https://www.pbs.org/newshour/politics/politics-still-drives-how-americans-feel->

With respect to patent protection—or more precisely, patent waiver—for COVID-19 vaccines, the United States initially joined a number of developed countries in March 2021 to block India’s and South Africa’s patent waiver request submitted to the World Trade Organization (WTO),<sup>80</sup> which aims to expedite COVID vaccine manufacture in developing countries and alleviate the worsening pandemic.<sup>81</sup> But after global pressure intensified, the Biden Administration in May 2021 recanted, stating that “[t]he US supports the waiver of IP protections on COVID-19 vaccines to help end the pandemic and we’ll actively participate in . . . negotiations [at the WTO] to make that happen.”<sup>82</sup> Nonetheless, wealthy countries (such as the U.K. and the European Union countries) and the pharmaceutical industry remain in opposition to the patent-waiver proposal.<sup>83</sup> This demonstrates that, at least in the United States, patent is political.<sup>84</sup> And it is just one piece of the larger puzzle of vaccine access. Waiving COVID-19 patent would, by definition, simply waive the legal right to exclude others from making, using, and selling the COVID-19 vaccine, without necessarily bringing along with it the technical know-hows and manufacturing equipment to effectively produce COVID-19 vaccines.<sup>85</sup> For instance, the technology behind the mRNA vaccine is so incredibly complicated from a technical standpoint that no laboratory in India is capable of producing the mRNA vaccine even without any IP protection on it.

FDA approved booster shots from Pfizer in September 2021, as well as Moderna and J&J in October 2021.<sup>86</sup> Soon after, CDC recommended that vaccinated people

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about-covid-response-one-year-in (PBS News Hour, NPR, and Marist polled 1,227 adults and 1,082 registered voters and found, *inter alia*, that “30 percent of Americans said they do not plan to get vaccinated . . .”).

<sup>80</sup> See generally Matiangai Sirleaf, *Entry Denied: COVID-19, Race, Migration, and Global Health*, FRONTIERS IN HUM. DYNAMICS (Dec. 15, 2020) (discussing WHO’s creation and missions).

<sup>81</sup> Haochen Sun, *Patent Responsibility*, 17 STAN. J. CIV. RTS. & CIV. LIBERTIES 321, 323 (2021).

<sup>82</sup> *Id.*; Matiangai Sirleaf, *Disposable Lives: COVID-19, Vaccines, and the Uprising*, 121 COLUM. L. REV. F. 71, 93 (2021) (quoting Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver, Off. of the U.S. Trade Representative (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>).

<sup>83</sup> Sirleaf, *Disposable*, *supra* note 82, at 93.

<sup>84</sup> See, e.g., *United States v. Arthrex*, 141 S. Ct. 1970, 1996 (2021) (Breyer, J., concurring in judgment, dissenting in part) (“The nature of the PTAB . . . calls for greater, not less, independence from those potentially influenced by political factors.”); Jasper L. Tran, *Unconstitutional Appointment of Patent Death Squad*, GEO. WASH. L. REV. ON THE DOCKET (June 29, 2021). For the historical background on the politics of the patent system, see generally Christopher Beauchamp, *The First Patent Litigation Explosion*, 125 YALE L.J. 848, 924–33 (2016).

<sup>85</sup> See, e.g., GARY LOCKE, ANDREI IANCU & DAVID J. KAPPOS, CTR. FOR STRATEGIC & INT’L STUD., THE SHOT HEARD AROUND THE WORLD: THE STRATEGIC IMPERATIVE OF U.S. COVID-19 VACCINE DIPLOMACY 4 (Nov. 2021), <https://www.csis.org/analysis/shot-heard-around-world> (“The truth is that every qualified manufacturing facility on the planet is churning out as many Covid-19 shots as is safely possible. . . . Waiving IP protections would not lead to the manufacture of a single additional dose of a vaccine. One key reason is that there is currently no capacity to make more; production facilities are running at full tilt, and the supply of key ingredients in the manufacturing process has already been fully tapped.”). For example, the fact that Moderna recently lost its Federal Circuit appeal on its COVID-19 vaccine patent does not mean that companies are now racing to produce mRNA vaccines in droves. See *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1377 (Fed. Cir. 2021) (affirming the PTAB’s obviousness finding).

<sup>86</sup> See News Release, U.S. Food & Drug Admin., FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations (Sept. 22, 2021), <https://www.fda.gov/news-events/press->

should receive a booster shot every six months.<sup>87</sup> In December 2021, Pfizer announced that its vaccine protects against COVID-19's Omicron variant.<sup>88</sup> Considering COVID-19's nature, high transmission rate, level of lethality, how quickly it mutates,<sup>89</sup> and the frequency of needing a vaccine booster shot, the public should be prepared to live with COVID-19—not unlike its seasonal flu cousin in many respects<sup>90</sup>—for a very long time, with no end in sight.<sup>91</sup> Therefore, COVID vaccines, like flu vaccines, are likely to become a permanent part of a public health approach to limiting its impact.

## II. VACCINE DISTRUST AND ITS CAUSES

After coming out as a leader in rolling out COVID-19 vaccines to the general population,<sup>92</sup> vaccine uptake in the United States has dramatically decreased to such a beleaguered pace that it threatens the progress on pandemic recovery. Even though two-thirds of the U.S. population have already received at least one dose of a COVID-19 vaccine as of mid-October 2021, vaccinating 90%—which experts now estimate would be necessary to reach herd immunity—is appearing less and less likely.<sup>93</sup> The

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announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations; News Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines (Oct. 20, 2021), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines> (allowing EUAs for Moderna's booster at least six months, and J&J's booster at least two months, after their primary vaccination and for "mix and match" booster).

<sup>87</sup> See *Staying Up to Date with COVID-19 Vaccines Including Boosters*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>.

<sup>88</sup> See Press Release, Pfizer, Pfizer and BioNTech Provide Update on Omicron Variant (Dec. 8, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant>.

<sup>89</sup> Michael Robillard, *On the Dangers of Big COVID*, QUILLETTE (July 3, 2021), <https://quillette.com/2021/07/03/on-the-dangers-of-big-covid/>.

<sup>90</sup> See, e.g., Momplaisir et al., *supra* note 32 (quoting an interviewee for stating: "I don't want to put anything in me even with a 10% chance that I might get [COVID-19] because I have underlying condition, so I don't know if that's going to make me sick, they don't know if you're going to get [COVID-19], like . . . how you could still get the flu even if you get a flu shot."); Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153 (2017); McCarthy, *supra* note 7. On the one hand, for instance, the influenza A viruses, which cause what people commonly refer to as the seasonal flu, have twenty-nine variants, and the predominance of one or any of them changes from year to year. This has led to the recommendation that people receive a flu vaccine every year. On the other hand, Republicans often liken COVID-19 to the season flu—in terms of their symptoms, complications, and how they spread, for example—to downplay COVID-19 as just another flu variant. See *Similarities and Differences between Flu and COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm>.

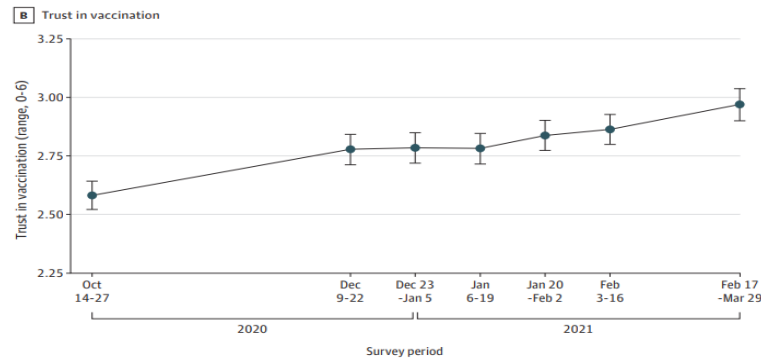
<sup>91</sup> See, e.g., Itay Ravid, Jordan M. Hyatt & Steven L. Chanenson, *A Dose of Dignity: Equitable Vaccination Policies for Incarcerated People and Correctional Staff During the COVID-19 Pandemic*, 95 S. CAL. L. REV. POSTSCRIPT 1, 22 (2021) ("COVID-19 is unlikely to fully disappear in the foreseeable future" because "it is mutating and as the new increase in cases with the spread of the Delta variant reveals, it poses challenges for vaccine makers striving to avoid future outbreaks.").

<sup>92</sup> By February 2021, the United States was administering vaccines "at a faster rate than any country worldwide." AJMC Staff, *A Timeline of COVID-19 Vaccine Developments in 2021*, AM. J. MANAGED CARE (June 3, 2021), <https://www.ajmc.com/view/a-timeline-of-covid-19-vaccine-developments-in-2021>. But the United States being in the lead did not last long.

<sup>93</sup> Early estimates for the original COVID-19 suggested achieving a 67% vaccination rate would suffice for herd immunity (also known as population immunity or community immunity), but with the prevalence of its various variants and how quickly it mutates into new strains, herd immunity may now

question whether people, or enough people, would take a COVID-19 vaccine when one was developed has been a concern since the early days of the pandemic.<sup>94</sup> Those concerns have borne out.

A survey, measuring public trust in vaccination by using a ranking from 0 (no trust in development/approval processes) to 6 (full trust in processes), found such a ranking slowly raising from 2.6 in October 2020 to 3.0 in March 2021, as shown in the following Graph.<sup>95</sup>



To put it another way, as of April 14, 2021, CDC estimates that at least some level of hesitancy exists across all fifty states, ranging from just under 3% of people to over 25% of people in any given area expressing an unwillingness to receive the COVID-19 vaccine.<sup>96</sup>

COVID-19 may not be the last pandemic that we will face—both domestically and internationally. It is not the only public crisis we are facing (e.g., climate change<sup>97</sup>), as others are certain to follow. Lessons from the past, including those learned from the

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require 90% vaccination rate. *See generally* Haley E. Randolph & Luis B. Barreiro, *Herd Immunity: Understanding COVID-19*, 52 IMMUNITY 737 (2020); Dorit Rubinstein Reiss, *Herd Immunity and Immunization Policy: The Importance of Accuracy*, 94 OR. L. REV. 1, 7–20 (2015).

<sup>94</sup> Philip Ball, *Anti-Vaccine Movement Could Undermine Efforts to End Coronavirus Pandemic, Researchers Warn*, NATURE (May 13, 2020), <https://www.nature.com/articles/d41586-020-01423-4>; Lauren Neergaard & Hannah Fingerhut, *AP-NORC Poll: Half of Americans Would Get a COVID-19 Vaccine*, ASSOCIATED PRESS (May 27, 2020), <https://apnews.com/article/donald-trump-us-news-ap-top-news-politics-virus-outbreak-dacdc8bc428dd4df6511bfa259cfc44>.

<sup>95</sup> Daly et al., *supra* note 11, at 2398. The Graph was reproduced from Daly et al.'s article.

<sup>96</sup> *Estimates of Vaccine Hesitancy*, *supra* note 14; *see also* Jagdish Khubchandani, Sushil Sharma, James H. Price, Michael J. Wiblehauser, Manoj Sharma & Fern J. Webb, *COVID-19 Vaccination Hesitancy in the United States: A Rapid National Assessment*, 46 J. COMMUNITY HEALTH 270, 273 (2021) (finding that 22% of participants in a survey conducted at the end of 2020 were hesitant to receive a vaccine).

<sup>97</sup> *See, e.g.*, Am. Elec. Power Co. v. Connecticut, 564 U.S. 410, 417 & n.2 (2011) (“Acknowledging that not all scientists agreed on the causes and consequences of the rise in global temperatures, . . . EPA concluded that ‘compelling’ evidence supported the ‘attribution of observed climate change to anthropogenic’ emissions of greenhouse gases . . . . The Court, we caution, endorses no particular view of the complicated issues related to carbon-dioxide emissions and climate change.”); Nat’l Rev., Inc. v. Mann, 140 S. Ct. 344, 348 (2019) (Alito, J., dissenting) (“Climate change has staked a place at the very center of this Nation’s public discourse. Politicians, journalists, academics, and ordinary Americans discuss and debate various aspects of climate change daily—its causes, extent, urgency, consequences, and the appropriate policies for addressing it.”).



public's perception and treatment of the COVID-19 vaccine, may inform and better equip us to deal with future pandemics,<sup>98</sup> including the extent we could eliminate, or at least minimize, disparities and inequalities related to vaccine hesitancy. Understanding the resistance to vaccination can better equip us to deal with not only future pandemics but also other crises where a collective response is necessary to protect the public at large: an increasingly difficult ask.

Before diving into the reasons for COVID-19 vaccine hesitancy, it is important to extract from the past the historical lessons we have learned from pre-COVID vaccine hesitancy.<sup>99</sup> Research conducted in developed countries reveals five main individual-level determinants of vaccine hesitancy<sup>100</sup>: 1) Confidence (trust in vaccine's effectiveness and safety, vaccine administrators, and their motives)<sup>101</sup>; 2) Complacency (perceiving infection risks as low and vaccination as unnecessary)<sup>102</sup>; 3) Convenience / Constraints (structural or psychological barriers to converting vaccination intentions into vaccine uptake)<sup>103</sup>; 4) Risk Calculation (perceiving higher risks related to vaccination than the infection itself)<sup>104</sup>; and 5) Collective Responsibility (willingness to vaccinate to protect others through herd immunity).<sup>105</sup> It is interesting to observe that COVID-19 vaccines see these five hesitancy determinants again, but in different forms, as further discussed below in this Part. If

<sup>98</sup> Cf. News Release, World Health Org., WHO Recommends Groundbreaking Malaria Vaccine for Children at Risk (Oct. 6, 2021), <https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk> (WHO Regional Director for Africa, Dr. Matshidiso Moeti, announced that “[w]e have long hoped for an effective malaria vaccine and now for the first time ever, we have such a vaccine recommended for widespread use.”).

<sup>99</sup> See Charles Shey Wiysonge, Duduzile Ndwandwe, Jill Ryan, Anelisa Jaca, Oumarou Batouré, Blanche-Philomene Melanga Anya & Sara Cooper, *Vaccine Hesitancy in the Era of COVID-19: Could Lessons from the Past Help in Divining the Future?*, 18 HUM. VACCINES & IMMUNOTHERAPEUTICS 1 (Mar. 8, 2021).

<sup>100</sup> These five determinates are commonly referred to as the 5C model drivers of vaccine hesitancy. *Id.* at \*2.

<sup>101</sup> Heidi J. Larson, Richard M. Clarke, Caitlin Jarrett, Elisabeth Eckersberger, Zachary Levine, Will S. Schulz & Pauline Paterson, *Measuring Trust in Vaccination: A Systematic Review*, 14 HUM. VACCINES & IMMUNOTHERAPEUTICS 1599 (2018).

<sup>102</sup> Noni E. MacDonald & the SAGE Working Group on Vaccine Hesitancy, *Vaccine Hesitancy: Definition, Scope and Determinants*, 33 VACCINE 4161 (2015).

<sup>103</sup> Cornelia Betsch, Philipp Schmid, Dorothee Heinemeier, Lars Korn, Cindy Holtmann & Robert Böhm, *Beyond Confidence: Development of a Measure Assessing the 5C Psychological Antecedents of Vaccination*, 13 PLOS ONE e0208601 (2018).

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

<sup>105</sup> Cornelia Betsch, Katrine Bach Habersaat, Sergei Deshevoi, Dorothee Heinemeier, Nikolay Briko, Natalia Kostenko, Janusz Kocik, Robert Böhm, Ingo Zettler, Charles Shey Wiysonge, Ève Dubé, Arnaud Gagneur, Elisabeth Botelho-Nevers, Amandine Gagneux-Brunon & Jonas Sivelä, *Sample Study Protocol for Adapting and Translating the 5C Scale to Assess the Psychological Antecedents of Vaccination*, 10 BMJ OPEN e034869 (2020); see also MORRIS R. COHEN, *THE FAITH OF A LIBERAL* 132 (1946) (“If human beings could be persuaded that the common enemies of humanity are disease, . . . ignorance, and superstition, many of the differences that cause conflicts would be minimized; but the inability of men [and women] to take a long-range view and to subordinate what seem immediate group and national advantages to the greater common good prevents the realization of the ancient ideal of peace through a world federation.”). To the extent a collective responsibility is essential to public health, this responsibility should run both ways: If the public benefits from vaccines, the public, and not the vaccinated, should bear the economic costs incurred as a result of vaccinations. To that end, Congress ought to enact some kind of compensation plan for those who suffer side effects and adverse reactions related to vaccines.

the same symptom (e.g., vaccine hesitancy) keeps reoccurring, it may be wise to follow the doctor's order and critically examine the root causes to cure (or at least treat) the disease once and for all and to (hopefully) prevent future reoccurrences.<sup>106</sup>

It would be fair to say that vaccinated individuals, like happy families, are all alike; each unvaccinated individual is hesitant for her own reason.<sup>107</sup> To wit, the causes for COVID-19 vaccine hesitancy are varied, throwing into sharp relief not only the highly politicized veneer that has taken shape around public discourse concerning the pandemic, but also the painful realities of health inequities in the United States, including historic trauma and systemic abuses in medical access and treatment.<sup>108</sup> This Part will showcase and illuminate some representative examples of the most prevalent trends in vaccine hesitancy,<sup>109</sup> with a particular eye toward the role governmental bodies have taken in shaping public perception and information dissemination.

### A. *Vaccine Safety and Efficacy Concerns*

Vaccines, like truth and beauty, do not always *give*.<sup>110</sup> The safety and efficacy of the COVID-19 vaccine continues to be a concern for many, even over a year into the post-trial administration. Even though major media outlets have largely reported that the vaccines have proven safe and effective, misinformation continues to spread in both mainstream and social media outlets.<sup>111</sup> A study reviewing several studies of social media posts measuring the amount of misleading content and audience reach concluded that “extensive anti-vaccine content is frequently shared across social media.”<sup>112</sup> Interestingly, content that treats vaccines negatively appears to be viewed,

<sup>106</sup> Who couldn't be cited here? See PIERRE SCHLAG, *THE ENCHANTMENT OF REASON* 153 n.11 (1998) (“Who could be cited here? Who couldn't?”); cf. Orin S. Kerr, *A Theory of Law*, 16 GREEN BAG 2D 111, 111 (2012) (“Some claims are so obvious or obscure that they have not been made before.”).

<sup>107</sup> Cf. LEO TOLSTOY, *ANNA KARENINA* 1 (1877) (page 1 of any edition) (“Happy families are all alike; each unhappy family is unhappy in its own way.”); *Bowen v. Gilliard*, 483 U.S. 587, 633 (1987) (Brennan, J., dissenting) (“Contemporary life offers countless ways in which family life can be fractured and families made unhappy.”); *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 461 (2015) (Breyer, J., concurring) (“What may be true of happy families . . . or of roses . . . does not hold true in elections of every kind.”). That is, all vaccinated people are alike, regardless of their reasoning, because at the end of the day they are protected via vaccination. As to their reasoning, it is possible that they all share the same reason for vaccination, like how all happy families have certain things in common (e.g., health, “[f]inancial security, leisure, physical or psychological comfort, social stability, and the like”), which are what allow them to be happy, but it is equally possible that each vaccinated person has her own reason for vaccination. See JOHN KEKES, *THE ART OF LIFE* 116 (2002).

<sup>108</sup> See, e.g., *Momplaisir et al.*, *supra* note 32.

<sup>109</sup> As the reasons of vaccine hesitancy are certainly diverse, up to each individual's unique belief based on one's knowledge and experience, it would be essentially impossible for this Article to comprehensively list all the possible reasons for vaccine hesitancy. To the extent that certain subsets of the reasons can be grouped together in representative trends, the Article can only endeavor to showcase such trends for further analysis.

<sup>110</sup> Cf. Katharine Fullerton Gerould, *What, Then, Is Culture?*, in *RINGSIDE SEATS* 164, 169 (1937) (“Like vaccine, truth and beauty do not always ‘take.’”).

<sup>111</sup> Neha Puri, Eric A. Coomes, Hourmazed Haghbayan & Keith Gunaratne, *Social Media and Vaccine Hesitancy: New Updates for the Era of COVID-19 and Globalized Infectious Diseases*, 16 HUM. VACCINES & IMMUNOTHERAPEUTICS 2586, 2587 (2020); see also Dorit Rubinstein Reiss, *Regulating in the Era of Fake News: Anti-Vaccine Activists Respond to the CDC Quarantine Rule*, 79 U. PITT. L. REV. 675 (2018) (describing pre-COVID fake news from anti-vaccine articles, sites, blogs, and Facebook pages).

<sup>112</sup> Puri et al., *supra* note 111, at 2588.

shared, and interacted with more frequently than content that promotes vaccination.<sup>113</sup> Thus, social media and alternative information sources continue to be a strong force for information and misinformation dissemination, which should not always be blindly trusted for accuracy.<sup>114</sup> Indeed, vaccine safety is not the only subject about which misinformation is being rapidly spread. For instance, former President Trump openly downplayed COVID-19's severity, touting unproven treatments and cures that defied conventional science: he not only promoted the use of chloroquine and hydroxychloroquine (antimalarial drugs) as treatments for COVID-19, even after its approval for that use had been revoked by FDA, and even after social media companies began censoring content promoting it,<sup>115</sup> but also remarked that injecting disinfectant and exposure to very powerful light were among other treatment options.<sup>116</sup> Another oft-cited source for COVID-19 treatment and prevention that FDA has cautioned against using is ivermectin (treatment for parasitic worms, head lice, and skin conditions like rosacea).<sup>117</sup> As an initial matter, policies should be explored to better regulate social media posts or at least mitigate the legitimizing of misinformation on social media platforms.<sup>118</sup> However, as discussed further below, perhaps these platforms can be leveraged to counter false information and to promote vaccine uptake as well.<sup>119</sup>

In addition to false information, the speed of successful vaccine development has led to the intuitive—but factually incorrect—concern that the vaccines were not well-

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<sup>113</sup> *Id.* It is indeed human nature to engage with and be entertained by news that excites and evokes rather than truthful reporting of facts. See ERIC BURNS, *INFAMOUS SCRIBBLERS: THE FOUNDING FATHERS AND THE ROWDY BEGINNINGS OF AMERICAN JOURNALISM* (2006) (describing the history of journalism around the time of the American Revolution); *The Newsroom* (HBO Ent. June 24, 2012–Dec. 14, 2014); see also Gill v. Hartshorn, No. 12-cv-77, 2014 WL 29450, at \*1 n.1 (M.D. Ga. Jan. 3, 2014) (“Truth is stranger than fiction . . . .” (quoting MARK TWAIN, *FOLLOWING THE EQUATOR* 156 (1897))).

<sup>114</sup> See Remarks by President Obama at YSEALI Town Hall (May 25, 2016), 2016 WL 2997085, at \*14 (“Don’t believe everything you read on the Internet . . . .”); H. Albert Liou & Jasper L. Tran, *Internet (Re)Search by Judges, Jurors, and Lawyers*, 9 IP THEORY 1, 2 n.1 (2019) (“The running joke, especially in light of the proliferation of ‘fake news,’ is that people nowadays believe everything they read on the Internet.”). For a thorough treatment of fake news and alternative facts, see generally Zahr K. Said & Jessica Silbey, *Narrative Topoi in the Digital Age*, 68 J. LEGAL EDUC. 103, 109–14 (2018).

<sup>115</sup> See, e.g., John Travis, *FDA Just Gave a Thumbs Down to Trump’s Favorite COVID-19 Drugs*, SCIENCEINSIDER (June 15, 2020), <https://www.science.org/content/article/fda-just-gave-thumbs-down-trump-s-favorite-covid-19-drugs>. In fact, an Arizona couple, upon hearing President Trump’s touting of the use of chloroquine and hydroxychloroquine against COVID-19, drank a solution of aquarium cleaner that contains chloroquine phosphate (which is a different chemical that is used to clean fish tanks) to prevent infection, but only found themselves sickened—the husband ultimately died, and the wife was hospitalized. Sarah C. Haan, *Facebook and Politicians’ Speech*, 70 AM. U. L. REV. F. 203, 207–08 (2021); Christine Nero Coughlin & Nancy M.P. King, *The Stories We Tell: Narrative, Policymaking, and the Right to Try*, 11 WAKE FOREST J.L. & POL’Y 17, 38 n.115 (2020).

<sup>116</sup> See, e.g., Sherwin, *supra* note 21, at 565–66 & n.226 (quoting Trump for saying “I see the disinfectant that knocks it [the COVID-19 virus] out in a minute, one minute . . . . And is there a way we can do something like that by injection inside, or almost a cleaning? Because you see it gets inside the lungs and it does a tremendous number on the lungs, so it would be interesting to check that.”).

<sup>117</sup> See *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>.

<sup>118</sup> There may, however, exist First Amendment implications of, and challenges to, such policies, if pursued through government legislation or regulation. See U.S. CONST. amend. I. The exploration of these First Amendment implications and challenges are outside the scope of this Article.

<sup>119</sup> Puri et al., *supra* note 111, at 2588–89.

researched or tested for safety and efficacy. As one interviewee stated: “No, I will not be taking a vaccine . . . One, they didn’t have enough studies. It takes a year and a half, two years or three years for them to complete a study and they did it in four months.”<sup>120</sup> Others expressed similar concerns about the vaccine being “too new,” and therefore potentially unsafe.<sup>121</sup> It has been suggested that the name “Operation Warp Speed” for the COVID-19 vaccine development program may have fueled “fears that things have progressed too quickly.”<sup>122</sup> Further, some vaccine hesitant have expressed concern that the great need and expedited timeline for development might have incentivized pharmaceutical companies to “cut corners” in order to meet expedited deadlines and make it first to the market.<sup>123</sup> There is already widescale distrust of pharmaceutical companies among the general public, dating to before the COVID-19 pandemic,<sup>124</sup> and other vaccine hesitant have perceived that it would be easy for a company to take advantage of such an urgent situation. Indeed, the fact that many companies began producing their vaccines before testing had even been completed raised suspicions that “the companies’ incentive to recoup their funds could lead them to misrepresent their products to the public or to approval agencies.”<sup>125</sup> These comments demonstrate the fact that few people are informed about the regulatory process for vaccine approval. As discussed above, manufacture in early stages of development is not uncommon, and was an intentional intervention in the case of COVID-19 EUA process, to ensure rapid delivery upon approval. Moreover, these comments reinforce the notion that issues of trust extend to the vaccine sponsors (the government), the developers (pharmaceutical companies), and the process (regulatory approval or EUA).

When asked whether a participant would take a vaccine that had been granted EUA, the fact of an EUA “had a particularly strong adverse effect on vaccine willingness among older Americans” and “modestly decreased vaccine acceptance” in those under sixty years old.<sup>126</sup> A CDC study found that as of May 22, 2021, 80% of elders over sixty-five years old had received at least one vaccine dose compared to just 38.3% of adults between eighteen and twenty-nine years old.<sup>127</sup> The young adults shrugged off the jab because of misinformation, apathy around risk levels, or feeling generally

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<sup>120</sup> Momplaisir et al., *supra* note 32.

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

<sup>122</sup> Lauren Bunch, *A Tale of Two Crises: Addressing Covid-19 Vaccine Hesitancy as Promoting Racial Justice*, 33 HEC F. 143, 145 (2021). Had Operation Warp Speed’s name—now looking back with the benefit of hindsight—been “chosen to connote positive, ‘warm and fuzzy’ feelings,” Heartsprings, Inc. v. Heartspring, Inc., 949 F. Supp. 1539, 1542 (D. Kan. 1996), *aff’d*, 143 F.3d 550 (10th Cir. 1998), it may have given the public more confidence in the vaccine’s safety and effectiveness.

<sup>123</sup> *See* Bunch, *supra* note 122, at 149.

<sup>124</sup> *See id.*

<sup>125</sup> *Id.* at 149–50.

<sup>126</sup> Sarah E. Kreps & Douglas L. Kriner, *Factors Influencing COVID-19 Vaccine Acceptance Across Subgroups in the United States: Evidence from a Conjoint Experiment*, 39 VACCINE 3250, 3252 (2021).

<sup>127</sup> Jill Diesel, Natalie Sterrett, Sharoda Dasgupta, Jennifer L. Kriss, Vaughn Barry, Kayla Vanden Esschert, Ari Whiteman, Betsy L. Cadwell, Daniel Weller, Judith R. Qualters, LaTrece Harris, Achal Bhatt, Charnetta Williams, LeAnne M. Fox, Dana Meaney Delman, Carla L. Black & Kamil E. Barbour, *COVID-19 Vaccination Coverage Among Adults—United States, December 14, 2020–May 22, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 922, 922 (June 21, 2021).

invincible.<sup>128</sup> Notwithstanding the significant gap between older and younger respondents, the fact that across all age groups vaccine willingness *decreased* with EUA is notable. EUA also reduced vaccine willingness across gender—by 4% by women and 0.5% by men.<sup>129</sup> Another study found that the odds of vaccine hesitancy in women was 44% more likely than males.<sup>130</sup> This suggests that, in public perception, EUA is, at best, not connected with safety, and at worst, might suggest the vaccine is *less safe or effective*.

To a certain degree, this concern about the EUA has some merit. Although hydroxychloroquine has since become notorious for its ill-effects in treating COVID-19—and is now lumped in the same category with other false treatments circulating the Internet, such as vitamin C, zinc, and the antiparasitic ivermectin<sup>131</sup>—many forget that it had actually been approved by FDA to begin with. On March 28, 2020, FDA issued EUA to allow hydroxychloroquine as a treatment for certain hospitalized COVID-19 patients,<sup>132</sup> only to revoke it less than three months later when reports of serious heart rhythm problems, blood and lymph system disorders, kidney injuries, and liver failure emerged in patients who had been treated with it.<sup>133</sup> Despite initially finding that the known and potential benefits outweigh the known and potential risks (the standard of safety for EUA), FDA then determined that hydroxychloroquine “showed no benefit for decreasing the likelihood of death or speeding recovery.”<sup>134</sup> Notably, FDA did not revoke authorization until more than two months after the American Heart Association published a report warning about cardiac risks of hydroxychloroquine.<sup>135</sup> There is some substance to the concern that the EUA is

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<sup>128</sup> See, e.g., Erin Hemlin, Matthew Eckle & Mina Schultz, *Young Adult Perspective on the COVID-19 Vaccine: Listening Tour Findings*, YOUNG INVINCIBLES (Aug. 2021), <https://younginvincibles.org/wp-content/uploads/2021/09/Perspectives-on-the-Covid-19-Vaccine-Final-Report-2.4.pdf>.

<sup>129</sup> Kreps & Kriner, *supra* note 126, at 3253.

<sup>130</sup> Khubchandani et al., *supra* note 96, at 275.

<sup>131</sup> See Raymond Chee Seong Seet, Amy May Lin Quek, Delicia Shu Qin Ooi, Sharmila Sengupta, Satish Ramapatna Lakshminarasappa, Chieh Yang Koo, Jimmy Bok Yan So, Boon Cher Goh, Kwok Seng Loh, Dale Fisher, Hock Luen Teoh, Jie Sun, Alex R. Cook, Paul Anantharajah Tambyah & Mikael Hartman, *Positive Impact of Oral Hydroxychloroquine and Povidone-Iodine Throat Spray for COVID-19 Prophylaxis: An Open-Label Randomized Trial*, 106 INT’L J. INFECTIOUS DISEASES 314 (2021) (finding that oral hydroxychloroquine and povidone-iodine throat spray (Betadine®) reduced COVID-19 infection, but oral ivermectin and zinc/vitamin C do not significantly affect infection rates). At most, the false treatments may result in a placebo effect on the patients. See *generally* Gen. Med. Co. v. FDA, 770 F.2d 214, 220 (D.C. Cir. 1985) (“[T]he treatment might have only a ‘placebo’ effect: the reduction in [symptoms] could be a purely psychological byproduct of the ambience of a medical experiment, an effect that might have been produced with equally good results by ‘treating’ the subjects with a completely inert device.”); Henry K. Beecher, *The Powerful Placebo*, 159 JAMA 1602 (1955).

<sup>132</sup> New Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: Daily Roundup March 30, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-30-2020>.

<sup>133</sup> *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine or COVID-19 Outside of Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.

<sup>134</sup> *Id.*

<sup>135</sup> Dan M. Roden, Robert A. Harrington, Athena Poppas & Andrea Russo, *Considerations for Drug Interactions on QTc in Exploratory COVID-19 Treatment*, 141 CIRCULATION 906 (2020), <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.120.047521>.

untrustworthy given that hydroxychloroquine received the same federal authorization as the current coronavirus vaccines (notwithstanding the recent full licensure for all three primary American vaccines).

### B. Political Division

Studies have also confirmed that there is distrust across political lines affecting a person's willingness to receive a vaccine. In general, self-identified Democrats are more likely to receive a vaccine than Republicans.<sup>136</sup> For example, one survey found that 29% of the Republicans were either unlikely or definitely unlikely to willingly receive a vaccine, whereas 16% of the Democrats surveyed were either unlikely or definitely unlikely to willingly receive a vaccine.<sup>137</sup> The same survey reported that Republicans were also less persuaded by increases in vaccine efficacy, such that an increase to 90% efficacy would persuade only 6% of the Republican respondents as compared to 11% of the Democrats. Thus, when presented with the option to receive vaccines of greater efficacy, respondents of both parties expressed greater willingness, but with Democrats doing so at greater rates than Republicans.<sup>138</sup> Across both groups, respondents were significantly more likely to accept a vaccine that had been endorsed by a politician in their same party, and Democrats' willingness also increased with endorsements from CDC.<sup>139</sup> Political tensions around the uncertainty of the 2020 presidential election, which overlapped with important stages of vaccine development, may have also seeded a general discomfort with the vaccine development process.<sup>140</sup> An August 2020 poll found that only 42% of respondents were willing to receive a vaccine if it were approved before the elections in November 2020 and that 62% of respondents "believed that sociopolitical factors and pressures may lead to a rushed approval for the COVID vaccine without the assurances of safety and efficacy."<sup>141</sup> In fact, along with the perceived threat of contracting and becoming ill from COVID-19, "political affiliation in the U.S. stood out among the strong predictors of vaccine hesitancy."<sup>142</sup>

In particular, Republicans generally disapprove of COVID-19 media coverage and sense that the public health officials exaggerated COVID-19 risks.<sup>143</sup> And Republican political officials are often vocal against COVID-19 vaccination in the media, playing on the question of whether the vaccines are safe, in favor of individual liberty over the collective public health.<sup>144</sup> Consider, for example, the following statement from the

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<sup>136</sup> See, e.g., Kreps & Kriner, *supra* note 126, at 3254.

<sup>137</sup> Khubchandani et al., *supra* note 96, at 273 (surveying 513 Republicans and 863 Democrats).

<sup>138</sup> Kreps & Kriner, *supra* note 126, at 3254.

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

<sup>140</sup> Khubchandani et al., *supra* note 96, at 273; Bunch, *supra* note 122, at 150.

<sup>141</sup> Khubchandani et al., *supra* note 96, at 273.

<sup>142</sup> *Id.* at 275.

<sup>143</sup> See, e.g., Amy Mitchell, Mark Jurkowitz, J. Baxter Oliphant & Elisa Shearer, *How Americans Navigated the News in 2020: A Tumultuous Year in Review*, PEW RSCH. CTR. (Feb. 22, 2021), <https://www.pewresearch.org/journalism/2021/02/22/republicans-views-on-covid-19-shifted-over-course-of-2020-democrats-hardly-budged/> (finding that "Republican approval of COVID-19 media coverage declined over time" and that "Republicans' sense that CDC exaggerated risks of COVID-19 grew over time").

<sup>144</sup> See, e.g., *League of Indep. Fitness Facilities & Trainers, Inc. v. Whitmer*, 814 F. App'x 125, 126 (6th Cir. 2020) ("In addressing the COVID-19 outbreak, executives at the national, state, and local levels

Republican Governor of Georgia, Brian P. Kemp: “[V]accination is a personal decision between each citizen and a medical professional.”<sup>145</sup> In the age of the social media “filter bubble,”<sup>146</sup> the general public receives information tailored to their political views, including through political-leaning news outlets, search engines based on prior search results, Facebook groups, and “bot” accounts. Receiving conflicting COVID-19 news depending on one’s political view would only further exacerbate the vaccine hesitancy issue. In short, COVID-19 and its vaccine are political.

Political division did in fact seep into the EUA process. In October 2020, FDA issued guidance asking vaccine makers to track trial participants for at least two months following a dosage of their vaccines to see if any major side effects emerged,<sup>147</sup> which ensured no vaccine approval before the presidential election.<sup>148</sup> Moreover, FDA asked companies to not seek an EUA until they had enough supply to widely distribute a vaccine, which further delayed the regulatory approval process for the vaccine.<sup>149</sup> FDA’s announcement came in contravention of White House statements that a vaccine could be authorized before the November 2020 election, a position which had forestalled the release of the contested guidelines in the first place. This contention caused seven former FDA commissioners to criticize the Trump Administration for “undermining the credibility” of the agency.<sup>150</sup> On the other hand, the delay in approval may have been “good for public health,” in that it might have reassured individuals concerned that the vaccines were being rushed through an approval process before election day to score political points.<sup>151</sup> But even so, inter-governmental contention like this—and not to mention the contention between the Trump Administration and Fauci—undoubtedly stoked already-heated concerns about vaccine safety being compromised by playing politics. Indeed, it’s clear that “[t]rust in government can be undermined if officials make premature statements of efficacy

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have had difficult decisions to make in honoring public health concerns while respecting individual liberties. Those decisions have now been the subject of numerous legal challenges, from coast to coast.” (citing cases)); *But see* Letters to Editor, *Understanding the Unvaccinated*, N.Y. TIMES (Oct. 30, 2021), <https://www.nytimes.com/2021/10/30/opinion/letters/covid-unvaccinated.html> (“The problem, of course, is that your liberty may contribute to my death.”). We have seen similar objections raised by super-macho motorcyclists against laws mandating the wearing of helmets while riding motorbikes. That situation, however, is different because no risk of harm falls to the general public, except a possibility of some economic burden as a result of preventable head injuries suffered by motorcyclists.

<sup>145</sup> Press Release, Off. of Gov. Brian P. Kemp, Gov. Kemp Issues Executive Order Prohibiting COVID-19 Vaccine Passports in State Government (May 25, 2021), <https://gov.georgia.gov/press-releases/2021-05-25/gov-kemp-issues-executive-order-prohibiting-covid-19-vaccine-passports>.

<sup>146</sup> *See generally* ELI PARISER, *THE FILTER BUBBLE* (2011).

<sup>147</sup> FDA, EMERGENCY USE AUTHORIZATION, *supra* note 60.

<sup>148</sup> Jamie Ducharme, *Why It’s Good the FDA is Slowing COVID-19 Vaccine Approval*, TIME (Oct. 7, 2020), <https://time.com/5897294/fda-covid-19-vaccine-approval/>.

<sup>149</sup> *Id.*

<sup>150</sup> Owen Dyer, *COVID-19: FDA Defies Trump to Publish Rigorous Vaccine Development Guidelines*, 371 *BMJ* m3918 (2020) (quoting Robert Califf, Scott Gottlieb, Margaret Hamburg, Jane Henney, David Kessler, Mark McClellan & Andy von Eschenbach, *7 Former FDA Commissioners: The Trump Administration is Undermining the Credibility of the FDA*, WASH. POST (Sept. 29, 2020), <https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/>); *see* Angelis & Darrow, *supra* note 54, at 2328 n.6; Dorit Rubinstein Reiss, *The COVID-19 Vaccine Dilemma*, 6 *ADMIN. L. REV. ACCORD* 49, 74 n.143 (2020).

<sup>151</sup> Ducharme, *supra* note 148.

or safety that are later contradicted by emerging evidence.”<sup>152</sup> Numerous examples of such disconnect between different government proclamations abound from this period. “This tug-of-war between the FDA and its parent agency reflects the tension between the ideals of public accountability to elected leaders and independent, evidence-based policy.”<sup>153</sup> Measures to combat vaccine hesitancy must also consider how to reach audiences across a deep political divide.

### C. Racial Disparities and Systemic Harms

Racial disparities in vaccine uptake have been well documented—numerous scholars have already opined on data revealing that Black and Latinx individuals in the United States exhibited higher rates of hesitancy than their white peers, with Blacks exhibiting the highest level of unwillingness to be vaccinated.<sup>154</sup> A major (as-yet unpublished) study that drew data from over 1.3 million people across the United States and U.K. found that 28% of Black survey participants in the United States were hesitant or unsure if they would be willing to receive a vaccine.<sup>155</sup> The same study found this was the case for 15.6% of Hispanic participants, but less than 10% of white participants.<sup>156</sup> When adjusted for other relevant covariates, the likelihood of hesitancy among racial subgroups did not change materially.<sup>157</sup> Another study including 1,878 participants showed less extreme discrepancy, with 34% of Black participants and 29% of Hispanic participants expressing hesitancy about receiving the COVID-19 vaccine, compared to 22% of white participants.<sup>158</sup> While data vary, and indeed, continue to change as the pandemic lingers, there is a consensus that vaccine hesitancy is prevalent, and more so among communities of color, particularly Black Americans.<sup>159</sup>

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<sup>152</sup> Angelis & Darrow, *supra* note 54, at 2328.

<sup>153</sup> *Id.*

<sup>154</sup> See, e.g., Momplaisir et al., *supra* note 32; Kreps & Kriner, *supra* note 126; Khubchandani et al., *supra* note 96; Mohammad S. Razai, Tasnime Osama, Douglas G. J. McKechnie & Azeem Majeed, *COVID-19 Vaccine Hesitancy Among Ethnic Minority Groups*, 372 *BMJ* n513 (2021); Bunch, *supra* note 122; Long H. Nguyen, Amit D. Joshi, David A. Drew, Jordi Merino, Wenjie Ma, Chun-Han Lo, Sohee Kwon, Kai Wang, Mark S. Graham, Lorenzo Polidori, Cristina Menni, Carole H. Sudre, Adjoa Anyane-Yeboah, Christina M. Astley, Erica T. Warner, Christina Y. Hu, Somesh Selvachandran, Richard Davies, Denis Nash, Paul W. Franks, Jonathan Wolf, Sebastien Ourselin, Claire J. Steves, Tim D. Spector & Andrew T. Chan, *Racial and Ethnic Differences in COVID-19 Vaccine Hesitancy and Uptake* (Feb. 28, 2021) (unpublished manuscript), available in preprint at <https://www.medrxiv.org/content/10.1101/2021.02.25.21252402v1.full>. To be clear, “[t]here is nothing innate in Black people that makes [them] more susceptible to COVID-19, nor is there a gene that accounts for the exceedingly high rates of Black death to this disease compared to other groups.” Sirleaf, *Racial Valuation of Diseases*, *supra* note 12, at 1851. Though COVID-19 itself does “not discriminate, societal actors do individually and systemically via direct and indirect action, which is exhibited by racialized health disparities and inequities.” Sirleaf, *Entry Denied*, *supra* note 80; see also Asad L. Asad & Matthew Clair, *Racialized Legal Status as a Social Determinant of Health*, 199 *SOC. SCI. & MED.* 19 (2018) (explaining racialized legal status as social position with fundamental health effects).

<sup>155</sup> Nguyen et al., *supra* note 154, at tbl. 2 (showing 611 out of 2,179 participants).

<sup>156</sup> *Id.* (showing 505 out of 3,235 Hispanic participants and 4,715 out of 64,144 white participants).

<sup>157</sup> *Id.* at 8.

<sup>158</sup> Khubchandani et al., *supra* note 96, at 274.

<sup>159</sup> And the relatively lower vaccination rate among Black Americans has resulted in real consequences. For instance, “Black Americans constitute 12.5 percent of the U.S. population, yet account for 22.4 percent of COVID-19 deaths.” Sirleaf, *Racial Valuation of Diseases*, *supra* note 12, at 1851. More specifically, just four months into the pandemic, “in Chicago greater than 50 percent of COVID-19 cases



The efficacy of the vaccine does not appear to be a reason for this discrepancy. In a study that asked participants to report their willingness to receive a vaccine given a variety of circumstances, the efficacy of the COVID-19 vaccine did not have a strong impact on Black respondents.<sup>160</sup> When asked whether it would make a difference in their willingness to be vaccinated with a vaccine that was 50% effective versus 90% effective, only 4% of Black respondents said they would be more likely to take the more effective vaccine, but a greater efficacy increased vaccine willingness by almost 10% among whites.<sup>161</sup> Similarly, white respondents were more likely to take a vaccine that lasted longer, whereas duration had little effect on Black respondents.<sup>162</sup> However, across all demographic groups studied, older Americans were significantly more hesitant than younger respondents to receive a vaccine.<sup>163</sup>

Rather, a significant reason for this discrepancy can be traced to historical abuses against African Americans in the United States and Europe in the context of access to healthcare and medical treatment.<sup>164</sup> Notable among numerous examples is the infamous Tuskegee experiment. From 1932–1972, the U.S. Public Health Service funded research into the effects of untreated syphilis, in which doctors mislead Black Americans into believing they were receiving treatment for the disease, when they were in fact being left untreated so that doctors could observe the disease's progression.<sup>165</sup> Still today, racial inequities in medical treatment abound.<sup>166</sup> For instance, an issue that is starting to receive more widespread public attention is that Black and some Indigenous women are two-to-three times more likely to die of pregnancy-related causes than white women.<sup>167</sup> There is, as one survey participant put it, “substance to the paranoia”<sup>168</sup> surrounding the safety and ethics of medical

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and almost 70 percent of COVID-19 deaths involved Black people, although Black people constitute only 30 percent of the population in Chicago,” and in New York, “the rate for Black people amounting to 92.3 deaths per 100,000 people, while the rate for White people was less than half of that at 45.2 deaths per 100,000 people.” *Id.* at 1855 (citing, *inter alia*, Clyde W. Yancy, *COVID-19 and African Americans*, 323 JAMA 1891, 1891 (2020)). The reason is probably due, in part, to the lower vaccination rate among Black Americans, which inevitably translates to their higher death rate, after prevention failed and there was no treatment (at the time).

<sup>160</sup> See Kreps & Kriner, *supra* note 126, at 3252.

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

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> See, e.g., Bunch, *supra* note 122; see also Razai et al., *supra* note 154.

<sup>165</sup> Bunch, *supra* note 122; see also JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 29 (1993) (noting Black Americans as a “notoriously syphilis-soaked race”). See generally Amy L. Fairchild & Ronald Bayer, *Uses and Abuses of Tuskegee*, 284 SCIENCE 919 (1999); David M. Smolin, *The Tuskegee Syphilis Experiment, Social Change, and the Future of Bioethics*, 3 FAULKNER L. REV. 229 (2012); Rukaiyah Yearby, *Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study*, 67 CASE W. RES. L. REV. 1171 (2017).

<sup>166</sup> See, e.g., Mary A. Gerend & Manacy Pai, *Social Determinants of Black-White Disparities in Breast Cancer Mortality: A Review*, 17 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2913 (2008) (using the social determinants of health disparities model to review disparities in mortality from breast cancer between White and Black women).

<sup>167</sup> Emily E. Peterson, Nicole L. Davis, David Goodman, Shanna Cox, Carla Syverson, Kristi Seed, Carrie Shapiro-Mendoza, William M. Callaghan & Wanda Barfield, *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007–2016*, 68 MORBIDITY & MORTALITY WKLY. REP. 762 (Sept. 6, 2019), [https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s\\_cid=mm6835a3\\_w](https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w).

<sup>168</sup> Momplaisir et al., *supra* note 32.

treatment as administered to people of color in the United States. This paranoia informs public response to receiving a government-recommended vaccine.

Indeed, a qualitative study of a local community in Pennsylvania in July–August 2020 documented statements revealing this distrust of the medical system.<sup>169</sup> For instance, one interviewee was quoted as saying the following: “I’m already against it. I’m paranoid . . . when I hear that Tuskegee experiment . . . I stay away from that. I wouldn’t get a vaccine.”<sup>170</sup> In addition to specific historical instances of mistreatment and abuse, participants were also concerned about the current “political environment fostering white supremacy and racial injustice,” which may have contributed to vaccine hesitancy given the vaccine’s “association with President Trump.”<sup>171</sup> As one participant expressed: “With that guy [President Trump] in office . . . in the black community, everybody is on high alert, very distrusting, because we don’t know what’s going to be perpetrated against us.”<sup>172</sup> This same participant went on to discuss the fact that although clear police brutality had been caught on tape, offending officers are being sanctioned only in the rarest of incidents.<sup>173</sup> Vaccine hesitancy may therefore be correlated not only with histories of injustice within the medical field but also with suspicion of government-recommended activity in general, as well as an overarching socio-political climate.

While the oft-cited Tuskegee experiment did happen, it is certainly not the sole reason that drives the individual decision-making of members of the African American community. This distant past is continuing to inform the present in terms of healthcare, healthcare decisions, and the receptiveness to entities that have not necessarily been acting with the best interest of certain populations in mind. Other factors continue to play on the legacy of segregated medicine or medical apartheid as well. That is, studies have shown the difference in healthcare depends on one’s racial status. For example, one study shows that Black patients in particular face higher rates of untreated pain because of stereotypical beliefs that they have a higher threshold of pain tolerance.<sup>174</sup>

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

<sup>170</sup> *Id.* With respect to the overrepresentation of people of color in prison, another interviewee expressed this distrust in the system: “[L]ook in the prisons. You have more people in prisons have gotten this [COVID-19]. People are trying to get help. But I see . . . what they used to do with vaccines, try it on prisoners and see how they respond.” *Id.*

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

<sup>172</sup> *Id.* Kreps & Kriner also found that Black respondents were significantly less likely to receive a vaccine endorsed by President Trump as compared to President Biden, CDC, or WHO. Kreps & Kriner, *supra* note 126.

<sup>173</sup> Momplaisir et al., *supra* note 32. Related to the distrust in the government is also the distrust in the scientific underpinnings of vaccination itself. For instance, when asked whether the surveyed participants would receive a COVID vaccine if President “Obama advocated for it,” one interviewee responded: “I don’t care who advocates for it . . . at the end of the day, if they . . . shoot the actual virus into your body to cure your body, . . . that will make no sense . . .” *Id.* Another interviewee said that even “if [Obama] advocated for [a COVID vaccine] I would still . . . have to say no way, so I would think it will be still under that umbrella of evil.” *Id.* What these responses illustrate is that having a Black spokesperson to speak on behalf of the government, no matter how authoritative and likeable that individual may be, could potentially move the needle by not much.

<sup>174</sup> See Ronald Wyatt, *Pain and Ethnicity*, 15 *AMA J. ETHICS: POL’Y F.* 449 (May 2013), <https://journalofethics.ama-assn.org/article/pain-and-ethnicity/2013-05> (“Race influences the experience of pain and of seeking treatment.”); Jana M. Mossey, *Defining Racial and Ethnic Minorities in Pain Management*, 469 *CLINICAL ORTHOPAEDICS & RELATED RSCH.* 1859 (2011) (finding that Blacks are more likely than non-Hispanic whites to underreport pain unpleasantness in the clinical setting, especially in the presence of physicians perceived as having “higher social status” and that Blacks are more likely than non-

Studies have also shown that people of color receive lesser quality of care and experience greater complications after surgery, including death, than white people.<sup>175</sup> And another study has demonstrated that Black and Latinx patients admitted with heart failure were less likely than white patients to be admitted to a specialized cardiologist.<sup>176</sup>

As to systemic challenges, existing structural laws and policies further amplify vaccine hesitancy in terms of vaccine distribution, such that vaccine access is prohibitive. Not only do the systemic access barriers play a role in the low vaccination rate among certain minority groups, which amplifies the problem of hesitancy, they also lead to further government distrust, which feeds hesitancy, creating an expanding feedback loop for increasing hesitancy. For instance, vaccine redlining was taking place in terms of the location of distribution centers for vaccines. In the United States, Dallas County, for example, recently advanced a plan to prioritize COVID-19 vaccine doses for communities of color within certain zip codes deemed more vulnerable than others, but the State of Texas threatened to cut off its vaccine supply if Dallas County went with that particular plan.<sup>177</sup> More broadly in the global context, a majority of countries in the Northern hemisphere have access to vaccines, whereas countries in the Southern hemisphere lack access to vaccines.<sup>178</sup>

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Hispanic whites to attribute pain to personal inadequacies and to use “passive” coping strategies, such as prayer).

<sup>175</sup> See, e.g., William J. Hall, Mimi V. Chapman, Kent M. Lee, Yesenia M. Merino, Tainayah W. Thomas, B. Keith Payne, Eugenia Eng, Steven H. Day & Tamera Coyne-Beasley, *Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review*, 105 AM. J. PUB. HEALTH e60, e61 (2015) (“White patients received better quality of care than Black American, Hispanic, American Indian, and Asian patients.”); Frances L. Lucas, Therese A. Stukel, Arden M. Morris, Andrea E. Siewers & John D. Birkmeyer, *Race and Surgical Mortality in the United States*, 243 ANNALS SURGERY 281, 281 (2006) (concluding that “Black patients have higher operative mortality risks across a wide range of surgical procedures, in large part because of higher mortality rates at the hospitals they attend”).

<sup>176</sup> See Lauren A. Eberly, Aaron Richterman, Anne G. Beckett, Bram Wispelwey, Regan H. Marsh, Emily C. Cleveland Manchanda, Cindy Y. Chang, Robert J. Glynn, Katherine C. Brooks, Robert Boxer, Rose Kakoza, Jennifer Goldsmith, Joseph Loscalzo, Michelle Morse & Eldrin F. Lewis, *Identification of Racial Inequities in Access to Specialized Inpatient Heart Failure Care at an Academic Medical Center*, 12 CIRCULATION: HEART FAILURE e006214 (2019).

<sup>177</sup> See, e.g., Emma Platoff & Juan Pablo Garnham, *Dallas County Axes Plan to Prioritize Vaccinating Communities of Color After State Threatens to Slash Allocation*, TEX. TRIBUNE (Jan. 20, 2021), <https://www.texastribune.org/2021/01/20/dallas-vaccine-plan-communities-of-color/>.

<sup>178</sup> See, e.g., Amy Maxmen, *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, NATURE (Sept. 15, 2021) (“Vaccines against COVID-19 are not reaching many people in the global south . . .”).

To the extent that a correlation between race and education,<sup>179</sup> especially outside of the metropolitan areas,<sup>180</sup> exists, the formal education level of content viewers unsurprisingly affects susceptibility to misinformation and coincides with the likelihood of vaccine hesitancy. For example, one survey found that only 13% of participants with at least a master's degree were either unlikely or not willing to receive a vaccine, as compared to a 31% hesitancy rate for participants with a high school education or lower.<sup>181</sup> Another survey by USC found that, as of February 2021, 76% of U.S. adults with at least a bachelor's degree have already been vaccinated or plan to be, compared to just 53% of those without a college degree.<sup>182</sup> Thus, addressing racial disparities in vaccine willingness and uptake must account for the issue of the educational disparities among the different ethnic groups. The flip side of the same coin is that fixing the educational disparities between the races is likely to alleviate, to a certain degree, the racial disparities in vaccine hesitancy.<sup>183</sup>

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<sup>179</sup> See, e.g., *Seamon v. Upham*, 536 F. Supp. 931, 993 (E.D. Tex. 1982) (“There is in Texas, then, a staggering correlation between race and inferior education, unemployment and underemployment, poverty, inadequate housing, poor health, and insufficient medical care.”); John V. Jacobi, *Prison Health, Public Health: Obligations and Opportunities*, 31 AM. J.L. & MED. 447, 450 (2005) (discussing “the correlations among education, race, and poverty”); Hillel Y. Levin & John W. Emerson, *Is There a Bias Against Education in the Jury Selection Process?*, 38 CONN. L. REV. 325, 330 n.19 & 334 n.50 (2006) (discussing “a correlation between race and education”); Govind Persad, *Evaluating the Legality of Age-Based Criteria in Health Care: From Nondiscrimination and Discretion to Distributive Justice*, 60 B.C. L. REV. 889, 938 n.241 (2019) (discussing “correlations between race, education”). This correlation between race and education is the very basis for universities’ affirmative action programs, whose goals are trying to address and remedy that same correlation. See, e.g., Jasper L. Tran, *In Defense of Excellence*, 73 VAND. L. REV. EN BANC 71, 84 & 90 (2020) (reviewing ANTHONY KRONMAN, *THE ASSAULT ON AMERICAN EXCELLENCE* (2019)) (discussing *Regents of the Univ. of Calif. v. Bakke*, 438 U.S. 265, 267 (1978), which held, *inter alia*, that race may be one of a number of factors considered by schools in passing on applications, and *Gratz v. Bollinger*, 539 U.S. 306, 308, 310 (2003), the majority in which “expects that 25 years from now, the use of racial preferences will no longer be necessary to further the interest” in “attaining a diverse student body.”); cf. *N. Sec. Co. v. United States*, 193 U.S. 197, 364 (1904) (Holmes, J., dissenting) (“Great cases, like hard cases, make bad law.”). *But see* Sandra Day O’Connor & Stewart J. Schwab, *Affirmative Action in Higher Education over the Next Twenty-five Years: A Need for Study and Action*, in *THE NEXT TWENTY-FIVE YEARS: AFFIRMATIVE ACTION IN HIGHER EDUCATION IN THE UNITED STATES AND SOUTH AFRICA* 62 (David Lee Featherman et al. eds., 2009) (“That 25-year expectation is, of course, far from binding on any justices who may be responsible for entertaining a challenge to an affirmative action program in 2028.”); Amy L. Wax, *On Not Dreaming of Affirmative Action*, 17 U. PA. J. CONST. L. 757, 768 (2015) (“Justice Sandra Day O’Connor’s twenty-five years of race-based admissions stretches out indefinitely on the horizon with no terminus in sight.”).

<sup>180</sup> See, e.g., Tracey Farrigan, *Racial and Ethnic Disparities in Educational Attainment Persist in Rural America*, ECON. RES. SERV., U.S. DEP’T OF ARGIC. (Nov. 2, 2020), <https://www.ers.usda.gov/amber-waves/2020/november/racial-and-ethnic-disparities-in-educational-attainment-persist-in-rural-america/> (“[R]esearch shows that Hispanic, Black or African American, and Native American or Alaska Native groups continue to have lower rates of educational attainment than Whites.” For example, among all rural residents who are twenty-five years old or older, “the share of Blacks without a high school degree remained nearly double that of Whites in 2018.”).

<sup>181</sup> Khubchandani et al., *supra* note 96, at 272.

<sup>182</sup> Jenesse Miller, *Education is a Bigger Factor than Race in Desire for COVID-19 Vaccine*, USC NEWS (Feb. 25, 2021), <https://news.usc.edu/182848/education-covid-19-vaccine-safety-risks-usc-study/> (reporting results of the study from University of Southern California (USC) Dornsife College of Letters, Arts and Sciences’ Center for Economic and Social Research (CESR)).

<sup>183</sup> It is obvious that fixing the educational disparities between the races cannot be accomplished overnight or in the short term, but it could be a worthwhile goal when thinking about vaccine hesitancy. And when speaking narrowly about vaccination education to fix the vaccine hesitancy problem, we need not fix the broader goalpost of formal-education level generally; rather, educational programs specifically

If we were to compare among the races, Native Americans, unlike African Americans, have an extremely high vaccination rate. The Native Americans “suffered terribly from Covid before the vaccine . . . [and] have contempt for the Indian Health Service.”<sup>184</sup> The reason for their higher vaccination rate is attributed to “both [] leadership by tribal governments and a sense of caring for fellow tribe members.”<sup>185</sup> This comparison appears to not differ from the reason behind the Democrats’ higher vaccination rate as compared to the Republicans’: the former cares more about the collective public health whereas the latter cares more about individual liberty.

Interestingly, the same disparities in vaccine willingness and uptake among Black communities were not found to be true outside the United States.<sup>186</sup> A major cross-national study comparing vaccine hesitancy in the United States and the U.K. found that while there was still vaccine hesitancy in the U.K., the racial gap was not as stark.<sup>187</sup> The authors surmised that the sources of hesitancy studied, therefore, likely relates to racial inequities specifically found in the United States, such as inequities in the “fairness of prioritization and distribution of vaccines to minority communities” and “the relative lack of a national public health infrastructure.”<sup>188</sup> “Taken together,” they conclude, “these findings support the need to address long-standing systemic disparities to achieve the health equity required for population-scale immunity.”<sup>189</sup>

### III. SOLUTIONS TO INCREASE VACCINE UPTAKE

Since the start of COVID-19, scientific and medical experts have been adjusting on the fly to new and more accurate data coming in concerning COVID-19’s nature, transmission, level of lethality, as well as the amount and frequency of its mutations.<sup>190</sup> Policymakers, including the government and its agencies, ought to be able to—or at least try their best to—do the same, with fast-paced changes and the shifting of goalposts.<sup>191</sup> And to meaningfully combat vaccine hesitancy, we ought to not only look backward at what actions have been taken that yield promising results, but also look forward at what else may work based on results from studies done on vaccine hesitancy.<sup>192</sup>

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about vaccination targeting the under-educated population may very well do the trick—depending on how receptive the audiences are in terms of their willingness to learn.

<sup>184</sup> Letters to Editor, *supra* note 144.

<sup>185</sup> *Id.* This is not to say that African Americans do not have a sense of caring for members of their community. It could be the case that the *actual* reason for the discrepancy of vaccination rates between Native Americans and African Americans may be culturally more complex than what is seemingly observable.

<sup>186</sup> *Cf.* DERRICK A. BELL, JR., RACE, RACISM, AND AMERICAN LAW (6th ed. 2013) (addressing why race remains a key to America’s economic, political, and social functioning).

<sup>187</sup> Nguyen et al., *supra* note 154.

<sup>188</sup> *Id.* at 13.

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

<sup>190</sup> Robillard, *supra* note 89.

<sup>191</sup> *See also id.*

<sup>192</sup> *See supra* note 4. It is important to make clear that any *ex ante* discussion of the future ought to be mindful of “what *will be* (as if the future were ever certain) instead of what we *want to be*.” Morris R. Cohen, *Book Reviews*, 33 COLUM. L. REV. 1273, 1273 (1933) (emphases in original); *see also, e.g.*, Albemarle

### A. *Ex Post: What Has Actually Worked*

Attempts to overcome vaccine hesitancy have been multifaceted, including public awareness campaigns (e.g., TV, radio), use of celebrity spokespeople, outreach to minority communities via churches and community groups, and appeals to social media companies like Facebook to identify posts potentially including misinformation about COVID-19/vaccines and flag them. Notably, states, local governments, and even private organizations have attempted to use incentive programs to encourage people to be vaccinated. As of July 30, 2021, at least twenty-eight states have offered some form of incentive for vaccinated individuals, ranging from a box of Girl Scout cookies with your vaccine (Indiana) to the chance to win a million dollars or more (California, Ohio, Washington, and others).<sup>193</sup> A study found that Ohio's Vax-A-Million initiative, which cost \$68 per person persuaded to vaccinate, yields an increase of the vaccinated share of state population by 1.5%, causing significant reductions in COVID-19 and preventing at least one infection out of six vaccinations that the lottery had successfully encouraged.<sup>194</sup> Some cities like Memphis, Tennessee, and New York City also launched their own incentive programs.<sup>195</sup> Some of these incentives came about after President Biden announced a "National Month of Action" to facilitate and encourage vaccinations in an attempt to get as many U.S. adults as possible at least one shot by July 4, 2021.<sup>196</sup> In the first week of June, when the program was announced, 64.9% of adults had received at least one dose of the vaccine. By the end of July 2021, that number had indeed increased to 70%, but the increasing slope of the vaccination rate was steadily incremental, and not as steep as one may intuitively expect. The following Graph from the CDC shows the increasing vaccination rate of all adults over time, from April 2021 through September 2022.<sup>197</sup>

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Paper Co. v. Moody, 422 U.S. 405, 448 (1975) (Blackmun, J., concurring) ("The simple truth is that . . . most attempts to predict the future, will never be completely accurate.").

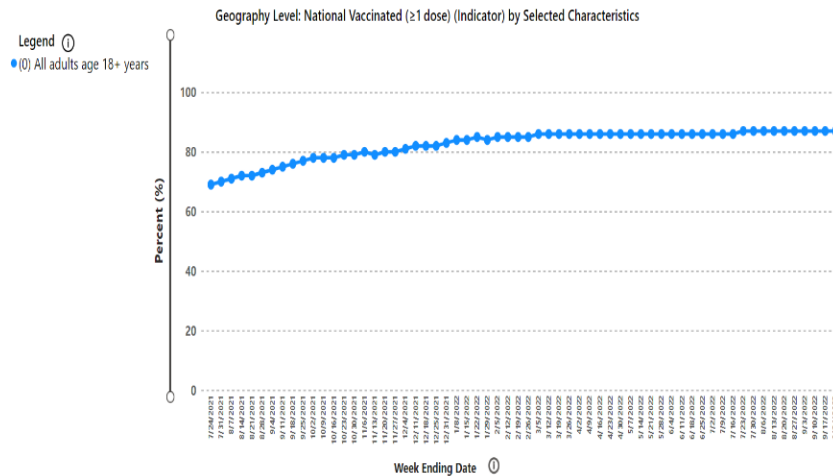
<sup>193</sup> *COVID-19 Vaccine Incentives*, NAT'L GOVERNORS ASS'N, <https://www.nga.org/center/publications/covid-19-vaccine-incentives/>. For example, California's "Vax for the Win" program offered people who were vaccinated between May 27 and July 18 of 2021 a \$50 virtual cash card or gift card to Albertson's or Kroger. *Vax for the Win: California's Vaccine Incentive Program*, CA.GOV, <https://covid19.ca.gov/vax-for-the-win/>. Some vaccination sites were also giving out free tickets to the Six Flags theme parks. *Id.* These incentives were in addition to lottery-based chances to win cash prizes of \$50,000 or \$1.5 million and vacation packages.

<sup>194</sup> Andrew Barber & Jeremy West, *Conditional Cash Lotteries Increase COVID-19 Vaccination Rates*, 81 J. HEALTH ECON. 102578 (Jan. 2022). Ohio Governor Mike DeWine considered its lottery program "a resounding success." New Release, Ohio's Final Vax-a-Million Drawing Winners Announced, Ohio Dep't of Health (June 23, 2021), <https://odh.ohio.gov/media-center/odh-news-release-06-23-21>. Yet, coincidental correlation does not necessarily establish causation. *E.g.*, Clerveaux v. E. Ramapo Cent. Sch. Dist., 984 F.3d 213, 237 (2d Cir. 2021). A different "study thus did not find evidence that a lottery-based incentive in Ohio was associated with increased rates of adult COVID-19 vaccinations" because "the announcement of the Ohio vaccine lottery closely coincided with" FDA's expansion of EUA for the Pfizer "vaccine to adolescents aged 12 to 15 years on May 10, 2021." Allan J. Walkey, Anica Law & Nicholas A. Bosch, *Lottery-Based Incentive in Ohio and COVID-19 Vaccination Rates*, 326 JAMA 766, 766-67 (2021).

<sup>195</sup> *COVID-19 Vaccine Incentives*, *supra* note 193.

<sup>196</sup> *National Month of Action for COVID-19 Vaccinations*, THE WHITE HOUSE, <https://www.whitehouse.gov/national-month-of-action>.

<sup>197</sup> *COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive.html> (last visited Oct. 2, 2022). The Graph from CDC defines "Vaccination" broadly, i.e., receiving at least one dose of any vaccine.



This, unsurprisingly, suggests that the incentivization schemes may have worked, but only on a subset—and not all—of the vaccine-hesitant people.<sup>198</sup> The vaccination rate appears to have plateaued at around 85% since January 2022.

What has also worked to a sizable extent since Fall 2021 is the collaboration between the federal government, states (in terms of lawmaking on vaccine mandate), and the private sector (in terms of enforcing and implementing the mandate). For instance, President Biden issued an executive order in September 2021, requiring COVID-19 vaccination for all federal employees,<sup>199</sup> whereas states remain split on whether to mandate vaccination.<sup>200</sup> And the Equal Employment Opportunity Commission (EEOC) issued guidance on vaccine mandates, indicating that mandatory

<sup>198</sup> *See id.*

<sup>199</sup> *Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees*, THE WHITE HOUSE BRIEFING ROOM (Sept. 9, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/>. *But see* BST Holdings, L.L.C. v. OSHA, 17 F.4th 604 (5th Cir. 2021) (staying Biden Administration’s mandate that all employees at companies with over 100 employees must receive COVID-19 vaccinations by January 4, 2022); *Georgia v. Biden*, No. 21-cv-163, 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021) (issuing nationwide preliminary injunction blocking the COVID-19 vaccine mandate for federal contractors, ruling the Biden Administration had likely exceeded its procurement authority).

<sup>200</sup> As of mid-August 2022, twenty Republican states have prohibited proof-of-vaccination requirement. *State Government Policies about Vaccine Requirements (Vaccine Passports)*, BALLOTPEdia, [https://ballotpedia.org/State\\_government\\_policies\\_about\\_vaccine\\_requirements\\_\(vaccine\\_passports\)](https://ballotpedia.org/State_government_policies_about_vaccine_requirements_(vaccine_passports)) (last updated Aug. 10, 2022). Several states brought suits against the President and other federal defendants challenging the Centers for Medicare and Medicaid Services’ interim final rule imposing COVID-19 vaccination mandates applicable to staff of healthcare facilities participating in Medicare and Medicaid, upon which a nationwide preliminary injunction was issued. *See Louisiana v. Becerra*, No. 21-cv-3970, 2021 WL 5609846 (W.D. La. Nov. 30, 2021); *Missouri v. Biden*, No. 21-cv-1329-MTS, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). On January 13, 2022, the Supreme Court stayed the injunction and allowed the mandate until the cases are decided on the merits. *Biden v. Missouri*, 142 S. Ct. 647, 655 (2022). In a parallel case, the Supreme Court also stayed the Emergency Temporary Standard (ETS) by the Occupational Safety and Health Administration (OSHA) that requires employees at companies with over 100 workers to get vaccinated or undergo routine COVID testing. *Nat’l Fed’n of Indep. Bus. v. Dep’t of Lab., OSHA*, 142 S. Ct. 661, 663 (2022). On January 26, 2022, OSHA effectively withdrew its vaccination-or-test mandate as an ETS but not as a proposed rule.

vaccination is not prohibited under federal anti-discrimination laws but must account for potential accommodation obligations and other legal nuances.<sup>201</sup> This has allowed universities<sup>202</sup> and private companies to require vaccination from their students and employees, with very limited medical or religious exemptions.<sup>203</sup> Employer mandates are important to have maximum effect on the powerless, such as in the context of meatpacking plants, with super-spreader conditions, unscrupulous employers, and powerless workers. Early numbers have shown that employment mandates in California and New York have substantially increased vaccination rates.<sup>204</sup> On the flip side, however, polling also shows that approximately half of employee respondents would quit, start looking for other employment, or both if their employer instituted a mandate.<sup>205</sup> But it turns out that some of the vaccine-hesitant employees value their careers more and chose not to lose their jobs over their decision not to receive a COVID-19 vaccine. For real-life examples:

After Houston Methodist Hospital required its workers to be vaccinated, 99.5% received the vaccine, with few resigning rather than getting vaccinated. Several companies that own more than 250 long-term care facilities have similarly mandated COVID-19 vaccines. There, too, more

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<sup>201</sup> See *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, EQUAL EMP. OPPORTUNITY COMM'N, <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (last updated July 12, 2022).

<sup>202</sup> See, e.g., I. Glenn Cohen & Dorit R. Reiss, *Can Colleges and Universities Require Student COVID-19 Vaccination?*, HARV. L. REV. BLOG (Mar. 15, 2021); Erwin Chemerinsky & Michele Goodwin, *Compulsory Vaccination Laws Are Constitutional*, 110 NW. U. L. REV. 589 (2016) (arguing that compulsory vaccination laws are constitutional and essential, such that vaccination for all children, except for medical reasons, should be required). On the topic of vaccinating children, courts may consider adopting a preventative measure and doing what they did with blood transfusions for children of Jehovah's Witnesses by temporarily taking away custody of the children from their parents and turn them over to guardian ad litem that would provide the necessary consent. See Adelaide Conti, Emanuele Capasso, Claudia Casella, Piergiorgio Fedeli, Francesco Antonio Salzano, Fabio Policino, Lucia Terracciano & Paolo Delbon, *Blood Transfusion in Children: The Refusal of Jehovah's Witness Parents*, 13 OPEN MED. 101, 101 (2018) ("In the case of Jehovah's Witness parents' refusal of blood transfusion for their child, Italian Courts adopt measures that prevents the parents from exercise their parental responsibility not in the child's best interest.").

<sup>203</sup> Certain employees have pushed back and filed suits challenging their employers' vaccine mandate. See, e.g., *United KP Freedom Alliance v. Kaiser Permanente*, No. 21-cv-7894, Dkt. 1 (N.D. Cal. Oct. 7, 2021) (Kaiser workers challenged their employer's vaccine mandate, arguing it was a violation of personal liberties protected by the Fourteenth Amendment); *Sambrano v. United Airlines, Inc.*, No. 21-cv-1074, Dkt. 1 (N.D. Tex. Sept. 21, 2021) (class action suit from six United Airlines employees challenged their employer's policy of placing workers with religious or medical exemptions from the vaccine mandate on indefinite unpaid leave, arguing that the company is effectively sacking people based on their faith or health conditions).

<sup>204</sup> See, e.g., Shawn Hubler, *'Mandates Are Working': Employer Ultimatums Lift Vaccination Rates, So Far*, N.Y. TIMES (Sept. 30, 2021), <https://www.nytimes.com/2021/09/30/us/california-vaccine-mandate-health-care.html> ("In California and New York, where mandates for health care workers have gone into effect, many are complying.").

<sup>205</sup> See Jack J. Barry, Ann Christiano & Annie Neimand, *Unvaccinated Workers Say They'd Rather Quit Than Get a Shot, but Data Suggest Otherwise*, SCI. AM. (Sept. 24, 2021), <https://www.scientificamerican.com/article/unvaccinated-workers-say-theyd-rather-quit-than-get-a-shot-but-data-suggest-otherwise/> (based on its own survey as well as citing Morning Consult polls and a June 2021 survey from the Kaiser Family Foundation). The same polling notes that "63% of all workers said a vaccine mandate would make them feel safer." *Id.*



than 95% of workers—and, in some cases, 100%—have been vaccinated, and few have quit rather than being vaccinated.<sup>206</sup>

Thus, employment mandates clearly work.

In addition to the employment mandates, other types of mandates (such as showing a COVID vaccine passport or vaccination certification) also work.<sup>207</sup> For example, restaurants, theaters, and other public venues in New York and California have required vaccine proof or recent (within three days) negative COVID-19 test results prior to entry, which makes it highly inconvenient for the unvaccinated. The inconvenience may serve to nudge the unvaccinated to become vaccinated and get it over with. While these increasingly aggressive measures have shown promising results—slowly but surely—it may be worth asking what else governmental agencies like FDA and CDC can do to intervene and meaningfully increase vaccine uptake.

### B. *Ex Ante: What Else May Work*

Other state or regulatory interventions to mitigate vaccine hesitancy and promote vaccine uptake must also account for the diverse causal factors in Part II.<sup>208</sup> Because of the great intersectionality of concern—rooted in both past and ongoing systemic inequities in healthcare—some measures to promote vaccine uptake may be more effective in some communities than others. However, all the sources of vaccine hesitancy described above can be characterized as kinds of distrust: distrust in scientific information<sup>209</sup> or in the people or organizations delivering it, distrust in the regulatory process to ensure vaccine safety, distrust in the substance and motives of political positions surrounding the virus and vaccination, and broad-based distrust of government programs. Former CDC Director Tom Frieden predicted such a situation: “The biggest challenge to getting a COVID-19 vaccine into enough people’s arms won’t be scientific, technical or logistical; it will come from a lack of trust.”<sup>210</sup> The resolutions therefore must be based on trust-building messaging.

#### 1. *Trust-Building Messaging*

Public trust is crucial in a global pandemic.<sup>211</sup> And messaging matters when it comes to a nationwide vaccination program.<sup>212</sup> Trust-building messaging means

<sup>206</sup> Ezekiel J. Emanuel & David J. Skorton, *Mandating COVID-19 Vaccination for Health Care Workers*, 174 ANNALS INTERNAL MED. 1308 (2021).

<sup>207</sup> See, e.g., Melinda C. Mills & Tobias Rüttenauer, *The Effect of Mandatory COVID-19 Certificates on Vaccine Uptake: Synthetic-Control Modelling of Six Countries*, 7 THE LANCET E15, E15 (2022) (finding that mandatory “COVID-19 certification led to increased vaccinations 20 days before implementation in anticipation, with a lasting effect up to 40 days after”).

<sup>208</sup> See *supra* Part II.

<sup>209</sup> See also, e.g., HEATHER MAC DONALD, *THE DIVERSITY DELUSION: HOW RACE AND GENDER PANDERING CORRUPT THE UNIVERSITY AND UNDERMINE OUR CULTURE 189–200* (2018) (analyzing “how identity politics is harming the sciences” by altering their standards of competence); Tran, *supra* note 179, at 88, 88 n.77 (discussing “the invasion of politics into specific departments [of universities] that have traditionally been shielded,” such as STEM).

<sup>210</sup> Kreps & Kriner, *supra* note 126, at 3256.

<sup>211</sup> Reiss, *The COVID-19 Vaccine Dilemma*, *supra* note 150, at 78; see also Allison M. Whelan, *Unequal Representation: Women in Clinical Trials*, 106 CORNELL L. REV. ONLINE 87, 88 (2021) (discussing “women of color’s distrust in the government, research institutions, and the medical system in general”).

<sup>212</sup> Reiss, *The COVID-19 Vaccine Dilemma*, *supra* note 150, at 78.

communication that aims to build trust—that is “transparent and honest, accurate and truthful, multimodal and frequent, [and] inclusive . . . .”<sup>213</sup> On the one hand, it ought to be not only empathetic and collaborative with the community members, healthcare professionals, and government officials<sup>214</sup> but also accessible. A “critical distance” ought to be established not only between those who might have interests beyond public health (such as pharmaceutical companies) and public entities sponsoring and disseminating the information,<sup>215</sup> but also between public health information and partisan political messaging.<sup>216</sup> On the other hand, trust-building messaging ought to avoid overselling (i.e., hyping the data and creating excessive expectations that later require correction, thereby undermining trust), under-sharing (lack of sufficient transparency about what steps are taken to ensure safety; failure to provide sufficient information about the process and findings, resulting in mistrust even when armed with safe and effective data), and enabling misinformation (e.g., leaving false messages without countering).<sup>217</sup> These principles require providing honest and accurate information that balance the benefits of vaccine and treatment with the limits of knowledge and potential risks.<sup>218</sup> Being honest about this kind of potentially unfavorable information means that communications must also be timely and up-to-date with current knowledge and guidance.<sup>219</sup> But effective use of trust-building messaging can “combat misinformation, myths, misperceptions, and conspiracy theories.”<sup>220</sup>

Healthcare workers are some of the most trusted sources of information regarding healthcare.<sup>221</sup> One way that agencies can promote trust-building messaging is to do more and ask healthcare workers to utilize social media platforms to facilitate interpersonal communications within the field and with patients.<sup>222</sup> Government agencies

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<sup>213</sup> Khubchandani et al., *supra* note 96, at 275–76.

<sup>214</sup> *Id.*; Bunch, *supra* note 122, at 149.

<sup>215</sup> Bunch, *supra* note 122, at 149.

<sup>216</sup> Khubchandani et al., *supra* note 96, at 275–76.

<sup>217</sup> Reiss, *The COVID-19 Vaccine Dilemma*, *supra* note 150, at 78–79.

<sup>218</sup> *Id.*; Bunch, *supra* note 122, at 149; Angelis & Darrow, *supra* note 54, at 2328.

<sup>219</sup> Khubchandani et al., *supra* note 96, at 275–76.

<sup>220</sup> *Id.*

<sup>221</sup> That said, people with strong anti-vaccination sentiments might also feel distrustful of healthcare workers, whom may be viewed as biased, so advice from healthcare workers might be less effective for these groups. Puri et al., *supra* note 111, at 2588; *see also* Momplaisir et al., *supra* note 32, at 1787 (quoting an interviewee who said: “I think we’ve all lost trust in our health system.”); *cf.* PAUL SABIN, PUBLIC CITIZENS: THE ATTACK ON BIG GOVERNMENT AND THE REMAKING OF AMERICAN LIBERALISM (2021) (describing how the steady drumbeat of criticism leveled by public-interest advocates against regulatory agencies over the past several decades has damaged the reputation of these agencies has had the unintended consequence of strengthening the anti-regulatory movement undertaken by conservatives and bearing fruit in 1981 in the Reagan Administration). For a thorough overview of cognitive biases and irrationality, *see generally* ELIEZER YUDKOWSKY, RATIONALITY: FROM AI TO ZOMBIES (2015).

<sup>222</sup> Puri et al., *supra* note 111, at 2588–89; *see also* Hallie Miller, Meredith Cohn & Lizzy Lawrence, ‘Vaccine Ambassadors’ Try to Persuade the Reluctant to Sit for Their Shots, WASH. POST (Nov. 4, 2021), [https://www.washingtonpost.com/local/vaccine-ambassadors-try-to-persuade-the-reluctant-to-get-their-shot/2021/11/04/65e4a010-35c3-11ec-8be3-e14aacfa8ac\\_story.html](https://www.washingtonpost.com/local/vaccine-ambassadors-try-to-persuade-the-reluctant-to-get-their-shot/2021/11/04/65e4a010-35c3-11ec-8be3-e14aacfa8ac_story.html) (explaining that the Baltimore City Health Department has deployed “vaccine ambassadors” into Black and Latino communities. The “messengers—ranging from full-time students to retired adults—are tasked with communicating the

can also leverage the widespread dependence on social media for information to deploy major public information campaigns to mitigate vaccine hesitancy.<sup>223</sup> However, for this to be successful, the agencies need to accomplish two things: first, they need to create a unified public health message—one not mired in political division, but rather informed only by science and best practice in public health given the conditions at hand and the current state of knowledge. Restructuring FDA into an independent agency—like the Federal Reserve<sup>224</sup>—might be one way to achieve this, as well as to protect scientific decision-making from political influence.<sup>225</sup> Second, the agencies ought to be *active* participants in the process of information dissemination: in addition to *passively* posting information only on official platforms (e.g., FDA’s and CDC’s main websites via press releases) or giving occasional interviews to news outlets, agencies ought to *actively* participate in the same modes of communication (such as social media) as the targeted audience to reach where they are most likely to receive and digest the information in a manner familiar to them.<sup>226</sup> In particular, this may include intentional communication specifically targeting certain minority groups, possibly in their own languages (e.g., in Vietnamese to communicate with both Vietnamese Americans and recent Vietnamese immigrants<sup>227</sup>), that could be statistically more susceptible to vaccine misinformation, as discussed earlier in Part II.C.

Public information campaigns like this ought to include campaigns to educate not only about the safety of vaccines but also about the regulatory approval process. It is certainly the case that the difference between an EUA and standard FDA licensure was not adequately explained to the public. The speed at which the vaccines were developed combined with a lack of communication about the authorization process would reasonably draw skepticism from anyone without inside knowledge about the development and regulatory process. In contrast to the lightning speed of vaccine development, the turtle-like speed of COVID-19 data sharing and vaccine approval, which is not uncommon for government agencies’ regulatory processes due to their bureaucratic red tape and excessive regulations,<sup>228</sup> has raised political concerns. To

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benefits of coronavirus vaccinations to those they meet and sharing the information people need to make informed decisions.”).

<sup>223</sup> Puri et al., *supra* note 111, at 2588–89 (“Health agencies and government websites should also improve their overall social media presence, and fostering partnerships with social media platforms may be a tool for accelerated promotion of evidence-based public health strategies.”).

<sup>224</sup> See generally IRWIN L. MORRIS, CONGRESS, THE PRESIDENT, AND THE FEDERAL RESERVE 19 (2000) (describing the Federal Reserve as one of the “world’s most independent central banks”); Peter Conti-Brown, *The Institutions of Federal Reserve Independence*, 32 YALE J. REGUL. 257 (2015) (discussing the history and implementation of the Federal Reserve Act of 1913, Pub. L. No. 73-66, 48 Stat. 162, enacted June 16, 1933, as amended in 1935).

<sup>225</sup> Angelis & Darrow, *supra* note 54, at 2328.

<sup>226</sup> To be fair, the CDC social media pages (e.g., Twitter and Facebook) have started doing what is recommended here to some extent, but they were not done well enough or widespread enough.

<sup>227</sup> See also, e.g., Heide Castañeda, Seth M. Holmes, Daniel S. Madrigal, Maria-Elena DeTrinidad Young, Naomi Beyeler & James Quesada, *Immigration as a Social Determinant of Health*, 36 ANN. REV. PUB. HEALTH 375 (2015) (applying “a broad social determinants lens to understand[ing] immigrants’ experiences and how related policies impact health”).

<sup>228</sup> See generally Edward L. Rubin, *Bureaucratic Oppression: Its Causes and Cures*, 90 WASH. U. L. REV. 291, 313–15 (2012); Mila Sohoni, *The Idea of “Too Much Law”*, 80 FORDHAM L. REV. 1585, 1617–

avoid likening FDA and CDC with a certain political agenda and consequently undermining their credibility, FDA, working in conjunction with CDC, could have relaxed its data-sharing and vaccine-approval processes to allow both processes to be done in a much shorter amount of time.<sup>229</sup> In any event, the recommendations for transparency and accuracy in communication to build trust might also mitigate another cause of concern for vaccine uptake—the EUA itself. Explaining the rigorous approval process, even for the EUA, might alleviate some concern about approval under an “emergency” rule.<sup>230</sup>

The public should also be educated about the fact that the development of the COVID-19 vaccine began well before the novel coronavirus pandemic, in the form of research into the viral RNA sequence and other coronaviruses: “the vaccine platforms that form the backbone for the most advanced of the SARS-CoV2 vaccines were not invented in 2020, but rather had been under development and even already tested in humans . . . .”<sup>231</sup> The currently approved vaccines therefore represent “decades of investment” in scientific research, rather than a speedy, uninformed regulatory experiment.<sup>232</sup> The speed is not the result of lack of care, but rather the result of an astronomical influx of public funds—the equivalent of five or more times the government investment in other vaccine development.<sup>233</sup> The result is a “triumph of our modern global biomedical research infrastructure.”<sup>234</sup>

These observations bear a few comments. First, this is an example of the direct correlation between public investment and public achievement. If greater funds were put toward other forms of medical research—or indeed, access to healthcare generally—on a more regular basis, triumphs like this might happen more often. One recommendation, therefore, is for the government to continue sponsoring needed

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18 (2012) (discussing how the United States suffers from the malady of too-much-law, whether statutory or regulatory).

<sup>229</sup> See, e.g., Letter from Dr. Lee Savio Beers, President, Am. Acad. Pediatrics, to Dr. Janet Woodcock, Acting Comm’r, U.S. Food & Drug. Admin. (Aug. 5, 2021), [https://downloads.aap.org/DOFA/AAP%20Letter%20to%20FDA%20on%20Timeline%20for%20Authorization%20of%20COVID-19%20Vaccine%20for%20Children\\_08\\_05\\_21.pdf](https://downloads.aap.org/DOFA/AAP%20Letter%20to%20FDA%20on%20Timeline%20for%20Authorization%20of%20COVID-19%20Vaccine%20for%20Children_08_05_21.pdf) (urging “authoriz[ation] as swiftly as possible” because “[w]aiting on a 6-month follow-up will significantly hinder the ability to reduce the spread of the hyper infectious COVID-19 Delta variant among [children under age 12], since it would add 4 additional months before an authorization decision can be considered”); Apoorva Mandavilli, *Behind the Masks, a Mystery: How Often Do the Vaccinated Spread the Virus?*, N.Y. TIMES (June 29, 2021), <https://www.nytimes.com/2021/07/29/health/cdc-masks-vaccinated-transmission.html> (“Just as with the development of vaccines, we didn’t cut any corners. We did all the steps, but we did it much, much faster. The F.D.A. has to go much, much faster.” (quoting interview with Dean Ashish Jha of Brown University’s School of Public Health)); Yasmeen Abutaleb & Lena H. Sun, *How CDC Data Problems Put the U.S. Behind on the Delta Variant*, WASH. POST. (Aug. 19, 2021), <https://www.washingtonpost.com/health/2021/08/18/cdc-data-delay-delta-variant/> (“It’s not acceptable how long it takes for th[e most up-to-date] data [about the Delta variant] to be made available . . . . It’s done in a very academic way. Cross every ‘t,’ and dot every ‘i,’ and unfortunately, we don’t have that luxury in a global pandemic. There’s going to be a need to have a significant cultural shift in the agency.” (quoting an anonymous senior CDC official)).

<sup>230</sup> Kreps & Kriner, *supra* note 126, at 3257; E. John Wherry, Elizabeth M. Jaffee, Nicholas Warren, Gypsyamber D’Souza & Antoni Ribas, *How Did We Get a COVID-19 Vaccine in Less Than 1 Year?*, 27 CLINICAL CANCER RSCH. 2136 (2021).

<sup>231</sup> Wherry et al., *supra* note 230, at 2136.

<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 2137.

<sup>234</sup> *Id.* at 2138.

medical research like this so that not only can the public continue to benefit from advancements in medical science, but also supporting agencies can increase their credibility. Second, the fact that the influx of funds and resources allowed scientists to build on decades of research and apply it to a novel disease and develop a safe and effective vaccine in the space of less than one year is indeed a triumph. Celebration of this fact across political spectrums and governmental bodies might in itself change attitudes toward what the vaccines are—something to be proud of, not skeptical of.<sup>235</sup>

Skeptics, however, may see the level of distrust in institutions like FDA as part of a deep-seated political strategy to undermine mainstream institutions in favor of a system of more personalized power. That is, a new economy has created dramatically greater inequality. The powers-that-be use distrust in institutions to enhance their own power, which sets the stage for a populist movement. The more politicized component of vaccine hesitancy is part of a deliberate attack on mainstream institutions. In that context, they may link the currently high level of distrust in FDA to the climate change debate, with no real hope of a broad-based nonpartisan approach to build trust at a societal level because that would unrealistically require bipartisan support and real leadership. With climate change, for instance, wind turbines and ethanol are big business in Iowa even among Republicans, and many localities are deeply attached to recycling surfaces at the curb in ways that bypass ideological divisions. Like the climate change movement, there is the opportunity to depoliticize and build support for constructive measures at the community level by localizing the efforts, using community mobilization campaigns, and individualizing the message through private doctors. Accordingly, the more effective vaccine approaches occur in these localized ways, such as targeting efforts at the African American community, for example, that employ a mix of African American celebrities and local nurses with mobile units.

## 2. *Addressing Race-Based Distrust*

Whether an individual has trust in the government to produce a safe and effective vaccine for a disease causing a public crisis is clearly based on much more than their race, or any one given category of identity, but studies across demographics reveal that trust has eroded on different levels for different communities. Indeed, there is certainly a degree of mistrust in the government among white populations, too, but as one study uncovered, displays of mistrust among white study participants “tended to be about an entity’s competence rather than its motives.”<sup>236</sup> This difference can have far-reaching implications for how policy interventions to mitigate hesitancy should look: whereas “[c]ompetence can be convincingly demonstrated by appealing to numbers, credentials, or previous successes,” such data will be “unlikely by themselves to sway a person whose mistrust stems from a skepticism regarding an institution’s motives.”<sup>237</sup> Approaches to mitigating racial disparities in vaccine uptake that are rooted in distrust of government programs must account for the broader historical and

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<sup>235</sup> On the other hand, transparent communication about the regulatory process includes transparency about mistakes and limitations. Indeed, suspicions about the safety of EUA products have proven to be well-founded even within the COVID-19 pandemic, such as with FDA’s approval of hydroxychloroquine discussed above. Some have criticized the way in which the public was expected to accept EUA as a measure of guaranteed safety when, in fact, “products made available under EUAs have not yet been proven either safe or effective.” Angelis & Darrow, *supra* note 54, at 2329.

<sup>236</sup> Bunch, *supra* note 122, at 147.

<sup>237</sup> *Id.* at 148.

social sources of distrust in addition to simply informing the public about the vaccine’s safety and efficacy. The trust-building messaging methods discussed above can help increase faith in vaccine safety and government competence, but addressing decades of mistrust based on systemic social abuses is more nuanced. For instance, if we were to accept that governmental motives, not competence, are the source of mistrust among many Black individuals, then any measures to increase vaccine uptake must be combined with measures to rebuild overall trust in the government itself—something that might be less of an issue for other hesitant groups.<sup>238</sup>

While restoring a sense of trust in the government is a complex issue in and of itself that is certainly outside the scope of this Article, hiring based on racial diversity and community engagement could be some of the ways to achieve this. For instance, employing more people of color, who are presumably more empathetic to their people and have their shared interests at heart, to do the research, to be involved with the regulatory and approval processes, and to represent the government agencies in front of the public may be a start.<sup>239</sup> Whether such a proposal may ultimately work, needless to say, requires a long time horizon both to find out and to achieve,<sup>240</sup> which reminds us of Søren Kierkegaard’s existential lament, that “[l]ife must be understood backwards. But . . . it must be lived forwards.”<sup>241</sup> If anything, we can only try our best to do everything in our power not only to remedy the past, to the extent it is possible,<sup>242</sup>

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<sup>238</sup> *Id.*

<sup>239</sup> *But see* discussion *supra* note 173. Diverse representation here means doing much more than tokenism and just giving lip service to diversity hiring in order to create and build trust. *See generally* Devon W. Carbado & Mitu Gulati, *Race to the Top of the Corporate Ladder: What Minorities Do When They Get There*, 61 WASH. & LEE L. REV. 1645, 1668–69 (2004) (discussing tokenism and its burdens in the corporate setting).

<sup>240</sup> *See, e.g.*, Frank H. Easterbrook, *When Is It Worthwhile to Use Courts to Search for Exclusionary Conduct?*, 2003 COLUM. BUS. L. REV. 345, 347 (2003) (“It is always hard to make predictions, especially about the future.’ Instead of making predictions that are impossible to test . . . wait to see what happens.” (quoting Yogi Berra)); *see also* *Cooper v. Aaron*, 358 U.S. 1, 25 (1958) (Frankfurter, J., concurring) (“Only the constructive use of time will achieve what an advanced civilization demands and the Constitution confirms.”).

<sup>241</sup> THE DIARY OF SØREN KIERKEGAARD, 111 (Peter Rohde ed., 1843); *see also* Daryl Lim, *AI & IP: Innovation & Creativity in an Age of Accelerated Change*, 52 AKRON L. REV. 813, 874 (2018) (“Hindsight allows us to look back and understand the consequences of our policy choices. Just as past is not necessarily prologue, hindsight does not necessarily translate into foresight. The law must embrace change and innovation as an imperative in a journey towards an ever-shifting horizon. The goal is to make better decisions today that shape the future, rather than try to regulate by predicting the future.”).

<sup>242</sup> *See, e.g.*, *United States v. Jefferson Cnty. Bd. of Ed.*, 372 F.2d 836, 876 (5th Cir. 1966) (“The Constitution is both color blind and color conscious. . . . It is color conscious to prevent discrimination being perpetuated and to undo the effects of past discrimination.”); *Furman v. Georgia*, 408 U.S. 238, 410 (1972) (Blackmun, J., dissenting) (“It is comforting to relax in the thoughts—perhaps the rationalizations—that this is the compassionate decision for a maturing society; that this is the moral and the ‘right’ thing to do; that thereby we convince ourselves that we are moving down the road toward human decency . . . .” Indeed, “we are less barbaric than we were in 1879, or in 1890, or in 1910, or in 1947, or in 1958, or in 1963, or a year ago . . . .”); Steven Lubet, *Why the Dreyfus Affair Does and Doesn’t Matter*, 13 GREEN BAG 2D 329, 342 (2010) (“Intellectuals are drawn by their nature to historical comparisons, invariably searching for the roots of contemporary injustices in the miscarriages of the past.”); *cf.* ARISTOTLE, NICOMACHEAN ETHICS 11 (W.D. Ross trans., 1999) (“[H]uman good turns out to be activity of soul in accordance with virtue, and if there are more than one virtue, in accordance with the best and most complete.”). *But see* *Forbes v. Appleyard*, 63 N.E. 894, 895 (Mass. 1902) (Holmes, J.) (“[T]he past cannot be undone.”); *Bell v. Beard*, No. 07-cv-1215, 2009 WL 689319, at \*5 (W.D. Pa. Mar. 16, 2009) (“As powerful as federal courts are, they cannot undo past deeds, they cannot change the past.”); AMY L. WAX, RACE, WRONGS, AND REMEDIES: GROUP JUSTICE IN THE 21ST CENTURY 7–13 (2009) (explaining how it is only the victim who can ultimately

but also to keep going after learning whatever lessons we could glean from history. to do everything in our power not only to remedy the past, to the extent it is possible, but also to keep going after learning whatever lessons we could glean from history.<sup>243</sup>

### 3. *Reducing Structural Barriers*

Without knowing each individual's personalized decision-making process, addressing all of the factors that go into such a process may actually help. For example, addressing systemic racism in health care and reducing structural barriers to vaccination may help to iron out the wrinkles of vaccine distribution and vaccine access as discussed in Part II.C *supra*.<sup>244</sup> Access to primary medical care helps, too.<sup>245</sup> And allowing for paid sick leave may help, to ensure employees do not fear losing their job or income because of potential vaccine side effects.<sup>246</sup> Many people are concerned with their lack of job security, which makes it hard for them to take time off for vaccination and go to outpatient clinics that only operate 9am–5pm. Expanding the locations and hours of vaccination clinics may help. Providing free rides to the clinics, childcare support, and other social assistances may help alleviate the unvaccinated's concerns.

## IV. CONCLUDING THOUGHTS ON FURTHER RESEARCH

This Article's title pays homage to Steinbeck's *Of Mice and Men* novella, which tells the story of two Depression-era wandering farmhands: the sharp-witted George

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save herself from drowning in—and pull herself out of—her own victimhood via the simple-yet-insightful “parable of the pedestrian”).

<sup>243</sup> See, e.g., GEORGE SANTAYANA, *THE LIFE OF REASON OR THE PHASES OF HUMAN PROGRESS* 284 (1906) (“Those who cannot remember the past are condemned to repeat it.”). At the same time, unfortunately, “[t]he younger generation [is] often bored with the past.” Louis Auchincloss, *Collaboration*, in *MANHATTAN MONOLOGUES* 89, 110 (2002). And most “Americans care so little about history. Even their own—so far as the history of other countries is concerned, they are perfectly blank.” JOHN DERBYSHIRE, *SEEING CALVIN COOLIDGE IN A DREAM* 21 (1996); see also HENRY WOOD NEVINSON, *RUNNING ACCOMPANIMENTS* 52 (1936) (“It is natural for each generation to scoff at its predecessor, and, like the bright young man in Homer, to boast itself much better than its fathers. A beggar mounted must naturally be taller than the horse, and a child on its father's shoulders glories in its elevation.”); cf. *Brown v. Allen*, 344 U.S. 443, 479 (1953) (“Past practice is evidence of past attitude of mind. That attitude is shown to no longer control the action of officials” in the present.); MORRIS R. COHEN, *THE MEANING OF HUMAN HISTORY* 17 (1947) (arguing that people “distrust history because it is largely created or written by diverse schools for partisan reasons.”); SIMONE WEIL, *THE NEED FOR ROOTS: PRELUDE TO A DECLARATION OF DUTIES TOWARD MANKIND* 48, 51–52 (Arthur Wills trans., 1952) (“The destruction of the past is perhaps the greatest of all crimes. Today the preservation of what little of it remains ought to become almost an obsession.”). Indeed, “the only thing we have learned from history is that we do not learn. But surely we can learn if we have the will to do so.” EARL WARREN, *THE MEMOIRS OF EARL WARREN* 354 (1977).

<sup>244</sup> See Letters to Editor, *supra* note 144.

<sup>245</sup> See *id.*

<sup>246</sup> Justice Williams Douglas once insightfully observed the paradox of fear: When a person “knows how to live dangerously, he is not afraid to die. When he is not afraid to die, he is, strangely, free to live.” WILLIAM O. DOUGLAS, *GO EAST YOUNG MAN* 202 (1974). Put differently, “the fear that is truly debilitating is the fear of the unknown in the environment around us. When we rid ourselves of that fear, we are free to live and can become more bold, courageous, and reliant.” *Id.* Indeed, “the only thing we have to fear is fear itself—nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat into advance.” Franklin D. Roosevelt, U.S. President, First Inaugural Address (Mar. 4, 1933).

Milton and his simple-minded sidekick, Lennie Small.<sup>247</sup> Both dream of having their own little farm and living “off the fat of the land.”<sup>248</sup> Such an American dream, however, dies when Lennie—perhaps accidentally—kills the young, flirtatious wife of a ranch owner’s son.<sup>249</sup> Steinbeck leaves readers with no doubt that Lennie—because of his lack of reasoning ability and adaptive skills—is not fully responsible for what he has done.<sup>250</sup> Is it not the case that the situation at hand is, in parallel, split into two camps: the vaccinated George and the vaccine-hesitant Lennie, the latter of which is not fully responsible for what he has done?<sup>251</sup>

When Justice Roberts stated on May 29, 2020 that “[a]t this time, there is no known cure, no effective treatment, and no vaccine” for COVID-19,<sup>252</sup> his statement fully captures the bleakness that COVID-19 had cast over the United States, from late March–early April (when state governors, one by one, started issuing strict lockdowns of businesses and stay-at-home orders) to late October–November 2020 (when FDA

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<sup>247</sup> See JOHN STEINBECK, *OF MICE AND MEN* (1937). A required reading for most American high schoolers, the story is certainly familiar to the public. Yet, the book has been targeted for censorship—for its vulgarity and what some consider offensive and racist language—fifty-four times in the course of eighty-five years since its publication, elevating it near the very top of the American Library Association’s list of the Top 100 Banned/Challenged Books—number five in the 2000–2009 list and number twenty-eight in the 2010–2019 list. (This list also includes, for example, J.K. Rowling’s *Harry Potter* series.) TOP 100 MOST BANNED AND CHALLENGED BOOKS: 2010–2019, AM. LIBR. ASS’N, <https://www.ala.org/advocacy/bbooks/frequentlychallengedbooks/decade2019> (last visited Aug. 12, 2022). Strictly speaking, this Article’s title, if it were to exactly follow Steinbeck’s line of thought, should have been *Of Hesitancy and Vaccine*. Otherwise, Steinbeck’s novel would have been titled *Of Men and Mice*. Nevertheless, *Of Vaccine and Hesitancy* (broad then narrow instead of narrow then broad) has a better ring to it.

<sup>248</sup> *Id.* at 14.

<sup>249</sup> *Id.* at 94.

<sup>250</sup> *E.g.*, *Ex Parte Briseno*, 135 S.W.3d 1, 6 (Tex. Crim. App. 2004) (“Most Texas citizens might agree that Steinbeck’s Lennie should, by virtue of his lack of reasoning ability and adaptive skills, be exempt [from the death penalty.]”). In 2017, the U.S. Supreme Court abrogated this so-called “Lennie standard” from *Briseno*. See *Moore v. Texas*, 137 S. Ct. 1039, 1053 (2017).

<sup>251</sup> We are, “of course, not perfect . . . ‘We have the qualities of our defects and the defects of our qualities.’ In many instances, qualities and defects are reciprocal and to correct a defect may damage a quality.” Robert B. von Mehren, *An International Arbitrator’s Point of View*, 10 AM. REV. INT’L ARB. 203, 208 (1999) (quoting Oscar Wilde); accord COHEN, *THE FAITH OF A LIBERAL*, *supra* note 105, at 77; *cf.*, *e.g.*, 3 Michel de Montaigne, *Of Experience*, in *THE ESSAYS OF MONTAIGNE* 815, 850 (Donald M. Frame trans., Stanford University Press 1976) (1580) (“We are great fools.”); MEMOIR OF HENRY BILLING BROWN, LATE JUSTICE OF THE SUPREME COURT OF THE UNITED STATES 129 (1915) (positing that “the papers own us” and that “most people are fools”); Michael McGonnigal, *This Is Who Will Die When Doctors Are Allowed to Kill Their Patients*, 31 J. MARSHALL L. REV. 95, 96–97 (1997) (“Ten years of practicing law leads one to conclude that most people are fools almost all of the time. [For example,] attorneys spend about three-fourths of the time rescuing clients from difficulties they should have averted in the first place. These clients sign contracts they do not read, marry spouses who have ‘wrong’ written all over them, and let profligate sons and daughters leech off of them . . . Everyone in the helping professions eventually realizes that the human race is united in folly. Doctors treat patients who smoke, drink, over-eat, over-work and refuse to take their medication. Counselors labor, usually in vain, to change behaviors which are self-defeating and self-destructive.”).

<sup>252</sup> *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (Roberts, J., concurring) (denying application for injunctive relief against California Governor Gavin Newsom’s Executive Order that aims to limit COVID’s spread).



approved Gilead's COVID-19 treatment,<sup>253</sup> and when the three American vaccines announced a 95% effectiveness rate for their COVID-19 vaccines, respectively). Fortunately, most of the statement is no longer true: we now have four COVID-19 vaccines (J&J, Moderna's Spikevax, Pfizer's Comirnaty, and AstraZeneca) and three COVID-19 treatments (Gilead's Veklury® (remdesivir),<sup>254</sup> Pfizer's Paxlovid, and Merck's Molnupiravir<sup>255</sup>) available, with more under development.<sup>256</sup> A complete cure may not be too far on the horizon—fingers crossed.

Despite ongoing efforts to reduce vaccine hesitancy and achieve herd immunity, it could be the case that the availability of COVID-19 treatments (and any potential cure) would further exacerbate the reasons to not receive a vaccine for the remaining—increasingly smaller—number of vaccine-hesitant people because they may confidently expect no need for prevention (with vaccine) when treatments are available. It may be worth watching whether they would also become hesitant toward receiving a COVID-19 treatment, giving rise to treatment hesitancy,<sup>257</sup> which is in and of itself an interesting topic for future research. That being said, the unfortunate people infected with COVID-19, when facing death's door, may not have much of a choice whether or not they can afford to refuse treatment.<sup>258</sup>

This Article briefly touched on,<sup>259</sup> but did not fully explore, whether vaccine hesitancy is a problem unique to the United States, which has had a long history of racial issues and is the location where three-quarters of the primary COVID-19

<sup>253</sup> See News Release, FDA Approves First Treatment for COVID-19, U.S. Food & Drug Admin. (Oct. 22, 2020), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>.

<sup>254</sup> See *id.*

<sup>255</sup> Merck, partnering with Ridgeback, announced the first oral antiviral treatment for COVID-19 that reduced hospitalization or death by approximately 50%. See News Release, Merck and Ridgeback's Investigational Oral Antiviral Molnupiravir Reduced the Risk of Hospitalization or Death by Approximately 50 Percent Compared to Placebo for Patients with Mild or Moderate COVID-19 in Positive Interim Analysis of Phase 3 Study, Merck (Oct. 1, 2021), <https://www.merck.com/news/merck-and-ridgebacks-investigational-oral-antiviral-molnupiravir-reduced-the-risk-of-hospitalization-or-death-by-approximately-50-percent-compared-to-placebo-for-patients-with-mild-or-moderat/>.

<sup>256</sup> FDA has issued EUAs for several monoclonal antibody treatments of mild or moderate COVID-19. *Know Your Treatment Options for COVID-19*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19> (last visited Aug. 12, 2022).

<sup>257</sup> See, e.g., Laura M. Bogart, Bisola O. Ojikutu, Keshav Tyagi, David J. Klein, Matt G. Mutchler, Lu Dong, Sean J. Lawrence, Damone R. Thomas & Sarah Kellman, *COVID-19 Related Medical Mistrust, Health Impacts, and Potential Vaccine Hesitancy Among Black Americans Living with HIV*, 86 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 200 (2021) (examining associations of COVID-19-related medical mistrust with COVID-19 vaccine and “treatment hesitancy” among Black Americans). Early surveys have shown that the vaccinated are far more likely to receive COVID treatment than the unvaccinated. Ed Silverman, *STAT/Harris Poll: Vaccinated Americans Far More Likely to Take Pfizer Covid-19 Pill Than Unvaccinated People*, STAT (Dec. 28, 2021), <https://www.statnews.com/pharmalot/2021/12/28/covid19-vaccine-pill-pfizer-fda/>.

<sup>258</sup> Cf. Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 288 (1985) (“[E]very dollar invested in vaccination reaps an estimated potential savings of eleven dollars in reduced costs of treatment.”); Tran, *supra* note 179, at 91 n.92 (“History and experience, time and time again, have shown that treatment costs much more than prevention.”). It could also be the case that the anti-treatment people infected with COVID-19 may behave like Jehovah Witnesses, who would “rather die than to have any blood transfusion.” R. Chua & K.F. Tham, *Will “No Blood” Kill Jehovah Witnesses?*, 47 SINGAPORE MED. J. 994, 995, 997 (2006) (estimating that about 1,000 Jehovah's Witnesses die each year through abstaining from blood transfusions).

<sup>259</sup> See *supra* Part II.C (discussing vaccine hesitancy in the U.K.).

vaccines available were developed. The answer is suspected to be a yes. For instance, Asian countries do not face a vaccine-hesitancy problem, as they have easily surpassed the United States in their vaccination rates even though they started vaccinating their citizens months later.<sup>260</sup> But more comparative research with other countries could be done to confirm this suspicion. And another avenue for future research is whether the vaccine-hesitant Americans would have been more receptive to receiving the U.K.'s AstraZeneca vaccine.<sup>261</sup> This question is worth asking because adding this vaccine choice on the table would eliminate the issue of deeply rooted historical distrust in the U.S. government. The result may inform whether it was FDA's fault for failing to approve the AstraZeneca vaccine for general use in the United States.<sup>262</sup>

Considering the Delta variant's rampage,<sup>263</sup> Omicron,<sup>264</sup> and other inevitable subsequent-Greek-alphabet-letter variants looming on the horizon,<sup>265</sup> we should do everything in our power to put a stop to COVID-19's transmission, infection, and mutations, and to not allow it to claim more lives than it has already done, as soon as possible. That means achieving herd immunity, when more than 90% of the population is vaccinated, which may very well begin with trust-building messaging, addressing race-based distrust, and reducing structural barriers to vaccine access in accordance with this Article's suggestions in Part III.B—as we should have done long ago. These unrecognized remedies for our vaccine hesitancy dilemma may—if we were to look to poets for guidance<sup>266</sup>—have not been unlike one aptly observed by T.S. Eliot seven decades prior:<sup>267</sup> “And the end of all our exploring / will be to arrive where we started

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<sup>260</sup> See, e.g., Sui-Lee Wee, Damien Cave & Ben Dooley, *How Asia, Once a Vaccination Laggard, Is Revving Up Inoculations*, N.Y. TIMES (Sept. 30, 2021), <https://www.nytimes.com/2021/09/30/business/economy/asia-covid-vaccinations.html>.

<sup>261</sup> But see Sirleaf, *Disposable*, *supra* note 82, at 80 (In June 2020, “the University of Oxford announced it would begin a new trial of its COVID-19 vaccine in Johannesburg, South Africa,” but “protestors challenged the trials as exploiting African people as ‘guinea pigs,’ informed by the ongoing disposability with which their lives are regarded.”). It could very well be the case that the history of racial subordination may transcend borders, causing the same resistance to vaccination.

<sup>262</sup> The AstraZeneca vaccine itself may still have significant safety issues (e.g., blood clotting). See, e.g., Gretchen Vogel & Kai Kupferschmidt, *Side Effect Worry Grows for AstraZeneca Vaccine*, 372 SCIENCE 14 (2021), <https://www.science.org/doi/full/10.1126/science.372.6537.14>. Regardless, one of the reasons for hesitancy is a distrust of the approval process or the established safety of the vaccines, which may remain a potential factor against Americans' willingness to accept the AstraZeneca vaccine instead. A parallel comparison worth exploring would be the public perceptions of the J&J vaccine versus the mRNA vaccines (Pfizer and Moderna), for instance.

<sup>263</sup> See generally Dana B. Taschner & Ashley Atwood, *COVID-19: Legal Framework for Vaccine Distributions and Mandates*, 24 SMU SCI. & TECH. L. REV. 65, 65–66 (2021) (noting that COVID-19's Delta variant “accounts for 83% of new cases nationwide” as of July 2021 and that “Delta variant viral loads are 1,260 times higher than those found in the earlier Covid pandemic wave”).

<sup>264</sup> See, e.g., Salim S. Abdool Karim & Quarraisha Abdool Karim, *Omicron SARS-CoV-2 Variant: A New Chapter in the COVID-19 Pandemic*, 398 LANCET 2126 (2021), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02758-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02758-6/fulltext).

<sup>265</sup> See, e.g., Robillard, *supra* note 89.

<sup>266</sup> *Skouras Theatres Corp. v. Radio-Keith-Orpheum Corp.*, 58 F.R.D. 357, 359 (S.D.N.Y. 1973) (“[I]n light of the conclusion which we come to here, we have been tempted to look to the poets for guidance and for reassurance that these efforts were well spent. T.S. Eliot has expressed these sentiments . . .”).

<sup>267</sup> Cf. Albert W. Alschuler, *Rediscovering Blackstone*, 145 U. PA. L. REV. 1, 55 (1996) (positing that “the unrecognized goal of our century's jurisprudential journey may have been one noted by T.S. Eliot”).

/ and know the place for the first time.”<sup>268</sup> The point is that what we have known these solutions all along, as they are not novel per se and are simply the same treatment for a different disease (COVID-19). But somehow, they have not been fully implemented. It is an issue of having the same symptoms over and over again. To *prevent* the next disease—in accordance with the true aim of *vaccine*—we ought to examine the root cause of the racial and hesitancy problem and treat it once and for all.

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<sup>268</sup> T.S. Eliot, *Little Gidding*, at stanza V, in *FOUR QUARTETS* (1942).