

# ARTICLES

## THE COVID-19 VACCINE DILEMMA

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*COVID-19 continues to lead to large numbers of deaths, harms, and financial costs. Without an effective vaccine, those will continue. The pressure to find a vaccine is high; and that pressure places a risk on the safeguards in place to assure that vaccines are safe and effective will be ignored. The United States has an extensive apparatus to oversee vaccine safety before and after licensing, including multiple federal committees and several monitoring systems, and that apparatus gave us, in 2020, an extraordinarily safe vaccine supply. This Article explains the different pressures that push for and against using the same apparatus for COVID-19 vaccines, including the extensive harms from the disease on one side and the need for a vaccine that is, in fact, safe and effective on the other. It examines the options for speeding up the process without sacrificing too much oversight. It examines which “shortcuts” are reasonable, which may be challenging, and which are bad ideas. Finally, it addresses three messaging challenges—overselling, under-sharing, and responding to misinformation—and suggests how to handle them.*

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## INTRODUCTION

On June 4, 2020, Science Magazine published an article stating that “Operation Warp Speed,” a public–private partnership started by the federal government with the purpose of developing an effective vaccine, “selected five experimental COVID-19 vaccines to fast-track through testing and, potentially, mass-scale production.”<sup>1</sup> Such news surprised top scientists involved with the White House-led program.<sup>2</sup> The article went on to explain that Operation Warp Speed will give chosen companies “access to additional government money, help in running clinical trials and financial and logistical support for a manufacturing base that is being built even before it is clear which if any of the vaccines in development will work.”<sup>3</sup> It is possible—and important—to speed up testing and production of COVID-19 vaccines without undermining trust in them. But it has to be done right, in a way that does not cast doubt on the process. The aforementioned article captured fears of many observers concerned about politically motivated corner cutting in developing COVID-19 vaccines. While there are several good reasons to want a vaccine as soon as possible, there are real concerns about rushing a vaccine to market in the wrong way. The “wrong way” could include forgoing input from experts or oversight bodies, lacking a basis on scientifically sound criteria, politicizing certain choices, or lacking transparency in the process.<sup>4</sup> Undermining trust could also increase hesitancy towards using the vaccine even by people who are usually pro-vaccine. The events described in the article were examples of speeding up vaccine development done wrong. It does not have to be this way.

In less than six months, COVID-19 dramatically changed our world, both globally and in the United States. COVID-19 has killed over two hundred and fifty thousand Americans, hospitalized many more, shut down the economy, and led most states to issue stay-at-home orders for a period of

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1. Jon Cohen, *Top U.S. Scientists Left Out of White House Selection of COVID-19 Vaccine Short List*, SCI. MAG. (June 4, 2020, 7:45 PM), <https://www.sciencemag.org/news/2020/06/top-us-scientists-left-out-white-house-selection-covid-19-vaccine-shortlist/> (giving the name “Operation Warp Speed” to a government project aimed to speeding up vaccine development); *see also Fact Sheet: Explaining Operation Warp Speed*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html> (Nov. 30, 2020) (noting the agencies and firms working on the operation).

2. Cohen, *supra* note 1.

3. *Id.*

4. *See* Ezekiel J. Emanuel & Paul A. Offit, *Could Trump Turn a Vaccine Into a Campaign Stunt?*, N.Y. TIMES (June 8, 2020), <https://nyti.ms/3h1k5CO> (concerning politicizing the process of releasing a coronavirus vaccine).

time.<sup>5</sup> Citizens, experts, and policymakers continue to struggle to deal with this disease. The long-term solution for all of the challenges that accompany COVID-19 is a vaccine that allows individuals to develop immunity to the virus without being infected.<sup>6</sup> Generally, the vaccine development process takes many years, but waiting years or decades will cause many more deaths and extensive harms.<sup>7</sup> The pressure to get a vaccine to market quickly is immense, as the costs of allowing COVID-19 to go unchecked are very high—but speeding up the process comes with real risks.<sup>8</sup> The United States has a very robust system for testing vaccines and monitoring their safety.<sup>9</sup> The current system has resulted in an extraordinarily safe vaccine supply thus far.<sup>10</sup> This Article examines not only what can or should be done to speed up COVID-19 vaccine development but also what should not be done.<sup>11</sup>

5. *Maps & Trends: Mortality Analyses*, JOHNS HOPKINS UNIV. & MED., <https://coronavirus.jhu.edu/data/mortality> (last visited Dec. 2, 2020); Robert O. Bonow et al., *Association of Coronavirus Disease 2019 (COVID-19) With Myocardial Injury and Mortality*, 5 J. AM. MED. ASS'N CARDIOLOGY 751, 751 (2020); Martin S. Andersen, *Early Evidence on Social Distancing in Response to Covid-19 in the United States 2* (June 25, 2020) (unpublished manuscript), [https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3635547\\_code1834306.pdf?abstractid=3569368&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3635547_code1834306.pdf?abstractid=3569368&mirid=1).

6. Stewart Lyman, *If Pharma Helps Quench the Covid-19 Pandemic, What Will it Want in Return?*, STAT NEWS (Apr. 21, 2020), <https://www.statnews.com/2020/04/21/vaccine-quenches-covid-19-what-will-pharma-want-in-return/>; Lois Privor-Dumm et al., *The Success of a Covid-19 Vaccine Will Hinge on its Delivery*, STAT NEWS (Apr. 25, 2020), <https://www.statnews.com/2020/04/25/success-covid-19-vaccine-hinge-on-delivery/>.

7. The usual process takes over a decade. Cecile Artaud et al., *Vaccine Development: From Preclinical Studies to Phase 1/2 Clinical Trials*, in MALARIA CONTROL & ELIMINATION 165, 165–66 (Frédéric Ariey et al. eds., 2019).

8. Julie Steenhuisen, *As Pressure for Coronavirus Vaccine Mounts, Scientists Debate Risks of Accelerated Testing*, REUTERS (Mar. 11, 2020, 7:07 AM), <https://www.reuters.com/article/us-health-coronavirus-vaccines-insight/as-pressure-for-coronavirus-vaccine-mounts-scientists-debate-risks-of-accelerated-testing-idUSKBN20Y1GZ>.

9. *U.S. Vaccine Safety – Overview, History, and How it Works*, U.S. CTRS. FOR DISEASE CONTROL & PREV., <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html> (Sept. 9, 2020).

10. *Ensuring Vaccine Safety*, U.S. CTRS. FOR DISEASE CONTROL & PREV., <https://www.cdc.gov/vaccinesafety/ensuringsafety/index.html> (July 1, 2020) (“The United States has the safest, most effective vaccine supply in its history. The . . . vaccine safety system ensures that vaccines are as safe as possible.”).

11. For some discussions on the topic, see Ezekiel J. Emanuel et al., *Fair Allocation of Scarce Medical Resources in the Time of Covid-19*, 382 NEW ENG. J. MED. 2049, 2049–50 (2020); Thomas J. Bollyky et al., *The Equitable Distribution of Covid-19 Therapeutics and Vaccines*, 323 J. AM. MED. ASS'N 2462 (2020). Another important question is how vaccines will be distributed once licensed since

Pressures may lead to errors and failures in three spheres: oversight failures, ethical failures, and messaging failures. With COVID-19, pressures derive both from the harms of the virus itself and from the presidential election since political factors impose pressures of their own.<sup>12</sup> These combined pressures could enable unjustified corner cutting in the testing process for the vaccine and allow oversight bodies to ignore problems even after the vaccine is licensed. At the same time, in the pandemic context, nonaction also carries real costs, and in such times, there is no cost-free or risk-free choice. Policymakers need to consider both sides of this dilemma when making choices. Other concerns include messaging failures, such as overly optimistic messaging that creates unrealistic expectations, as well as messaging that creates concerns throughout the public that the vaccine produced will be unsafe—even when that is not the reality.

While the reactions to COVID-19 are specific to this pandemic, this general scenario—a tension between a dangerous, harmful disease and the potential risks of not going through the full process of overseeing and vetting a vaccine—is not new and will likely recur.<sup>13</sup> The general tensions described in this piece, and the considerations around choosing between options, will be relevant in future crises.

This Article proceeds in four parts. Part I explains the regulatory framework governing vaccine licensing and monitoring in routine times. Part II explains the dilemma COVID-19 poses for vaccine development. Part III sets out possible scenarios addressing regulatory concerns and ethical concerns. Part IV addresses potential messaging pitfalls and their harms. I then conclude that while we should make adjustment to allow for fast development where we can, we need to make sure we are not sacrificing safety or effectiveness in the process.

## I. REGULATORY FRAMEWORK

Vaccines are classified as biologics under the Public Health Service Act of 1944.<sup>14</sup> In practice, this means that vaccines are subject to both the

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at least, at first, there will likely be limited quantities available. That topic is beyond this article; it deserves its own treatment.

12. Aimee Picchi, *Could Trump Push a Vaccine Through Before Election Day?* CBS NEWS (Sept. 11, 2020, 3:04 PM), <https://www.cbsnews.com/news/coronavirus-vaccine-process-fda-political-pressure/>.

13. Brit Trogen et al., *Adverse Consequences of Rushing a SARS-CoV-2 Vaccine Implications for Public Trust*, 323 J. AM. MED. ASS'N 2460 (2020).

14. 42 U.S.C. § 262(i). Biologics are defined as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product or

requirements of the Public Health Service Act and of the Food and Drug Administration (FDA), which applies to licensing drugs under the Food, Drug and Cosmetics Act.<sup>15</sup> Marketing a biologic requires the sponsor, usually a pharmaceutical company, to submit a Biologics License Application,<sup>16</sup> which requires showing that the biologic is “safe, pure, potent and effective.”<sup>17</sup> The FDA interprets the Public Health Safety Act to require that biologics—like other drugs—undergo “controlled clinical investigations” in humans.<sup>18</sup> To get to human clinical trials, the sponsor must submit an Investigational New Drug (IND) application to the FDA.<sup>19</sup> An IND application requires that “preclinical studies should be sufficient to rule out overt toxicity and identify potential toxic effects that might occur during the clinical trial.”<sup>20</sup> The FDA “has 30 days” to object after the agency receives an IND submission or the clinical “trial may proceed.”<sup>21</sup> The IND application usually requires evidence of safety and immunogenicity (ability to elicit an immune response—that the vaccine candidate works) in animals, as well as other data.<sup>22</sup> The vaccine then undergoes three stages of clinical trials, described by the FDA:<sup>23</sup>

Pre-marketing (pre-licensure) vaccine clinical trials are typically done in three phases, as is the case for any drug or biologic. Initial human studies, referred to as Phase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide

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arsphenamine or derivative of arsphenamine . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” Kathleen R. Kelleher, Note, *FDA Approval of Generic Biologics: Finding a Regulatory Pathway*, 14 MICH. TELECOMM. TECH. L. REV. 245, 247 (2007).

15. Edward L. Korwek, *Human Biological Drug Regulation: Past, Present, and Beyond the Year 2000*, 50 FOOD & DRUG L.J. (SPECIAL ISSUE) 129 (1995); Kelleher, *supra* note 14 at 248.

16. 42 U.S.C. § 262(a)(1)(A).

17. Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77, 84 (2007).

18. *Id.*; see also U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, *THE JOURNEY OF YOUR CHILD’S VACCINE* (2018), <https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine-h.pdf> (describing the three phases of clinical trials researchers use to test new vaccines).

19. 21 C.F.R. § 312.20(a).

20. Valerie Marshall & Norman W. Baylor, *Food and Drug Administration Regulation and Evaluation of Vaccines*, 127 PEDIATRICS S23, S26 (Supp. 2011).

21. *Id.* at S27.

22. *Vaccine Development - 101*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccine-s-blood-biologics/development-approval-process-cber/vaccine-product-approval-process> (Nov. 20, 2020).

23. *Id.*

the critical documentation of effectiveness and important additional safety data required for licensing.<sup>24</sup>

The completed trials are then submitted to the FDA’s Center for Biologics Evaluation and Research (CBER), where a “multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.)” reviews the evidence.<sup>25</sup> If the team gives the go ahead, the material is submitted to the FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC), which advises the FDA about the vaccine’s “safety and effectiveness.”<sup>26</sup> Since one of the aspects that separates biologic licensing from drug licensing is that for biologics the manufacturing plant is also licensed, during the review period the manufacturing plant and process of producing the vaccine is also subject to inspection and review.<sup>27</sup> Normally, this takes time.<sup>28</sup>

**Table 1: Vaccine Development Timeline, an Estimate<sup>29</sup>**

<b><u>Time Period</u></b>	<b><u>Stage</u></b>	<b><u>Description</u></b>
“Month 0-24” (This can also take many years).	“Preclinical”	During this period, scientists study the pathogen to decide what type of vaccine to do. They may choose to focus on the

24. *Id.*

25. *Id.*; see also Marshall & Baylor, *supra* note 20, at S23, S27.

26. *Vaccine Development - 101*, *supra* note 22; see also Marshall & Baylor, *supra* note 20 at, S28.

27. Marshall & Baylor, *supra* note 20 at, S27.

28. Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 731 (2019) (noting that the time that inspection and review takes is not only an issue during a pandemic; generally, this means that vaccines are not ready when the threat of a new pathogen is highest).

29. This table heavily draws on a blog post created by an anonymous blogger with pharmaceutical experience and, with the permission of the author, with some information I added. I have made changes to the language for clarity, but by and large, this is drawn from: *Coronavirus Vaccine Development – It’s Going to Take a Long Time*, SKEPTICAL RAPTOR: BLOG (Apr. 19, 2020), [hereinafter *Vaccine Development Timeline*] <https://www.skepticalraptor.com/skepticalraptorblog.php/coronavirus-vaccine-development-its-going-to-take-a-long-time/>. Note that this description assumes the virus or bacterial causing the disease has been identified—a necessary first step, which in many cases takes additional time - and that the timeline is likely “optimistic.” *Id.* For example, the rotavirus vaccine took twenty-six years to develop. *Sabin Institute Honors Paul Offit, MD, Vaccine Champion*, CHILD. HOSP. OF PHILA. RSCH. INST.: CORNERSTONE BLOG (May 2, 2018), <https://www.research.chop.edu/cornerstone-blog/sabin-institute-honors-paul-offit-md-vaccine-champion>; Greg Johnson, *Q&A with Paul Offit*, PENN TODAY (May 14, 2015), <https://penntoday.upenn.edu/2015-05-14/interviews/qa-paul-offit>.

		<p>part of the virus or bacteria, or on the entire organism. Scientists are looking for the best way to trigger an immune response without causing the disease or causing harm to humans. They then need to develop an animal model in which they can test the vaccine candidate to see if produces immunity in a safe manner. The hope is that the model will be sufficiently relevant to allow scientists to draw conclusions for the effects in humans; though, those conclusions will be tentative until human testing is done.</p>
“Month 24”	“IND application”	<p>Once the preclinical studies are completed, the “sponsoring organization” (which is usually an experienced vaccine manufacturer) submits an IND application to FDA. The application is reviewed by the Center for Biologics Evaluation and Research (CBER) in FDA. If it is approved, the company can prepare for—and then begin—clinical trials in humans.</p>
“Month 24-60 (or more)”	“[C]linical trials”	<p>The vaccine manufacturing company applies to an Institutional Review Board (IRB) for permission to test the drug in human. Then, the product undergoes three stages of clinical trials:</p> <p>“Phase 1 clinical trials usually include around 100 healthy patients (. . . no comorbidities and generally lack any chronic health conditions). This study is not usually randomized or blinded, as there is only one group, those that receive the vaccine.” Phase 1 clinical trials are intended to alert you to safety problems or signals, and help determine vaccine dose. Many studies terminate after Phase</p>

		<p>I because of safety concerns. But at this point, you do not have good information about safety or effectiveness.</p> <p>“Phase 2 clinical trials usually include around 200-300 patients. This study is a randomized, double-blind trial . . . .” It provides initial indications of effectiveness and safety, which help researchers determine if there is justification to move to the next phase.</p> <p>“Phase 3 clinical trials, sometimes called pivotal studies, include around 2–3 thousand patients” though for vaccines there could be tens of thousands of subjects. “These studies must be randomized, double-blinded, [and] placebo-controlled (. . . [or using] a standard of care control).”</p> <p>The results of “[P]hase 2 and 3 clinical trials”, when showing success, “are often published in peer-reviewed journals.”</p>
“Month 60-78”	“[R]egulatory review and approval”	<p>Once the testing of the vaccine candidate is complete, the company manufacturing it can—if the results justify it—submit a Biologics License Application (BLA) to CBER. It will simultaneously develop a manufacturing plan and prepare to build manufacturing facilities with enough capacity to produce the needed amount of vaccine. These facilities, in turn, need also be approved by the FDA.</p>

Vaccine development takes time for a number of reasons. It can take time to set up clinical trials and get volunteers.<sup>30</sup> For example, although Moderna

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30. *Vaccine Development Timeline*, *supra* note 29.



opened its clinical trial in late July, by September 11, 2020, they only had 23,497 participants out of the intended 30,000.<sup>31</sup> Other obstacles include reaching the broad diversity needed for a clinical trial.<sup>32</sup> Then, data needs to be collected by closely monitoring participants over a long enough period, and analyzed in multiple ways, to ensure accuracy.<sup>33</sup> Normally, exposing participants to the virus intentionally is unethical, so researchers need to wait long enough for natural exposure to happen in a large enough segment of participants.<sup>34</sup> As discussed below, one of the approaches considered to expedite COVID-19 vaccines is to intentionally expose volunteers to the virus.<sup>35</sup> Further, to see whether immunity is more than transient, the trial will have to proceed for multiple months.<sup>36</sup> To give some examples, Gardasil—a vaccine against the Human Papilloma Virus—involved Phase III trials that followed participants for about three years.<sup>37</sup> For rotavirus, infants were followed for a year.<sup>38</sup> There are problems that may arise and consequently slow down the process. Sometimes vaccines need to be reworked. When a vaccine does not produce intended results, scientists need to go back to the beginning and find a solution, if possible. It is also important to remember that there is no guarantee any vaccine candidate will pass clinical trials; in fact, clinical trials fail over 80% of the time.<sup>39</sup> In the case of COVID-19 vaccines, there are over one hundred in development and tens

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31. Brian Orelli, *Moderna Slowed Enrollment in Its Phase 3 Coronavirus Vaccine Clinical Trial*, MOTLEY FOOL (Sept. 13, 2020, 12:13 PM), <https://www.fool.com/investing/2020/09/13/moderna-slowed-enrollment-in-its-phase-3-coronavir/>.

32. Jenae Barnes, *A Black Participant in Moderna's Covid-19 Vaccination Trial: Trust the Vaccine*, ABC NEWS (Aug. 30, 2020, 3:05 PM), <https://abcnews.go.com/Health/black-participant-modernas-covid-19-vaccination-trial-trust/story?id=72654085>.

33. *Vaccine Development Timeline*, *supra* note 29.

34. *Id.*

35. *See infra* Part III, at 56–57.

36. Smriti Mallapaty and Heidi Ledford, *COVID-vaccine Results are on the Way – and Scientists' Concerns are Growing*, NATURE (Sept. 25, 2020) <https://www.nature.com/articles/d41586-020-02706-6>.

37. *See generally* Suzanne M. Garland et al., *Quadrivalent Vaccine Against Human Papillomavirus to Prevent Anogenital Diseases*, 356 NEW ENG. J. MED. 1928 (2007); The FUTURE II Study Group, *Quadrivalent Vaccine Against Human Papillomavirus to Prevent Anogenital Diseases*, 356 NEW ENG. J. MED. 1915, 1915–16, 1924 (2007).

38. Timo Vesikari et al., *Safety and Efficacy of a Pentavalent Human–Bovine (WC3) Reassortant Rotavirus Vaccine*, 354 NEW ENG. J. MED. 23, 26 (2006).

39. *See* JA DiMasi et al., *Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs*, 87 CLINICAL PHARMA. & THERAPEUTICS 272, 272–74, 276–77 (2010), (observing that the success rate in clinical trials in the United States was 16% between 1999–2004).

that have started clinical trials in humans.<sup>40</sup> The data suggests that we will have more than one successful vaccine candidate, at some point.

Licensing is not the end of the process or scrutiny. First, production is subject to continuing scrutiny—the FDA exercises some oversight over “lot[s]”, or batches, of vaccines.<sup>41</sup> Historical experience supports this requirement: one of the worst vaccine disasters in the United States was the result of a mishandled manufacturing process.<sup>42</sup> In the Cutter incident, nearly 200 children were paralyzed and ten died because a polio vaccine that should have contained an inactivated virus included a live, virulent virus instead.<sup>43</sup> Close oversight of the manufacturing process helps prevent similar tragedies. Another concern is the potential contamination of vaccines, as there are several instances of contamination in the past.<sup>44</sup> Each lot of the licensed vaccine is subject to testing.<sup>45</sup> Licensed vaccine production facilities need to be “inspected at least every 2 years.”<sup>46</sup> In addition, multiple oversight mechanisms exist to oversee vaccine safety after licensing (like VRBPAC does before licensing).<sup>47</sup> These mechanisms are not only used to discover issues that may have been missed during trials but also to find issues trials are too small to discover.<sup>48</sup> While clinical trials include up to tens of thousands of people, they would not identify a problem that is as rare as, say, one per a hundred thousand.<sup>49</sup>

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40. Ewen Callaway, *The Race for Coronavirus Vaccines: A Graphical Guide*, NATURE (Apr. 28, 2020), <https://www.nature.com/articles/d41586-020-01221-y>; see also *Draft Landscape of COVID-19 Candidate Vaccines*, WORLD HEALTH ORG., <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> Dec 2, 2020).

41. *Vaccine Development - 101*, *supra* note 22; Dinh, *supra* note 17.

42. Paul A. Offit, *The Cutter Incident, 50 Years Later*, 352 NEW ENG. J. MED. 1411, 1411 (2005).

43. *Id.*; Trogen et al., *supra* note 13; Johnson, *supra* note 29.

44. See generally John Petricciani et al., *Adventitious Agents in Viral Vaccines: Lessons Learned from 4 Case Studies*, 42 BIOLOGICALS 223 (2014).

45. Marshall & Baylor, *supra* note 20, at S23, S28–29 (2011); Theresa M. Finn, *U.S. FDA Requirements for Human Vaccine Product Safety and Potency Testing*, 5 PROCEEDIA VACCINOLOGY 137, 139 (2011).

46. Marshall & Baylor, *supra* note 20, at S29.

47. *Id.* at S28–29.

48. *Id.* at S29.

49. Steven Black, *The Importance of Active Surveillance in the Assessment of Vaccine Safety* 1 CCDC WKLY. 26, 26 (2019) (“[W]ith rare events, such as Guillain–Barre Syndrome, detecting a 2-fold increased relative risk with a background incidence of 1/100,000 would require a study of more than 4.7 million people. This would be impossible in a clinical trial, but by using large clinical datasets, however, such an association can be assessed.”).

However, continuous monitoring can uncover these rare problems.<sup>50</sup> In the United States, the Department of Health and Human Services (HHS) uses a combination of methods to monitor vaccine safety.<sup>51</sup> These methods include oversight by federal expert committees and maintaining sophisticated databases for researchers to analyze and discover problems.<sup>52</sup> First, the Advisory Committee on Immunization Practices (ACIP), made up of fifteen experts in “infectious diseases, pediatrics, internal medicine, family medicine, virology, immunology, public health, preventive medicine, vaccine research and policy, economics and cost-effectiveness”—as well as a “consumer representative”—monitors vaccines, usually starting about two years before licensure.<sup>53</sup> ACIP makes recommendations about the vaccine schedule for both children and adults and reviews vaccine safety data during its meetings, which take place three times a year, and continuously through its work groups.<sup>54</sup> For COVID-19 vaccines, a work group started in April 2020 made progress on a vaccine.<sup>55</sup> Also meeting three times a year is the National Vaccine Advisory Committee (NVAC), whose duties include to “[s]tudy and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States,” and to “[r]ecommend research priorities and other measures the Director of the National Vaccine Program, an office in HHS should take to enhance the safety and efficacy of vaccines.”<sup>56</sup> NVAC includes fifteen public members, “selected from individuals who are engaged in vaccine research or the manufacture of vaccines, or who are physicians, members of parent organizations concerned with immunizations, representatives of State or

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50. See *Vaccine Safety Scientific Agenda*, U.S. DEPT. OF HEALTH & HUM. SERVS. 1, 3–5, <https://www.hhs.gov/vaccines/national-vaccine-plan/vaccine-safety-scientific-agenda/index.html> (June 10, 2019) (explaining systems for vaccine safety, including VAERS, VSD, and PRISM).

51. *Id.* at 1–4.

52. *Id.*

53. See Jean Clare Smith, *The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)*, 285 VACCINE A68, A68, A71 (2010).

54. *Id.* at A70–A72. See generally ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES POLICIES AND PROCEDURES 4–5, 7, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (2018), <https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf>.

55. See Beth Bell, Work Group Chair, U.S. Ctrs. for Disease Control & Prevention, Introduction for Presentation on ACIP COVID-19 Vaccines Work Group 2–3, 8 (June 24, 2020), <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-06/COVID-05-Bell-508.pdf> (discussing mission and founding of Work Group, and introducing presenters on COVID-19 vaccine development, considerations, and next steps).

56. *NVAC Charter*, U.S. DEP’T OF HEALTH & HUM. SERVS. <https://www.hhs.gov/vaccines/nvac/charter/index.html> (last visited Dec. 2, 2020).

local health agencies or public health organizations,” and two representatives of the vaccine industry.<sup>57</sup> Finally, among the responsibilities of the Advisory Committee on Childhood Vaccines (ACCA) are the duties to “advise the Secretary . . . regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions.”<sup>58</sup> The Committee also collects data on vaccines’ adverse reactions and suggests research related to it.<sup>59</sup> The ACCA committee’s members are “three . . . health professionals” with “expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians,” “three members from the general public,” at least two “legal representatives of children who have suffered a vaccine-related injury or death,” and “three . . . attorneys,” at least one specializing in representing vaccine injury cases, and one who represents vaccine manufacturers.<sup>60</sup> Since these committees are all subject to the Federal Advisory Committee Act, meetings and materials are public and easily accessible, allowing for public scrutiny of proceedings.<sup>61</sup>

In addition to advisory committees, there are four large computerized systems that collect data on vaccine risks.<sup>62</sup> These include the Vaccine Adverse Events Reporting System (VAERS), a passive reporting system that anyone can report to, designed to provide early warnings of issues.<sup>63</sup> Although, VAERS has real limits as a passive monitoring system, it has successfully caught issues in the past. For example, VAERS has caught a rare (1:10,000), serious side effect of the first Rotavirus vaccine to be licensed in the United States, which was confirmed in an independent investigation.<sup>64</sup> The other three monitoring systems are active monitoring systems. The Vaccine Safety Datalink (VSD) is a collaboration between the Centers for Disease Control and

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57. *Id.*

58. CHARTER: ADVISORY COMMISSION ON CHILDHOOD VACCINES, U.S. DEP’T. OF HEALTH & HUM. SERVS. 1 (2020), <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-charter.pdf>.

59. *Id.*; see also Efthimios Parasidis, *Recalibrating Vaccination Laws*, 97 B.U. L. REV. 2153, 2227 (2017) (suggesting the Committee should be used more).

60. *Advisory Comm’n on Childhood Vaccines Charter*, *supra* note 58.

61. 5 U.S.C. app. §§ 2, 10.

62. See generally *Vaccine Safety*, U.S. DEP’T. OF HEALTH & HUM. SERVS., <https://www.vaccines.gov/basics/safety> (Feb. 2020) (identifying components of vaccine monitoring system).

63. *Vaccine Adverse Event Reporting System (VAERS)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/> (Sept. 11, 2020).

64. Jason Schwartz, *The First Rotavirus Vaccine and the Politics of Acceptable Risk*, 90 MILBANK Q. 278, 285–289 (2012). Although Prof. Schwartz’ account is cautionary, it highlights that the problems with the vaccine were raised—and followed on—within a few months of its use. *Id.*

Prevention (CDC) and healthcare organizations covering millions of people. It includes both constant active monitoring of signals, by comparing on an ongoing basis people who have received a vaccine and those who have not. VSD also allows researchers to do in-depth analyses of specific issues.<sup>65</sup> Many studies are done using VSD data, including a 2018 whitepaper on studying the safety of the entire schedule.<sup>66</sup> The Post-Licensure Rapid Immunization Safety Monitoring System (PRISM), another large active system, is part of the FDA Sentinel System—a system designed to monitor medical products by tracking health insurance claims.<sup>67</sup> PRISM covers 171 million people, allowing for studies larger than other systems.<sup>68</sup>

Finally, the Clinical Immunization Safety Assessment Project (CISA) allows providers to submit queries and get an expert evaluation about specific patients, including evaluations of whether a problem is vaccine-related or whether an existing condition is a contraindication to a vaccine.<sup>69</sup> CISA also conducts direct research on vaccine safety for specific issues and special populations.<sup>70</sup>

Besides these mechanisms in HHS, research is conducted in other parts of the United States government:

The Department of Defense (DoD) and U.S. Department of Veterans Affairs (VA) have systems to monitor vaccine safety and do vaccine safety research. The National Institutes of Health (NIH) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP) also support ongoing research on vaccines and vaccine safety.<sup>71</sup>

In other words, extensive institutional arrangements for monitoring vaccine safety exist in the United States in relation to routine vaccines. These

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65. *Vaccine Safety Datalink (VSD)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/> (Aug. 24, 2020).

66. JASON GLANTZ ET AL., NAT'L CTR. FOR EMERGING & ZOO NOTIC INFECTIOUS DISEASES, WHITE PAPER STUDYING THE SAFETY OF THE CHILDHOOD IMMUNIZATION SCHEDULE FOR THE VACCINE SAFETY DATALINK (2016), [https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety\\_web.pdf](https://www.cdc.gov/vaccinesafety/pdf/whitepapersafety_web.pdf).

67. See *Vaccine Safety*, *supra* note 62; see also *Vaccines, Blood, & Biologics Assessments*, SENTINEL, <https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments/> (last visited Dec. 2, 2020).

68. *Public Workshop: The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) System*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/workshops-meetings-conferences-biologics/public-workshop-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system> (Sept. 18, 2018).

69. *Clinical Immunization Safety Assessment (CISA) Project*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html> (July 20, 2020).

70. *Id.*

71. *Vaccine Safety*, *supra* note 62.

arrangements result in a very high level of safety.<sup>72</sup> Summarizing that data, the National Academies of Sciences, Engineering, and Medicine concluded that “[v]accines are extremely safe. They have many health benefits and few side effects.”<sup>73</sup>

## II. COVID-19 AND THE CHALLENGE TO VACCINES

Normally, vaccine development takes years. But between February 2020 and the end of September 2020, over a million people worldwide died from COVID-19.<sup>74</sup> By December 2, 2020, deaths in the United States topped 269,000.<sup>75</sup> By many indications, this is an undercount of deaths.<sup>76</sup> Millions have been infected by the virus.<sup>77</sup> Looking at the United States alone, as of the week ending November 7, 2020, just under 21 million people have applied for unemployment insurance, and during the week ending

72. Sarah Geoghegan et al., *Vaccine Safety: Myths and Misinformation*, 11 FRONTIERS MICROBIOLOGY, Mar. 2020, at 5; Frank DeStefano et al., *Principal Controversies in Vaccine Safety in the United States*, 69 CLINICAL INFECTIOUS DISEASES 726 (2019). *But see* Parasidis, *supra* note 59, at 2210, 2223–2225, 2227 (concluding systems are insufficient). Note, however, that the article downplays the role of the active monitoring systems described above, *id.* at 2223–2225, and only briefly mentioned one of the four advisory committees described here. *Id.* at 2210 fn.460, 2217, 2227.

73. *Vaccines are Safe*, NAT’L ACADS. OF SCI., ENG’G & MED., <https://sites.nationalacademies.org/BasedOnScience/vaccines-are-safe/index.htm> (last visited Dec. 2, 2020); *see also* FE Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 BULLETIN OF THE WORLD HEALTH ORGANIZATION [WHO] 140, 140 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2647387/pdf/07-040089.pdf> (“[I]ndependent experts and WHO have shown that vaccines are far safer than therapeutic medicines. Modern research has spurred the development of less reactogenic products, such as acellular pertussis vaccines and rabies vaccines produced in cell culture. Today, vaccines have an excellent safety record and most “vaccine scares” have been shown to be false alarms.”).

74. Emiliano Rodrigues Mega, *COVID has Killed More than One Million People. How Many More Will Die?* NATURE (Sept. 30, 2020), <https://www.nature.com/articles/d41586-020-02762-y>.

75. *CDC Covid Data Tracker United States Covid-19 Cases and Deaths by State*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html> (Dec. 2, 2020); *Coronavirus Resource Center*, JOHNS HOPKINS UNIV. & MED., <https://coronavirus.jhu.edu/us-map> (last visited Dec. 2, 2020).

76. Stephanie Pappas, *How COVID-19 Deaths are Counted*, SCI. AM. (May 19, 2020), <https://www.scientificamerican.com/article/how-covid-19-deaths-are-counted1/>.

77. *Coronavirus Disease (Covid-19) Situation Report – 127*, WORLD HEALTH ORG., (May 26, 2020, 10:00 AM), [https://www.who.int/docs/default-source/coronaviruse/situation-report-s/20200526-covid-19-sitrep-127.pdf?sfvrsn=7b6655ab\\_8](https://www.who.int/docs/default-source/coronaviruse/situation-report-s/20200526-covid-19-sitrep-127.pdf?sfvrsn=7b6655ab_8).

November 21, 2020 778,000 filed initial claims.<sup>78</sup> Since the beginning of the crisis, hundreds of thousands of small business have closed and others are at risk of closure.<sup>79</sup> Children are out of school and daycare, imposing burdens on families and depriving children of a variety of important social goods.<sup>80</sup> The costs are not evenly distributed, exacerbating existing inequalities.<sup>81</sup> The harms, also, disproportionately (though not exclusively) fall on minority groups.<sup>82</sup> The economic impacts are not limited to the United States economy—many other countries are struggling as well.<sup>83</sup>

The virus, both directly and through diverse disruptive impacts, poses real risks to people's health and lives.<sup>84</sup> For individuals who already live on the margins of poverty, losing a job means they may not be able to cover all their basic needs.<sup>85</sup> Some may face the loss of their home, and homelessness—or poverty generally—worsens health outcomes.<sup>86</sup> Not taking measures to

78. See Press Release, U.S. Dep't of Labor, Unemployment Insurance Weekly Claims 1, 4, 6 (Nov. 25, 2020), <https://www.dol.gov/ui/data.pdf>.

79. STEVEN HAMILTON, THE HAMILTON PROJECT, POLICY PROPOSAL 2020-14, FROM SURVIVAL TO REVIVAL: HOW TO HELP SMALL BUSINESSES THROUGH THE COVID-19 CRISIS 4 (Brookings Inst. 2020), [https://www.brookings.edu/wp-content/uploads/2020/09/PP\\_Hamilton\\_Final.pdf](https://www.brookings.edu/wp-content/uploads/2020/09/PP_Hamilton_Final.pdf); MICHAEL POWE & MATTHEW WAGNER, NAT'L MAIN ST. CTR., THE IMPACT OF COVID-19 ON SMALL BUSINESSES: FINDINGS FROM MAIN STREET AMERICAN'S SMALL BUSINESS SURVEY 3-4 (2020), [https://higherlogicdownload.s3.amazonaws.com/NMSC/390e0055-2395-4d3b-af60-81b53974430d/UploadedImages/Resource\\_Center/COVID\\_19/NMSC57\\_MSA\\_COVID19IMPACTSURVEY\\_F.pdf](https://higherlogicdownload.s3.amazonaws.com/NMSC/390e0055-2395-4d3b-af60-81b53974430d/UploadedImages/Resource_Center/COVID_19/NMSC57_MSA_COVID19IMPACTSURVEY_F.pdf).

80. See NAT'L ACADS. OF SCI., ENG'G, & MED., REOPENING K-12 SCHOOLS DURING THE COVID-19 PANDEMIC: PRIORITIZING HEALTH, EQUITY, AND COMMUNITIES 25-31 (2020); Russel M. Viner et al., *School Closure and Management Practices During Coronavirus Outbreaks Including Covid-19: A Rapid Systematic Review*, in 4 LANCET CHILD & ADOLESCENT HEALTH 397, 398 (2020).

81. Emily A. Benfer & Lindsay F. Wiley, *Health Justice Strategies to Combat COVID-19: Protecting Vulnerable Communities During a Pandemic*, HEALTHAFFAIRS: BLOG (Mar. 19, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200319.757883/full/>.

82. Monica Webb Hooper et al., *COVID-19 and Racial/Ethnic Disparities*, 323 J. AM. MED. ASS'N 2466, 2466 (2020); Cato T. Laurencin & Aneesah McClinton, *The COVID-19 Pandemic: A Call to Action to Identify and Address Racial and Ethnic Disparities*, 7 J. RACIAL ETHNIC HEALTH DISPARITIES 398, 398-400 (2020).

83. Peterson K. Ozili & Thankom Arun, *Spillover of COVID-19: Impact on the Global Economy* 1-3, 5-14, 20 (Mar. 27, 2020) (unpublished manuscript), [https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3584485\\_code1996195.pdf?abstractid=3562570&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3584485_code1996195.pdf?abstractid=3562570&mirid=1); *COVID-19's Historic Economic Impact, In the U.S. and Abroad*, JOHNS HOPKINS UNIV.: HUB (Apr. 16, 2020), <https://hub.jhu.edu/2020/04/16/coronavirus-impact-on-european-american-economies/>.

84. Martin McKee & David Stuckler, *If the World Fails to Protect the Economy, COVID-19 Will Damage Health Not Just Now but Also in the Future*, 26 NATURE MED. 640 (2020).

85. Benfer & Wiley, *supra* note 81.

86. *Id.*

contain spread would not necessarily spare the economy: people would respond to an uncontrolled pandemic by taking actions that would harm the economy.<sup>87</sup> The high costs of the pandemic and its containment—measured in lives, health, and economic harms—put pressure on policymakers and scientists to find a quick solution.<sup>88</sup> The long-term solution, experts agree, is having a safe, effective vaccine that will ideally prevent COVID-19 from infecting people and spreading throughout the population.<sup>89</sup> The public and business interests are also anxiously awaiting a vaccine.<sup>90</sup> Going through the regular process means a long wait for the vaccine. Understandably, policymakers—and citizens—are concerned about that long wait.<sup>91</sup> Policymakers correctly point out that while rushing a vaccine through the process has risks, so does waiting until the usual testing is complete.<sup>92</sup> Letting COVID-19 rage unchecked will kill many and cause additional harms through economic consequences.<sup>93</sup> On the other hand are the costs of having an unsafe vaccine. First, an unsafe vaccine can directly harm people. During previous vaccine scandals, like the Cutter Incident or the 1976 swine flu episode, people died or were paralyzed by a vaccine.<sup>94</sup> There is also some risk that a COVID-19 vaccine could predispose recipients to a more severe case of the disease.<sup>95</sup> Dr. Douglas Green of St. Jude’s Research Hospital explained:

In 1966, a large trial of a vaccine for Respiratory Syncytial Virus (RSV) found that the immunized cohort actually fared [sic] significantly worse upon infection. Additionally, many worry that the same may occur with some SARS-CoV2 vaccines. . . . There are

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87. Sergio Correia et al., *Pandemics Depress the Economy, Public Health Interventions Do Not: Evidence from the 1918 Flu 1–2, 12–13, 15–16* (June 5, 2020) (unpublished manuscript), [https://papers.ssrn.com/sol3/Delivery.cfm/SSRN\\_ID3624939\\_code2423067.pdf?abstractid=3561560&mirid=1](https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3624939_code2423067.pdf?abstractid=3561560&mirid=1); Pierre-Olivier Gourinchas, *Flattening the Pandemic and Recession Curves, in MITIGATING THE COVID ECONOMIC CRISIS: ACT FAST AND DO WHATEVER IT TAKES* 31, 35, 38 (Richard Baldwin & Beatrice Weder di Mauro eds., 2020).

88. Stanley A. Plotkin & Arthur Caplan, *Extraordinary Diseases Require Extraordinary Solutions*, 38 *VACCINE* 3987, 3897 (2020).

89. *Id.*

90. See Sarah Zhang, *A Vaccine Reality Check*, *ATLANTIC* (July 25, 2020, 7:56 PM) <https://www.theatlantic.com/health/archive/2020/07/covid-19-vaccine-reality-check/614566/>.

91. Moncef Slaoui & Matthew Hepburn, *Developing Safe and Effective Covid Vaccines — Operation Warp Speed’s Strategy and Approach*, 383 *NEW ENG. J. MED.* 1701 (Oct. 29, 2020).

92. Bijayeeta Deb et al., *Current Global Vaccine and Drug Efforts Against COVID-19: Pros and Cons of Bypassing Animal Trials*, 45 *J. BIOSCIENCES* 82 (2020).

93. *Id.*

94. Trogen et al., *supra* note 13.

95. Douglas R. Green, Editorial, *SARS-CoV2 Vaccines: Slow is Fast*, *SCI. ADVANCES* (May 22, 2020), <https://advances.sciencemag.org/content/early/2020/05/22/Sciadv.abc7428.full>.



potential reasons why an immune response to a vaccine can predispose an individual to a worse outcome upon infection. One is the phenomenon of antibody-dependent enhancement (ADE). In this effect, antibodies that bind to the virus also bind to antibody receptors on cells, facilitating uptake and infection of the cell bearing the receptors. ADE was observed for vaccines against Dengue, Ebola, and HIV. As recently as 2017, a large-scale efficacy trial of a Dengue vaccine resulted in ADE in vaccinated children. Troublingly, ADE was also seen in vaccines for a feline coronavirus. There is also evidence for ADE in SARS-CoV. Studies show that rodent and human antibodies to the S protein enhance infection *in vitro*. However, several small preclinical studies of a SARS-CoV vaccine in rhesus monkeys failed to observe evidence of ADE.<sup>96</sup>

Testing must assure that a vaccine is not worse than the disease and does not predispose the recipient to worse cases going forward. But that comparison is not as straightforward as it may seem. Every vaccine is approved on a risk–benefit analysis: are the risks greater than the benefits? All vaccines carry at least a theoretical risk of a severe allergic reaction, which if untreated can be fatal; though, that risk is extremely small.<sup>97</sup> The polio vaccine used in the United States between 1961–1997 (and a few years afterward, since the process of transition was gradual) was the oral polio vaccine (OPV).<sup>98</sup> OPV causes paralysis in recipients in about one in 2.4 million doses.<sup>99</sup> However, the benefits of the vaccine were considered high enough to justify the risk.<sup>100</sup> For a COVID-19 vaccine, too, the question is not simply whether it will have any rare hidden risks, but whether the potential of rare hidden risks is higher than the risks of not giving the vaccine. That comparison depends on several factors. During the pandemic, when cases are high and the effects of the pandemic are severe and visible, we may tolerate a higher risk than when the

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96. *Id.* (“One SARS-CoV2 vaccine, employing inactivated virus, was tested in several large cohorts of rhesus monkeys, with substantial efficacy and no evidence of ADE. While this is clearly encouraging, the need to ensure that any vaccine is, indeed, safe is of vital importance.”).

97. Michael M. McNeil et al., *Risk of Anaphylaxis After Vaccination in Children and Adults*, 137 J. ALLERGY & CLINICAL IMMUNOLOGY 868, 871, 874–75, 877 (2016) (noting that the risk is around one per million overall, and for some vaccines the risk is purely theoretical).

98. *Poliomyelitis Prevention in the United States: Introduction of a Sequential Vaccination Schedule of Inactivated Poliovirus Vaccine Followed by Oral Poliovirus Vaccine; Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 24, 1997), <https://www.cdc.gov/mmwr/preview/mmwrhtml/00046568.htm>.

99. *Id.*

100. *Notice to Readers: Recommendations of the Advisory Committee on Immunization Practices: Revised Recommendations for Routine Poliomyelitis Vaccination*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (July 16, 1999), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a4.htm>.

case rate declines.<sup>101</sup> But this, too, needs to be examined more closely. First, the risks of the vaccine may not be equally distributed with the risks of the disease. For example, the risks of COVID-19, though they exist in every age group, vary—the risk of direct death or severe outcomes increases with age.<sup>102</sup> At the same time, there is growing evidence of a special inflammatory syndrome in children caused by COVID-19.<sup>103</sup> The highest risks associated with a new vaccine, however, may be in a group for whom the risks of COVID-19 are low. Is it ethical to impose a created risk on one group to protect another? Incomplete testing means we may not know who bears the risk, or the nature and severity of uncommon risks. Further, scientists, policymakers, and members of the public do not treat the risks of vaccines as equivalent to the risks of the disease. As mentioned above, in 1998, a rotavirus vaccine with a 1:10,000 risk of a severe side effect was taken off the market because that risk was deemed too high to be acceptable in a vaccine—even though the risks of the disease were higher than 1:10,000 severe harm.<sup>104</sup> Giving a vaccine to a healthy person is not the same as treating someone who is sick, and the standard is not simply whether the risks are higher than the benefits. Since modern routine childhood vaccines have extremely low risks, our safety expectations from vaccines are high. We have already seen several examples where rush led to potential harm in the context of the COVID-19 pandemic. For example, the FDA authorized hydroxychloroquine (HCQ) after the medication was touted as a cure for COVID-19, even though there was insufficient evidence for doing so.<sup>105</sup> The FDA pulled the aforementioned

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101. See Frank Destefano et al., *Vaccine Safety*, in PLOTKIN'S VACCINES 1584, 1595–96 (Stanley A. Plotkin et al. eds., 7th ed. 2018).

102. Dale Fisher & David Heymann, *Q&A: The Novel Coronavirus Outbreak Causing Covid-19*, 18 BMC MED. 57 (2020).

103. See Jennifer Couzin-Frankel, *Doctors Race to Understand Rare Inflammatory Condition Associated with Coronavirus in Young People*, SCI. MAG. (May 21, 2020, 4:10 PM), <https://www.sciencemag.org/news/2020/05/doctors-race-understand-rare-inflammatory-condition-associated-coronavirus-young-people>; Crystal Phend, *Targeting Immune Responses in Kids' COVID-19 Inflammatory Disorder*, MEDPAGE TODAY (May 21, 2020), <https://www.medpagetoday.com/infectiousdisease/covid19/86614>. The CDC labeled it “multisystem inflammatory syndrome in children,” and pointed out that most children recover with treatment. See *for Parents: Multisystem Inflammatory Syndrome in Children (MIS-C) associated with Covid-19*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/mis-c.html> (May 20, 2020).

104. *Withdrawal of Rotavirus Vaccine Recommendation*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 5, 1999), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm>.

105. See Jinoos Yazdany & Alfred H.J. Kim, *Use of Hydroxychloroquine and Chloroquine During the COVID-19 Pandemic: What Every Clinician Should Know*, 172 ANNALS INTERNAL MED. 754,

authorization after increasing amounts of data suggested no benefit from using HCQ to treat COVID-19.<sup>106</sup> The initial recommendation, in the meantime, was not harmless. HCQ as a treatment had risks—and touting it as a cure for COVID-19 created availability-related risks for those who need it to treat diseases for which HCQ actually helps.<sup>107</sup> Panic prescribing is a real risk associated with the pandemic, as is the risk of panic approval of vaccines with negative results.<sup>108</sup> Political pressures facing the administration during an election year exacerbate such risks.<sup>109</sup> These pressures already led to clear and extensive political interference in public health agencies, and raise concerns about hasty vaccine approval.<sup>110</sup> An unsafe vaccine creates harms that are ethically—and publicly—unacceptable. This can result in a lack of trust towards other vaccines, which can lead to lower vaccination rates and attendant risks of outbreaks for other diseases.<sup>111</sup> Additionally, unsafe vaccines negatively affect the willingness to comply with other public health recommendations that are dependent on trust.

### III. OUR OPTIONS

There are multiple ways to increase the speed of vaccine development. None are perfect or unproblematic; some are reasonable, some ethically

754–55 (2020); *Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients*, U.S. FOOD & DRUG ADMIN. (Apr. 27, 2020), <https://www.fda.gov/media/136537/download>.

106. Letter from Dinesh M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow, Dir., Biomedical Advanced Rsch. & Dev. Auth., U.S. Dep’t of Health & Hum. Servs. 1–2 (June 15, 2020), <https://www.fda.gov/media/138945/download>; *see also* Joe Palca, *FDA Withdraws Emergency Use Authorization for Hydroxychloroquine*, NPR (June 15, 2020, 2:30 PM), <https://www.npr.org/sections/coronavirus-live-updates/2020/06/15/877498151/fda-withdraws-emergency-use-authorization-for-hydroxychloroquine>.

107. Camela Thompson, *Life with Lupus: Trump’s Hydroxychloroquine Hype Puts My Treatment — and Himself — at Risk*, STAT NEWS (May 20, 2020), <https://www.statnews.com/2020/05/20/hydroxychloroquine-trump-hype-jeopardize-supply-may-harm-him/>.

108. Holly Fernandez Lynch et al., *‘Panic Prescribing’ Untested Coronavirus Treatments: A Danger to Patients Today and Tomorrow*, HEALTHAFFAIRS: BLOG (Mar. 31, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200330.265604/full/>.

109. Kevin Liptak & Kaitlan Collins, *Trump Puts Pressure on FDA for Coronavirus Silver Bullet Ahead of Election Day*, CNN (Sept. 3, 2020, 9:34 PM) <https://www.cnn.com/2020/09/03/politics/white-house-fda-coronavirus-vaccine/index.html>.

110. Dan Diamond, *Trump Officials Interfered with CDC Reports on Covid-19*, POLITICO, <https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809> (Sept. 12, 2020 11:11 AM).

111. Trogen et al., *supra* note 13.

challenging, and some outright dangerous. Dangers come in two varieties: some approaches increase the risk of ending with an unsafe or ineffective vaccine, a result that does not improve the pandemic situation. Others do not risk the final result but can dramatically increase the risks to trial participants. One caveat: this section focuses on the process before licensing. I see no reason to relax the oversight and requirements in place after a vaccine is licensed and, indeed, it is particularly important to preserve oversight and respect the role of advisory committees in the process and assuring transparency towards them. Oversight mechanisms after licensing should carefully monitor any licensed COVID-19 vaccines. As a final preliminary point, it is important to acknowledge the institutional framework the Administration put in place to oversee vaccine development. To coordinate the process of vaccine approval, the Administration created “Operation Warp Speed.”<sup>112</sup> Operation Warp Speed is in charge of coordinating between the many actors involved—

[c]omponents of the Department of Health and Human Services (HHS), including the Centers for Disease and Prevention (CDC), the Food and Drug Administration (FDA), the National Control Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense . . . private firms and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.<sup>113</sup>

I find the title unfortunate, suggesting as it does rushing ahead without caution. However, it is a positive thing to have a government entity coordinating something as large as the effort to create and provide vaccines to three hundred thousand plus citizens. The Administration chose a veteran military man and a pharmaceutical insider to lead the process.<sup>114</sup> Nonprofits complained to the HHS Inspector General about the appointment of Dr. Slaoui, who has direct investments and roles with a variety of pharmaceutical companies. In July 2020, the Inspector General rejected the complaints, ruling Dr. Slaoui can remain in that role.<sup>115</sup> Although this choice raises questions about the project, other participants are veteran civil servants with extensive

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112. *Fact Sheet: Explaining Operation Warp Speed*, *supra* note 1.

113. *Id.*

114. *See id.* (appointing HHS Secretary Alex Azar and Defense Secretary Mark Esper, Dr. Moncef Slaoui, and General Gustave F. Perna).

115. Christopher Rowland, *Chief of White House’s ‘Operation Warp Speed’ Vaccine Effort Can Keep Investing in Pharma Firms, Under IG Ruling*, WASH. POST (July 14, 2020, 08:24 PM), <https://www.washingtonpost.com/business/2020/07/14/chief-white-houses-operation-warp-speed-vaccine-effort-can-keep-investing-pharma-firms-under-ig-ruling/>.

expertise in the area; like Dr. Peter Marks, who directs the FDA's CBER.<sup>116</sup> The main concern I see about Operation Warp Speed is not its leadership, but the lack of transparency with which, apparently, it has been operating. This will be addressed again later.

So, what are the options? A straightforward approach that has been used before is to conduct multiple testing phases together. For example, several companies are conducting Phase 1 and Phase 2 trials simultaneously.<sup>117</sup> Overlapping trial stages are not unusual, and there may be good reasons to go back and forth. For example, there may be something that needs testing in a smaller, more intensive trial while a large trial is going on. In addition, as mentioned previously, Phase 1 trials do not typically provide a lot of information about the vaccine, so combining Phase 1 trials with Phase 2 trials may speed up the development process. Another time-saving approach is to prepare large trials early, which is a reasonable and likely uncontroversial step.<sup>118</sup>

While an early set up has financial risks, it will not undermine vaccine safety or effectiveness.<sup>119</sup> As further suggested in an editorial, these could be done as “adaptive randomized-controlled” trials:

These trials can be structured to evaluate multiple vaccine candidates against a common control group and can shift enrollment based on which vaccines are most promising. Vaccines would be selected based on their promise in early studies and how quickly their manufacturing can be scaled. With so many patients developing mild or no symptoms, clinical trials will need to be large. But this is the best shot at quickly identifying safe and effective vaccines.<sup>120</sup>

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116. *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'*, U.S. DEPT OF HEALTH & HUM. SERVS. (May 15, 2020), <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

117. *Coronavirus Vaccine Trials – Updating Current Studies Across the World*, SKEPTICAL RAPTOR: BLOG (July 8, 2020), <https://www.skepticalraptor.com/skepticalraptorblog.php/coronavirus-vaccine-trials-updating-current-studies-across-world/>.

118. Arthur Allen, Op-Ed, *While the U.S. Rushes to Develop a COVID-19 Vaccine, Here's What Science Tells Us*, L.A. TIMES (May 21, 2020, 3:00 AM), <https://www.latimes.com/opinion/story/2020-05-21/coronavirus-vaccine-testing-approval>. For example:

Under a proposal under discussion by a committee set up by the National Institutes of Health, each of four or five experimental vaccines would be tested on about 20,000 trial participants with a placebo group of 10,000 for each vaccine. Some 50 U.S. medical centers—and perhaps an equal number overseas—would participate in these trials.

*Id.*

119. *Id.*

120. Luciana Borio & Scott Gottlieb, Opinion, *A Fast Coronavirus Vaccine, Without Cutting Corners*, WALL ST. J. (May 31, 2020, 3:47 PM), [https://www.wsj.com/articles/a-fast-coronaviru-s-vaccine-without-cutting-corners-11590954444?mod=opinion\\_lead\\_pos8](https://www.wsj.com/articles/a-fast-coronaviru-s-vaccine-without-cutting-corners-11590954444?mod=opinion_lead_pos8).

These trials are costly and, when they are government funded, costs that usually fall on companies—costs of testing vaccines that may well never make it to market—will fall on the taxpayers.<sup>121</sup> But in the context of a harmful, disruptive pandemic, that may be justified. That said, these trials need to be focused on the best vaccine candidates from a scientific perspective. Political selection of vaccine candidates to be supported by the government—or those receiving production support—undermines legitimacy and can directly counter the search for a better vaccine.<sup>122</sup> In the United States, coordinated by Operation Warp Speed, the Biomedical Advanced Research and Development Authority (BARDA) is collaborating with three different companies—Moderna, Janssen Research (which is part of Johnson & Johnson), and AstraZeneca—on clinical trials.<sup>123</sup> The trials themselves are overseen and regulated by the FDA (with a secondary role to NIH), and companies have to work out problems with those agencies.<sup>124</sup> Also costly, but not controversial from the point of view of safety, is setting up production before trials are complete—something suggested both in the United Kingdom and in the United States.<sup>125</sup> In the United States, BARDA is managing the preparation for scaling up production.<sup>126</sup> These approaches, too, carry an economic risk: preparing for production is costly, and if the vaccine candidate in question does not succeed in a clinical trial, the investment would have been for nothing. The investment itself does not,

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121. See *Fact Sheet: Explaining Operation Warp Speed*, *supra* note 1 (demonstrating that the government is funding the private companies).

122. Emanuel & Offit, *supra* note 4.

123. Press Release, U.S. Dep't of Health & Hum. Servs., HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines (Mar. 30, 2020), <https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccine-s.html>; *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to be Available Beginning in October*, U.S. DEP'T OF HEALTH & HUM. SERVS. (May 21, 2020), <https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazenec-a-covid-19-vaccine-to-be-available-beginning-in-october.html>.

124. Marisa Taylor & Robin Respaut, *Moderna Spars with U.S. Scientists Over COVID-19 Vaccine Trials*, REUTERS (July 7, 2020, 7:04 AM), <https://www.reuters.com/article/us-health-coronavirus-moderna-exclusive/exclusive-moderna-spars-with-u-s-scientists-over-covid-19-vaccine-trials-idUSKBN2481EU>.

125. See Ian Sample, *UK plans £38m Centre to Start Production of Coronavirus Vaccine*, GUARDIAN (May 17, 2020, 1:31 PM), <https://www.theguardian.com/society/2020/may/17/uk-plans-38m-centre-to-start-production-of-coronavirus-vaccine> (demonstrating the United Kingdom approach); Christopher Rowland et al., *Even Finding a Covid-19 Vaccine Won't Be Enough to End the Pandemic*, WASH. POST (May 11, 2020, 4:16 PM), <https://www.washingtonpost.com/business/2020/05/11/coronavirus-vaccine-global-supply/> (demonstrating the U.S. approach).

126. See *Fact Sheet: Explaining Operation Warp Speed*, *supra* note 1.

however, create a risk of an unsafe outcome; though, it can create political pressures on the participants and raise the stakes, making it tempting to hide bad results. Such investments should be accompanied by careful oversight of the companies whose vaccine candidates are chosen for this support.

Another potential approach is to permit use through an Emergency Use Authorization (EUA) for vaccines that have successfully passed one or more stages of trial in some circumstances.<sup>127</sup> We can likely expect such requests as soon as there is partial robust data that the vaccines in trials work, assuming no major safety concerns are discovered because of the level of harm the pandemic is causing. EUA requires a declaration by the HHS Secretary that justifies issuing an EUA, following a determination of a domestic, military, public health emergency or material threat.<sup>128</sup> The Secretary should then consult “(to the extent feasible and appropriate given the applicable circumstances) with the Assistant Secretary for Preparedness and Response (ASPR), the Director of the National Institutes of Health (NIH), and the Director of CDC,” and if the statutory criteria have been met, issue the authorization.<sup>129</sup>

The criteria to institute an EUA for “an unapproved medical product” are where there are:

- (1) Serious or life-threatening illness or condition caused by CBRN agent as set forth in HHS declaration;
- (2) Reasonable belief that the product may be effective in diagnosing, treating, or preventing the illness or condition caused by the agent (based on totality of scientific data);
- (3) The product’s known and potential benefits outweigh known and potential risks when used for disease or condition; and
- (4) There is no adequate approved, available alternative.<sup>130</sup>

In February 2020, the HHS Secretary announced an emergency surrounding the pandemic, and approved a number of EUA for COVID-19-related products, including “use of in vitro diagnostics for the detection and/or diagnosis of COVID-19 (February 4, 2020), personal respiratory protective devices (March 2, 2020), and other medical devices, including alternative

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127. See John D. Blum & Jordan Paradise, *Public Health Preparedness & Response: An Exercise in Administrative Law*, 20 DEPAUL J. HEALTH CARE L., June 2018, at 15; Charles G. Kels, *Dispensing Medical Countermeasures: Emergency Use Authorities and Liability Protections*, 13 HEALTH SEC. 139 (2015).

128. Blum & Paradise, *supra* note 127, at 15.

129. U.S. FOOD & DRUG ADMIN., U.S. DEPT’ OF HEALTH & HUM. SERVS., OMB CONTROL NO. 0910-0595, EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES: GUIDANCE FOR INDUSTRY AND OTHER STAKEHOLDERS 6 (2017), <https://www.fda.gov/media/97321/download>.

130. *Id.*

products used as medical devices (March 24, 2020).”<sup>131</sup> We can reasonably expect requests for such use of vaccines to start rolling in as soon as the data supports them. This is an approach whose desirability really depends on the details. Vaccines were approved for emergency use before in analogous circumstances, though not through an EUA. For example, a meningococcal B vaccine licensed elsewhere, but not in the United States, was used during a meningococcal outbreak in several college campuses.<sup>132</sup> In 2014–2015, a vaccine not yet approved for Ebola was allowed use during an outbreak in Africa.<sup>133</sup> The vaccine was later approved.<sup>134</sup> Both cases involved an outbreak of a potentially fatal disease, creating a vivid and visible life-threatening emergency. In the COVID-19 context, an example could be an outbreak overwhelming hospitals, which occurred in Italy and New York City, or an outbreak in a high-risk environment like a nursing home.<sup>135</sup> The legitimacy of this approach would also depend on the evidence on the potential benefits compared to the potential risks. The meningococcal B vaccine underwent several clinical trials, and was approved—and used—in Europe after enough safety data was provided to European regulatory authorities to justify it, and

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131. *Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Device*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices> (Aug. 3, 2020).

132. See Blair Capitano et al., *Experience Implementing a University-Based Mass Immunization Program in Response to a Meningococcal B Outbreak*, in 15 *HUM. VACCINES & IMMUNOTHERAPIES* 717, 717 (2019); JoNel Aleccia, *Emergency Meningitis Vaccine Will be Imported to Halt Ivy League Outbreak*, NBC NEWS (Nov. 15, 2013, 4:38 PM), <https://www.nbcnews.com/healthmain/emergency-meningitis-vaccine-will-be-imported-halt-ivy-league-outbreak-2D11603651>.

133. Marissa Fritz, *Drug Approval During a Public Health Crisis*, REG. REV. (Feb. 11, 2020), <https://www.theregreview.org/2020/02/11/fritz-drug-approval-during-public-health-crisis/>.

134. Press Release, U.S. Food & Drug Admin., *First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response* (Dec. 19, 2019), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>.

135. See Carrie Arnold, *New York City’s Coronavirus Outbreak is Already Overwhelming Hospitals*, NEWSIDENTIST (Mar. 31, 2020), <https://www.newsidentist.com/article/2239247-new-york-citys-coronavirus-outbreak-is-already-overwhelming-hospitals/#>; Sharon Begley, *A Plea From Doctors in Italy: To Avoid Covid-19 Disaster, Treat More Patients at Home*, STAT NEWS (Mar. 21, 2020), <https://www.statnews.com/2020/03/21/coronavirus-plea-from-italy-treat-patients-at-home/>; Christina Maxouris, *The Most Alarming Coronavirus Numbers in Some States are in Prisons and Nursing Homes*, CNN (May 7, 2020, 5:47 AM), <https://www.cnn.com/2020/05/07/us/coronavirus-cases-prisons-nursing-homes/index.html>.



during its use, no new safety concerns emerged.<sup>136</sup> The situation for Ebola vaccines was different. A candidate vaccine “was given to at-risk HCW/FLWs and at-risk adults and children during the 2014–2016 West African outbreak during clinical trials using investigational expanded access protocols,” during an efficacy trial in Guinea that showed very high efficacy, justified by the severity of the disease.<sup>137</sup> During the 2018 and 2019 Ebola outbreaks in the Democratic Republic of Congo (DRC), the vaccine was not yet licensed, but there was evidence of human trials supporting its use.<sup>138</sup> Even in the DRC, there was initial hesitancy to use the vaccine in lactating and pregnant women—in which the vaccine had not been tested—but the severe risks allowed for the vaccine to be used on that population after some debate.<sup>139</sup> Similar questions about use of COVID-19 vaccines in pregnancy may come up in the U.S.; the FDA is reluctant to allow trials in pregnant women, and for COVID-19 there is no special reason to deviate from that rule. Though, there could be a question about making these vaccines available to that population without such trials.<sup>140</sup> In other words, emergency use decisions depend not only on the existence of an emergency but also on other factors, such as the danger from the disease and the already existing data on the vaccine. Both Ebola and meningococcal disease have higher rates of mortality than COVID-19, and meningococcal has a substantial risk of long-lasting disability even in survivors.<sup>141</sup> Allowing emergency use of a vaccine with very little safety data may be less likely for COVID-19—but that balance may shift as more data accumulates. An obvious concern there is that political pressures will lead to approval of emergency use of COVID-19 vaccines where there is no objective

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136. See Aleccia, *supra* note 132.

137. Jenny A. Walldorf et al., *Considerations for Use of Ebola Vaccine During an Emergency Response*, 37 VACCINE 7190, 7195 (2019).

138. See *Second Ebola Vaccine to Complement “Ring Vaccination” Given Green Light in DRC*, WORLD HEALTH ORG. (Sept. 23, 2019), <https://www.who.int/news-room/detail/23-09-2019-second-ebola-vaccine-to-complement-ring-vaccination-given-green-light-in-drc>.

139. Archana Asundi & Nahid Bhadelia, *Making Emergency Use of Experimental Vaccines Safer*, 22 AM. MED. ASS’N J. OF ETHICS 43, 44 (2020).

140. See Sam F. Halabi, *Zika and the Regulatory Regime for Licensing Vaccines for use During Pregnancy*, 26 ANN. HEALTH L., Summer 2017, at 20–21.

141. See U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES 232, 241 (2015); *Ebola Virus Disease*, WORLD HEALTH ORG. (Feb. 10, 2020), <https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>; *Mortality Analyses*, JOHNS HOPKINS CORONAVIRUS RES. CTR., <https://coronavir.us.jhu.edu/data/mortality> (Dec. 2, 2020, 3:00 AM).

justification. Arguably, that has already happened with HCQ.<sup>142</sup> Whether political pressures will lead to emergency use approval in the COVID-19 context is under extensive debate, the result of which will be unclear when this Article goes to publication; but it is a concern.<sup>143</sup> Another step that can and should occur early on is setting up work groups by the different oversight committees once vaccine candidates advance in the trials. The NIH already set up multiple expert committees to work on the different steps.<sup>144</sup> An executive committee chaired by Dr. Francis Collins, the NIH Director, with a co-chair from industry Dr. Paul Stoffels, from Johnson & Johnson, and other officials—most from the government but some from pharmaceutical companies—lead this effort.<sup>145</sup> Under it are four working groups: a Preclinical Working Group, a Therapeutics Clinical Working Group, a Clinical Trial Capacity Working Group, and a Vaccines Working Group.<sup>146</sup> The Vaccines Working Group involves pharmaceutical industry members (like Dr. Paula Annunziato from Merck and Dr. Tal Zaks from Moderna), public servants (like Dr. Douglas Lowy from NIH, and Dr. Peter Marks from the FDA), experts from abroad (like Dr. Marco Cavaleri from the European Medicines Agency), and academics (like Dr. Beth Bell from the University of Washington, who also leads the ACIP working group on COVID-19 vaccines; Dr. Peter Hotez from Baylor College of Medicine; and Dr. Paul Offit from the School

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142. See John Timmer, *FDA Approves the Emergency Use of Chloroquine for COVID-19*, ARSTECHNICA (Mar. 31, 2020, 4:52 PM), <https://arstechnica.com/science/2020/03/fda-approves-the-emergency-use-of-chloroquine-for-covid-19/>; Nicholas Florko, *Why was an Obscure Federal Bureaucrat Involved in Trump's Emergency Hydroxychloroquine Authorization?*, STAT NEWS (Apr. 24, 2020), <https://www.statnews.com/2020/04/24/why-rick-bright-involved-hydroxychloroquine/> (supporting the view that this was unjustified comes from the FDA's warning against use of the drug outside hospital settings, issued less than a month after the emergency use authorization); *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the 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> (July 1, 2020).

143. Robert Califf et al., *7 Former FDA Commissioners: The Trump Administration is Undermining the Credibility of the FDA*, WASH. POST (Sept. 29, 2020, 5:16 PM) <https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/>; Kashmira Gander, *Trump Must Stop Criticizing Scientists Amid COVID-19 Vaccine Talks: Experts to FDA*, NEWSWEEK (Sept. 26, 2020, 11:07 AM) <https://www.newsweek.com/trump-criticizing-scientists-coronavirus-vaccine-1534439>.

144. *Governance*, NAT'L INSTS. OF HEALTH, <https://www.nih.gov/research-training/medical-research-initiatives/activ/leadership> (Sept. 11, 2020).

145. *Id.*

146. *Id.*

of Medicine at the University of Pennsylvania).<sup>147</sup> ACIP, as mentioned, set up a work group to monitor COVID-19 vaccines in April 2020.<sup>148</sup>

More controversial is the question of whether to allow challenge/rechallenge trials.<sup>149</sup> Challenge/rechallenge trials involve intentionally exposing consenting volunteers who received the vaccine to the virus; i.e., injecting them with live COVID-19 virus, under medical supervision.<sup>150</sup> This technique is advantageous because it does not depend on trial participants' natural exposure to COVID-19—something that could take time, especially in areas where the pandemic is under control. Several experts strongly recommend challenge/rechallenge trials.<sup>151</sup> Experts point out that there is low risk and high reward when these trials are limited to young volunteers, and the benefits of having a vaccine sooner are meaningful, including in terms of lives saved.<sup>152</sup> The problem, as discussed by some of these experts, is that challenge/rechallenge trials ask people to “take on risk of severe illness or death.”<sup>153</sup> The risk is especially high since there is much unknown about COVID-19 and there is no good treatment for it.<sup>154</sup> Nonetheless, supporters argue these trials will save lives.<sup>155</sup> Volunteers are lining up for it: a grassroots hotline has signed up thousands of people saying they are willing to take the risk (though, such

147. *Vaccines Working Group*, U.S. NAT'L INSTS. OF HEALTH, <https://www.nih.gov/research-training/medical-research-initiatives/activ/vaccines-working-group> (Oct. 20, 2020).

148. Michael Devitt, *Coronavirus Remains Front and Center at June ACIP Meeting*, AM. ACAD. OF FAM. PHYSICIANS (July 1, 2020, 3:00 PM), <https://www.aafp.org/news/health-of-the-public/20200701acipjunemtg.html>.

149. See *Vaccine Challenge Studies—Can it Speed up Coronavirus Vaccine Licensing*, SKEPTICAL RAPTOR: BLOG (Apr. 20, 2020), <https://www.skepticalraptor.com/skepticalraptorblog.php/vaccine-challenge-studies-can-it-speed-up-coronavirus-vaccine-licensing/>.

150. WORLD HEALTH ORG., KEY CRITERIA FOR THE ETHICAL ACCEPTABILITY OF COVID-19 HUMAN CHALLENGE STUDIES 1 (2020) [hereinafter HUMAN CHALLENGE STUDIES], [https://apps.who.int/iris/bitstream/handle/10665/331976/WHO-2019-nCoV-Ethics\\_criteria-2020.1-eng.pdf?ua=1](https://apps.who.int/iris/bitstream/handle/10665/331976/WHO-2019-nCoV-Ethics_criteria-2020.1-eng.pdf?ua=1).

151. See Plotkin & Caplan, *supra* note 88; Nir Eyal et al., *Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure*, 221 J. INFECTIOUS DISEASES 1752, 1754 (2020).

152. See Plotkin & Caplan, *supra* note 88.

153. See Eyal et al., *supra* note 151.

154. See Shayla Love, *People Are Willing to Risk Their Lives for a COVID Vaccine. Should We Let Them?*, VICE (Apr. 28, 2020, 7:00 AM), [https://www.vice.com/en\\_us/article/5dm7na/why-intentionally-infecting-people-with-coronavirus-could-be-worth-it](https://www.vice.com/en_us/article/5dm7na/why-intentionally-infecting-people-with-coronavirus-could-be-worth-it); Carolyn Y. Johnson, *Inside the Extraordinary Race to Invent a Coronavirus Vaccine*, WASH. POST (May 3, 2020, 3:57 PM), <https://www.washingtonpost.com/science/2020/05/02/coronavirus-vaccine/>.

155. See Plotkin & Caplan, *supra* note 88; Eyal et al, *supra* note 151 at 1753–54.

signing up is no substitute for a fully informed consent process).<sup>156</sup> Another challenge is that to be ethical, challenge/rechallenge studies should consist of healthy, young volunteers—people for whom the risks of COVID-19 are low.<sup>157</sup> But results from young volunteers would not necessarily teach us about the effect of tested vaccines in high-risk populations, such as the elderly. For example, influenza vaccines are much less effective in older people than in younger ones, and special variations of influenza vaccines are developed for that population.<sup>158</sup> Similarly, COVID-19 vaccines shown to be effective in young volunteers in challenge/rechallenge studies would not signify similar protection of an older population, those that are most at risk of harm from the disease. An additional risk is a setback during the challenge/rechallenge trials, such as the death of a participant from COVID-19, which could undermine vaccine development—even if the vaccine did not directly cause the setback.<sup>159</sup> Allowing an EUA based on antibody data alone would be highly problematic as well (something which, to my knowledge, has not been done before). At this point, the level of antibodies needed to protect against severe COVID-19 and the level that protects against infecting others is unclear—the link between antibody levels and protection can be complex, and we do not yet have that data for COVID-19 vaccines, so acting on that alone can lead to unsupported decisions.<sup>160</sup> Additionally, the mutation rate and effect of the virus, both of which can contribute to a less viable vaccine, is also uncertain.<sup>161</sup> If a mutation is more infectious than another, the vaccine may not target the more virulent form of the virus.<sup>162</sup> If the mutation rate is much higher than predicted, then a vaccine could be ineffective within a year or even just a

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156. See HUMAN CHALLENGE STUDIES, *supra* note 150 at 1, 5; Ewen Callaway, *Hundreds of People Volunteer to be Infected with Coronavirus*, NATURE (Apr. 22, 2020), <https://www.nature.com/articles/d41586-020-01179-x>.

157. See HUMAN CHALLENGE STUDIES, *supra* note 150, at 3.

158. *Flu & People 65 Years and Older*, U.S. CTRS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/highrisk/65over.htm> (Sept. 22, 2020). See generally *Vaccine Effectiveness: How Well do the Flu Vaccines Work?*, U.S. CTRS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm#older-vaccinated> (Jan. 3, 2020).

159. Michael Rosenblatt, *Human Challenge Trials with Live Coronavirus Aren't the Answer to a Covid-19 Vaccine*, STAT NEWS (June 23, 2020), <https://www.statnews.com/2020/06/23/challenge-trials-live-coronavirus-speedy-covid-19-vaccine> (raising this and other points).

160. See “Immunity Passports” in the Context of Covid-19, WORLD HEALTH ORG. (Apr. 24, 2020), <https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>.

161. See Ewen Callaway, *The Coronavirus is Mutating – Does it Matter?*, NATURE (Sept. 16, 2020), <https://www.nature.com/articles/d41586-020-02544-6>.

162. *Id.*

few months.<sup>163</sup> Committing too soon to one company producing vaccines is just as problematic; we do not know which vaccine candidate will succeed in trials. The UK may have done just that when the government committed large sums of money to the production of one candidate vaccine that is still in early stages of testing.<sup>164</sup> The U.S. government addressed this, in part, by choosing four companies with which to partner on the vaccine development process.<sup>165</sup> But those are still only four, and it is not clear whether the government would be willing—or able—to admit error and change if needed. It is important to remember, though, that most vaccines do not rely on government money to develop, and that the larger vaccine companies can—and are—going ahead with their trials without government support.<sup>166</sup> Government support allows smaller companies—who would have had to contract with a large company in order to reach testing—to go ahead without that support.<sup>167</sup> Still, the choices need to be data driven; if a company’s results do not show that its vaccine candidate is safe and effective, money devoted to production may be better spent by rechanneling it to a more promising candidate. Similarly, skipping steps in testing increases the risks of bad safety outcomes and may undermine the use of a plausibly safe vaccine by decreasing trust.<sup>168</sup> Going to human studies without animal studies would not necessarily mean that the final vaccine is unsafe.<sup>169</sup> If enough human testing occurs, we can still end up with good data on safety and effectiveness. However, it could mean that risks that could be discovered before humans were given the vaccine were not discovered—creating additional risks for trial volunteers and presenting

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163. *Id.*

164. See Sample, *supra* note 125 (showing the UK’s intent to invest in production).

165. See *Fact Sheet: Explaining Operation Warp Speed*, *supra* note 1.

166. Press Release, Nat’l Insts. Of Health, NIH to Launch Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options (Apr. 17, 2020) <https://www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options>.

167. See Mark Terry, *Moderna and Lonza Enter Large-Scale Manufacturing Deal for Potential COVID-19 Vaccine*, BIOSPACE (May 1, 2020) <https://www.biospace.com/article/moderna-partners-with-swiss-company-lonza-to-manufacture-covid-19-vaccine/>.

168. See Sara Murray, *Even Once a Vaccine Gets Approved, Big Hurdles Remain for Distribution*, CNN: POLITICS, <https://www.cnn.com/2020/07/22/politics/coronavirus-vaccine-distribution-concerns/index.html> (noting that a third of Americans surveyed in May 2020 responded that they would not get the vaccine even if it was “affordable and widely available”) (July 23, 2020, 12:58 PM).

169. Nicoletta Lanese, *Researches Fast-Track Coronavirus Vaccine by Skipping Key Animal Testing First*, LIVE SCI. (Mar. 13, 2020), <https://www.livescience.com/coronavirus-vaccine-trial-no-animal-testing.html> (noting that one of the vaccine candidates skipped animal trials).

an opportunity for vaccine opponents who seek to frame all vaccines as unsafe. Finally, a major problem to avoid is lack of transparency. Oversight and advisory committees involved in the vaccine process—the regular committee, and those created to focus on a COVID-19 vaccine—need full, transparent information to do their job of meaningful oversight and help lead us to a vaccine that is, in fact, safe and effective. In the June 2020 meeting of ACIP, Dr. Matthew Hepburn from Operation Warp Speed spoke about the operation, but provided very few details on what is actually going on.<sup>170</sup> While there is a need to protect companies' trade secrets during vaccine production, oversight committees need information to do their job and the public needs information to maintain trust.<sup>171</sup> Operation Warp Speed must preserve transparency towards the oversight committees. In an unusual move, three vaccine companies voluntarily published their trial protocols.<sup>172</sup> While a laudable increase of transparency, publishing trial protocols is not a substitute to agencies sharing other information (like contract conditions).<sup>173</sup> These committees need information pertaining to the vaccine development process to achieve a safe and effective vaccine.

#### IV. MESSAGING CHALLENGES

Public trust is crucial in a pandemic; if the state wants to impose broad-reaching measures, it has to rely either on voluntary compliance or on very aggressive measures, which are costly and not always available or effective.<sup>174</sup> When it comes to a vaccination program, messaging matters. In relation to the COVID-19 vaccine, we face at least three potential messaging problems:

- (1) Overselling: hyping the data, creating excessive expectations that will then have to be corrected, undermining trust;

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170. Murray, *supra* note 168.

171. See also Diana Kwon, *How the Pharma Industry Pulled Off the Pivot to COVID-19*, THE SCIENTIST (July 13, 2020), <https://www.the-scientist.com/bio-business/how-the-pharma-industry-pulled-off-the-pivot-to-covid-19-67719> (comparing how companies have adopted collaborative information sharing processes and responded to requests to make their research public).

172. Editorial, *Covid Vaccine Confidence Requires Radical Transparency*, NATURE, Sept. 29, 2020, at 8, <https://media.nature.com/original/magazine-assets/d41586-020-02738-y/d41586-020-02738-y.pdf>.

173. *Id.*

174. See Jay J. Van Bavel et al., *Using Social and Behavioural Science to Support COVID-19 Pandemic Response*, 4 NATURE HUM. BEHAV. 460, 466 (2020).

- (2) Under-sharing: not being transparent enough about what is being done to ensure safety; not providing people enough information about the process and results, so that people may mistrust even a vaccine that actual data shows is safe and effective;
- (3) Enabling misinformation, including by leaving false messages without a counter.

We had already seen several instances of overselling vaccines by June 2020, with potentially bad consequences. For example, early results published by Moderna, a company producing one of the vaccine candidates, led to headlines that strongly suggested the vaccine was effective.<sup>175</sup> Scientists spoke up to caution against over extrapolating from these press releases too quickly.<sup>176</sup> Among the problems with Moderna's results was the fact that, out of forty-five participants in the trial, Moderna provided data on only eight participants who developed an antibody response, raising the question of what other participant data showed.<sup>177</sup> The fact that Moderna's executives sold large amounts of their stock in the company for large profits did not increase confidence in the results, either.<sup>178</sup> I would add that the data has since been published in a peer reviewed article, the results were transparently set out—and it looks like the hype problem did not recur with the publication of the actual data.<sup>179</sup> Similarly, results from the UK vaccine trials appear to have

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175. Elizabeth Cohen, *Early Results From Moderna Coronavirus Vaccine Trial Show Participants Developed Antibodies Against the Virus*, CNN, <https://www.cnn.com/2020/05/18/health/coronavirus-vaccine-moderna-early-results/index.html> (May 18, 2020, 7:55 PM); Press Release, Moderna, Moderna Announces Positive Interim Phase 1 Data for its mRNA Vaccine (mRNA-1273) Against Novel Coronavirus (May 18, 2020), <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine>; Helen Branswell, *Vaccine Experts Say Moderna Didn't Produce Data Critical to Assessing Covid-19 Vaccine*, STAT NEWS (May 19, 2020), <https://www.statnews.com/2020/05/19/vaccine-experts-say-moderna-didnt-produce-data-critical-to-assessing-covid-19-vaccine/>.

176. See Branswell, *supra* note 175; *Moderna Coronavirus Vaccine – Tempering the Breathless Pharma Hype*, SKEPTICAL RAPTOR: BLOG (May 19, 2020), <https://www.skepticalraptor.com/skepticalraptorblog.php/moderna-coronavirus-vaccine-tempering-breathless-pharma-hype/>.

177. Branswell, *supra* note 175; Jonathan Gardner, *More Questions Than Answers as Moderna's Coronavirus Vaccine Speeds Ahead*, BIOPHARMA DIVE (May 19, 2020), <https://www.biopharmadive.com/news/moderna-coronavirus-vaccine-data-more-questions/578229/>.

178. Damian Garde, *Moderna Executives Have Cashed Out \$89M in Shares This Year, as Stock Price has Soared on Vaccine Hopes*, STAT NEWS (May 27, 2020), <https://www.statnews.com/2020/05/27/moderna-executives-cashed-out-shares-stock-price-soared/>.

179. See Lisa A. Jackson et. al, *An mRNA Vaccine Against SARS-CoV-2 – Preliminary Report*, 2020 NEW ENG. J. MED. 1920, <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483?articleTools=true>. The coverage I have seen for the article was more cautious than the first press release. See, e.g., Berkeley Lovelace Jr., *Moderna Stock Surges after Company Announces Promising Coronavirus*

been, initially, overstated.<sup>180</sup> What was first touted as success in immunizing monkeys was later questioned because the vaccine appeared to prevent pneumonia in the monkeys but not infection, thus suggesting the vaccine would not prevent spread of disease.<sup>181</sup> These situations—initial promising press releases following by dampening down—lead to loss of trust. Dr. Paul Offit, a vaccine expert, described it as “science by press release,” and noted the risk of speaking up before there is sufficient data.<sup>182</sup>

Another potential problem is not informing the public on how vaccine safety is monitored and overseen. While vaccine experts know that multiple oversight committees and multiple monitoring systems to evaluate vaccine safety exist, the public does not—and should.<sup>183</sup> Even in pre-pandemic times, not enough is made public about the extensive institutional arrangements surrounding vaccines. It is not because the information does not exist; rather, it is likely that technical bureaucratic details do not make for a good story, even if they are very, very important.<sup>184</sup> In regard to COVID-19 vaccines, too, more information about the process would be useful. For instance, while Dr. Paul Offit mentioned publicly the existence of an NIH committee and the mobilization to prepare for large trials,<sup>185</sup> the Administration has not publicized it, and it should. Being upfront about the steps taken to assure the safety of a new vaccine would help build public confidence. For example, a news release—and communication to major media companies—along the lines of “*NIH Set up Oversight Committees for Vaccine Development.*” Similarly, “*The*

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*Vaccine Trial Data*, CNBC, <https://www.cnn.com/2020/07/15/moderna-stock-surges-after-releasing-promising-coronavirus-vaccine-trial-data.html> (July 15, 2020, 11:06 AM)

180. See Sarah Newey & Paul Nuki, *Doubts Over Oxford Vaccine as it Fails to Stop Coronavirus in Animal Trials*, TELEGRAPH (May 18, 2020, 12:43 PM) <https://www.telegraph.co.uk/global-health/science-and-disease/doubts-oxford-vaccine-fails-stop-coronavirus-animal-trials/>.

181. Rachel Schraer, *Coronavirus Vaccine: Macaque Monkey Trial Offers Hope*, BBC NEWS (May 15, 2020), <https://www.bbc.com/news/health-52674739>; see also Andy Gregory, *Coronavirus: Scientists Warn Oxford Vaccine May Only Offer ‘Partial Protection’ After Results of Monkey Trial*, INDEPENDENT (May 19, 2020), <https://www.independent.co.uk/news/health/coronavirus-vaccine-oxford-trials-concerns-transmission-astrazeneca-latest-a9521241.html>. See generally Callaway, *supra* note 40.

182. Gardner, *supra* note 177.

183. MONICA SCHOCH-SPANAN ET AL., *THE PUBLIC’S ROLE IN COVID-19 VACCINATION: PLANNING RECOMMENDATIONS INFORMED BY DESIGN THINKING AND THE SOCIAL, BEHAVIORAL, AND COMMUNICATION SCIENCES* 7, 9 (John Hopkins Univ. 2020), [https://www.cdc.gov/enterforhealthsecurity/our-work/pubs\\_archive/pubs-pdfs/2020/200709-The-Publics-Role-in-COVID-19-Vaccination.pdf](https://www.cdc.gov/enterforhealthsecurity/our-work/pubs_archive/pubs-pdfs/2020/200709-The-Publics-Role-in-COVID-19-Vaccination.pdf).

184. *Id.* at 9, 24–25.

185. See generally Emanuel & Offit, *supra* note 4 (discussing NIH plans to mobilize Phase 3 testing for some of the 10 vaccines).



*Advisory Committee for Immunization Practices Created a Work Group and is Actively Seeing Vaccine Development Can Help Improve Confidence.*” Even better, openly providing regular updates from Operation Warp Speed to these committees—and posting summaries or fact sheets online about where things are in regular intervals—can improve transparency. Operation Warp Speed put up one fact sheet, which seems updated through November 30, 2020.<sup>186</sup> Monthly updates detailing the progress on government-supported companies would help.

Companies involved in vaccine development must be transparent about problems that arise and steps taken to address them. For example, in the high-dose group of Moderna’s trial, about 25% of recipients had a fever and flu-like symptoms.<sup>187</sup> Moderna decided not to use that high dose.<sup>188</sup> However, that information was not included in the company’s press release, and was later published by journalists.<sup>189</sup> This scenario allows for the appearance that problems were swept under the rug—which is not what happened—and creates unnecessary mistrust. It is preferable to openly describe any issues. The company—or government oversight officials—can explain why results from a high-dose group would not, necessarily, be a deal breaker; a few days of flu-like symptoms might still leave a vaccine with a favorable risk/benefit balance. In this case, the company has also already decided not to use the dose that created this risk out of an abundance of caution. When AstraZeneca’s vaccine trial had an adverse event, data about it was only made publicly available via a leak to a journalist—again, raising questions about transparency.<sup>190</sup> Open, transparent communication builds trust and avoids a nonissue turning into something those seeking to create mistrust can build on.<sup>191</sup> There are limits: medical privacy may prevent giving full information, but companies need

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186. See *Fact Sheet: Explaining Operation Warp Speed*, *supra* note 1.

187. Matthew Herper, *He Experienced a Severe Reaction to Moderna’s Covid-19 Vaccine Candidate. He’s Still a Believer*, STAT NEWS (May 26, 2020), <https://www.statnews.com/2020/05/26/moderna-vaccine-candidate-trial-participant-severe-reaction/>.

188. See Jackson et al., *supra* note 179, at 11 (reporting that phase 2 and phase 3 trial will only go as high as 100-ug, after the 250-ug dose had two adverse events).

189. See Herper, *supra* note 187 (discussing how only “tidbits” of information about the new vaccine are being released).

190. Adam Feuerstein, *Covid-19 Vaccine Trial Participant had Serious Neurological Symptoms, but Could be Discharged Today, AstraZeneca CEO Says*, STAT NEWS (Sept. 9, 2020), <https://www.statnews.com/2020/09/09/astrazeneca-covid19-vaccine-trial-hold-patient-report/>.

191. Here is an example of how an anti-vaccine group took this issue and used it to create mistrust by misrepresenting it. Robert F. Kennedy, Jr., *Vaccine Trial Catastrophe: Moderna Vaccine has 20% ‘Serious’ Injury Rate in High Dose Group*, CHILD’S HEALTH DEF. (May 22, 2020), <https://childrenshealthdefense.org/news/vaccine-trial-catastrophe-moderna-vaccine-has-20-serious-injury-rate-in-high-dose-group/>.

to be as transparent as possible. It is also pointless not to do that, since real problems cannot be hidden. For example, when companies have to pause trials, that becomes public, as happened to Johnson & Johnson in October.<sup>192</sup> Finally, steps must be taken to prepare to respond to anti-vaccine misinformation about a new vaccine. Anti-vaccine groups already started preparing the ground to create mistrust, or build on natural mistrust for a new vaccine or as a result of the previously mentioned issues.<sup>193</sup> While this is not the only type of COVID-19 misinformation being spread, it is part of it and it needs to be countered. Addressing the issues above reduces the fertile ground available for those seeking to create mistrust. But it is not enough. Responses must point out misinformation quickly. For example, anti-science groups aggressively and cleverly spread the movie, *Plandemic*, on social media.<sup>194</sup> But responses demonstrating the movie's many inaccuracies were quickly created and shared on social media.<sup>195</sup> While preempting and responding to misinformation before it spreads is preferable, at the very least, misinformation about COVID-19 vaccines should not be left unanswered.

## CONCLUSION

COVID-19 continues to turn our world upside down. While many desperately await a vaccine, we as a nation should be cautious not to take steps that will worsen the ongoing situation and halt improvement. Substantive pressures to prevent harms are not the only risk. In a recent editorial, Dr. Paul Offit and oncologist Zeke Emanuel sounded caution against potential political intervention in COVID-19 vaccine development:

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192. Maggie Fox, *Johnson & Johnson Pauses Covid-19 Vaccine Trial after 'Unexplained Illness'*, CNN, <https://www.cnn.com/2020/10/12/health/johnson-coronavirus-vaccine-pause-bn/index.html> (Oct. 13, 2020, 12:20 PM).

193. See, e.g., Bennie Badger, FACEBOOK (May 26, 2020, 10:29 PM), <https://www.facebook.com/hu.suc/posts/10157154200392551>; Hear This Well, FACEBOOK (May 23, 2020, 10:26 AM), <https://www.facebook.com/HearThisWell/posts/3213865541990895>; Joshua Coleman, *Coronavirus and What We Do Next!*, FACEBOOK (Mar. 18, 2020), <https://www.facebook.com/1172767973/videos/10221388003307534/>.

194. Renee DiResta & Isabella García-Camargo, *Vitality Project (US): Marketing Meets Misinformation*, STAN. UNIV.: INTERNET OBSERVATORY (May 26, 2020), [https://cyber.fsi.stanford.edu/io/news/manufacturing-influence-0?fbclid=IwAR39LI FmXSHY6rQ36c804KOBkpIFgSKAv\\_eKJJo0AI81KvJ3GMsbQ91ExY](https://cyber.fsi.stanford.edu/io/news/manufacturing-influence-0?fbclid=IwAR39LI FmXSHY6rQ36c804KOBkpIFgSKAv_eKJJo0AI81KvJ3GMsbQ91ExY).

195. See Liz Ditz, *Judy Mikovits: Not a Reliable Source of Information on COVID19, Vaccines, or Anything in Science*, I SPEAK OF DREAMS (May 8, 2020), [https://lizeditz.typepad.com/i\\_speak\\_of\\_dreams/2020/05/judy-mikovits-not-a-reliable-source-of-information-on-covid19-vaccines-or-anything-in-science.html](https://lizeditz.typepad.com/i_speak_of_dreams/2020/05/judy-mikovits-not-a-reliable-source-of-information-on-covid19-vaccines-or-anything-in-science.html) (containing a list of responses).

... the F.D.A. could issue an Emergency Use Authorization for one or more vaccines. . .

An emergency authorization would allow Mr. Trump to hold his news conference and declare victory. But like President George W. Bush's "Mission Accomplished" proclamation, it has the potential to be a travesty. Millions of vaccines could be distributed without proof that the vaccine can prevent disease or transmission.<sup>196</sup>

...

Thousands of Americans have already died as Donald Trump has perpetually postponed effective public health interventions and made poor therapeutic recommendations. We must be on alert to prevent him from corrupting the rigorous assessment of safety and effectiveness of Covid-19 vaccines in order to pull an October vaccine surprise to try to win re-election.<sup>197</sup>

President-Elect Joe Biden's COVID-19 plan emphasizes the need for expertise and states that his Administration will: "Put scientists in charge of all decisions on safety and efficacy; publicly release clinical data for any vaccine the FDA approves; and authorize career staff to write a written report for public review and permit them to appear before Congress and speak publicly uncensored."<sup>198</sup> Sticking to this statement can help assuage concerns, but the timing is tricky: the new Administration will not come in until January, and companies may well move to request an Emergency Use Authorization before that.<sup>199</sup> Practical and political pressures can lead to inappropriately rushed vaccine development—and can backfire. The United States has a remarkable system for testing vaccines and monitoring their safety, and we should let it work in this case, too. Adjustments can be made without forgoing safety, and we should make sure we are, indeed, not sacrificing safety or effectiveness.

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196. Emanuel & Offit, *supra* note 4.

197. *See id.* (concerning politicizing the process).

198. *The Biden-Harris Plan to Beat Covid-19*, BIDEN-HARRIS TRANSITION <https://buildbackbetter.com/priorities/covid-19/> (last visited Dec. 2, 2020).

199. Lisa Schniring, *Feds Update Vaccine Arrival Amid Record US Covid-19 Rise*, UNIV. OF MINN. CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (Nov. 13, 2020) <https://www.cidrap.umn.edu/news-perspective/2020/11/feds-update-vaccine-arrival-amid-record-us-covid-19-rise>.