UNEQUAL REPRESENTATION: WOMEN IN CLINICAL RESEARCH

Allison M. Whelan†

INTRODUCTION

The underrepresentation of women in clinical research throughout history is a well-recognized problem. Progress has been made, but there is still room for improvement and it must be recognized that not all women have been or continue to be treated equally in the context of clinical research. On the one hand, there is a long history of paternalism and lack of respect for women's autonomy that has resulted in the exclusion of women from research, particularly pregnant women and women of childbearing potential. The potential consequences of this are many, including harm to women's health because

† Associate, Covington & Burling LLP, Washington D.C.; J.D., University of Minnesota Law School; M.A. Bioethics, University of Minnesota. Special thanks to Professor Michele Goodwin and the editors of the *Cornell Law Review*. The views expressed in this article are the author's and do not represent those of any past, current, or future employer.

diseases and treatments can affect men and women differently.

On the other hand, there is also a long history of women of color being unknowingly or unwillingly subjected to unethical medical experiments and procedures. This includes experimentation during human enslavement, carried out most famously by doctors like James Marion Sims, who abused and terrorized Black women who he rented as slaves.[1] He performed myriad gynecological experiments on these women, often without providing them any anesthesia. It is a glaring reflection on the multiple cruelties of slavery as well as the American experience of medical experimentation.

However, the horrors experienced by women of color in the medical setting are far more extensive, spanning into the nineteenth, twentieth, and twenty-first centuries. Famously, throughout the Jim Crow period, Black women became the unwitting subjects of eugenics platforms, legally blessed by the 1927 Supreme Court decision *Buck v. Bell*.[2] In Mississippi, the frequency and normalization of sterilizations are revealed by the term "Mississippi Appendectomy" becoming associated with the practice.[3] The term reveals the mistruths told to Black women and girls, as well as the callousness and neglect used to obtain consent for the real surgeries taking place. Most recently, during the COVID-19 pandemic, allegations of sterilizations at immigrant detention centers only further the concerns related to these matters, particularly as they affect vulnerable, poor women.[4] This history has contributed to women of color's distrust in the government, research institutions, and the medical system in general.

These two historical wrongs are distinct, yet related in that they both harm women's health, dignity, and autonomy. As this Article will discuss, much progress has been made to increase women's overall representation in clinical trials, but there is far more work to be done with respect to the representation of women of color, and people of color in general. The primary focus of this Article, therefore, is the inadequate representation of women of color, and people of

---

1 *See infra* section I.B.1.

2 274 U.S. 200 (1927) (upholding a Virginia law authorizing a state's right to forcibly sterilize a person deemed unfit to procreate). *Buck* was considered a victory for America's eugenics movement, "deliver[ing] a clarion call to Americans to identify those among them who should not be allowed to reproduce—and to sterilize them in large numbers." ADAM COHEN, IMBECILES: THE SUPREME COURT, AMERICAN EUGENICS, AND THE STERILIZATION OF CARRIE BUCK 2 (2016).

3 *See* HARRIET A. WASHINGTON, MEDICAL APARTHEID 202-06 (2006).

4 *See infra* note 56.

color more generally, in clinical trials. After providing historical background on these issues in Part I, Part II discusses some of the consequences of this history, with a particular focus on the import of those consequences in the context of the COVID-19 pandemic. Part III turns to immediate considerations and urges further scholarly consideration and engagement on these issues. The Article concludes by proposing policy considerations rooted in law and society in an effort to address the harms caused by this problematic history.

I
HISTORICAL BACKGROUND

A. Women's Underrepresentation in Clinical Research

There is a long history of women being underrepresented in clinical research, particularly since the mid-twentieth century when federal policies, research ethics, and other standards began to emphasize the need to protect human subjects.[5] Paternalism and concerns about potential adverse effects on pregnant women, women of childbearing potential, fetuses, and future children have played a significant role in this exclusion.[6] Women of childbearing potential, who make

---

5 Karen L. Baird, *The New NIH and FDA Medical Research Policies: Targeting Gender, Promoting Justice*, 24 J. OF HEALTH POL., POL'Y & L. 531, 533 (1999); Katherine A. Liu & Natalie A. DiPietro Mager, *Women's Involvement in Clinical Trials: Historical Perspective and Future Implications*, PHARMACY PRAC., Jan.-Mar. 2016, at 2. The history of women's exclusion from research is extensive. This Part is not meant to be exhaustive and focuses primarily on U.S. Food and Drug Administration ("FDA") rules and guidance related to women's involvement in drug development research. This Article does not discuss requirements and policies of the National Institutes of Health ("NIH"), some of which are discussed in Lori Andrews & Bora Ndregjoni, *Covid, Sex Discrimination, and Medical Research*, 106 CORNELL L. REV. 3 (forthcoming May 2021).

6 Liu & DiPietro, *supra* note 5, at 2. Catalysts of protectionist policies included the thalidomide and diethylstilbestrol ("DES") tragedies in the mid-twentieth century. Thalidomide, used primarily as a sedative and antidote for nausea in early pregnancy, caused a rare set of deformities in children born to women who used the drug, including severe limb malformations. DES, widely prescribed in the 1940s and 1950s to prevent miscarriages, has been linked to adenocarcinoma in the children of women who took DES during pregnancy. INSTITUTE OF MEDICINE (US) COMMITTEE ON THE ETHICAL AND LEGAL ISSUES RELATING TO THE INCLUSION OF WOMEN IN CLINICAL STUDIES, WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 40–41 (Anna C. Mastroianni, Ruth Faden & Daniel Federman eds., 1994). Controversy over the Dalkon Shield, an intrauterine device, also likely played a role. Women claimed it caused unwanted pregnancies, ectopic pregnancies, septic abortions, miscarriages, birth defects, excessive bleeding and cramping, pelvic inflammatory disease, infertility, and a few deaths. *See* Carrie Menkel-Meadow, *Taking the Mass Out of Mass Torts: Reflections of a Dalkon Shield Arbitrator on Alternative Dispute Resolution, Judging, Neutrality, Gender, and Process*, 31 LOY. L.A. L. REV.

up a large portion of the population, have been viewed as a "vulnerable population" in the context of research, resulting in their exclusion from clinical trials based on federal recommendations.[7] Additionally, liability concerns make many pharmaceutical companies hesitant to test investigational drugs on pregnant women and women of childbearing potential.[8] While the protection of human research subjects is a key ethical principle and is required by law,[9] the exclusion of pregnant women and women of childbearing potential from clinical trials implies a lack of respect for their autonomy and decision-making capacity, violating basic ethical principles set forth in The Belmont Report.[10]

The requirement to establish the safety of a drug prior to marketing has been in place since the Federal Food, Drug, and Cosmetic Act ("FD&C Act") was promulgated in 1938.[11] The Kefauver-Harris Amendments of 1962 established the requirement that a drug also be proven effective.[12] These laws did not establish any requirements related to the representation of men and women in the studies used to support the safety and effectiveness of a drug.

Before a drug may be approved, clinical trials are conducted, which typically involve three phases of human studies.[13] After preclinical testing, Phase I studies are conducted, which are generally small (approximately twenty to one hundred healthy subjects) and designed to determine the

---

513, 514–15 (1998); Ameeta Parekh, Emmanuel O. Fadiran, Kathleen Uhl & Douglas C. Throckmorton, *Adverse Effects in Women: Implications for Drug Development and Regulatory Policies*, 4 EXPERT REV. CLIN. PHARMACOLOGY 453, 453 (2011).

7 Liu & DiPietro, *supra* note 5, at 2. Other populations frequently considered vulnerable include children, prisoners, individuals with impaired decision-making capacity, and the economically-disadvantaged. *See, e.g.*, 45 C.F.R. §§ 46.107(a), 46.111(a)(3) & (b) (2009).

8 *See* Baird, *supra* note 5, at 533.

9 *See* 45 C.F.R. 46 (2009) (regulating the protection of human subjects).

10 The Belmont Report identifies basic ethical principles and guidelines for human subjects research. NAT'L COMMISSION FOR THE PROTECTION OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (Apr. 18, 1979) [hereinafter "The Belmont Report"].

11 Federal Food, Drug, and Cosmetic Act ("FD&C Act"), Pub. L. No. 717, § 505(b) 52 Stat. 1040, 1052 (1938).

12 Drug Amendments Act of 1962, Pub. L. No. 87-781, § 102, 76 Stat. Ann. 780,781 (1962)

13 *See* U.S. FOOD & DRUG ADMIN., STEP 3: CLINICAL RESEARCH (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/56JZ-8LLQ].

safety and dosage of the drug.[14] Phase II studies can include up to several hundred subjects with the target disease or condition and are designed to evaluate the effectiveness and side effects of the drug.[15] Phase III studies can involve several hundreds or thousands of subjects with the target disease or condition and are designed to verify the safety and efficacy of the drug.[16] After approval, Phase IV postmarketing studies are often conducted (or required) to monitor or confirm the drug's safety and effectiveness.[17]

In light of concerns about the underrepresentation of women in clinical trials and the potential consequences for women's health, changes have been made over time to various rules and guidance promulgated by the United States Food and Drug Administration ("FDA" or "the Agency").[18] In 1977, FDA issued *General Considerations for the Clinical Evaluation of Drugs*, which set forth acceptable current approaches to clinical trials with investigational drugs (hereinafter "the 1977 Guidelines").[19] Like all Agency guidance, the 1977 Guidelines were not considered mandatory,[20] although in practice FDA guidance is generally followed by those to whom it is directed (*e.g.*, industry).

The 1977 Guidelines stated that "females who are pregnant, or at risk of becoming pregnant"[21] should be excluded from Phase I trials.[22] Instead, the 1977 Guidelines indicated that only "normal" individuals are typically included

---

14 21 C.F.R. § 312.21(a) (2020).

15 *Id.* § 312.21(b).

16 *Id.* § 312.21(c).

17 *Id.* § 312.85. Postmarketing studies or clinical trials can be required, for example, to demonstrate clinical benefit for drugs approved under the accelerated approval requirements in 21 C.F.R. §§ 314.510 and 601.41 (2020).

18 *See* U.S. FOOD & DRUG ADMIN., REGULATIONS, GUIDANCE, AND REPORTS RELATED TO WOMEN'S HEALTH (last updated June 4, 2019), https://www.fda.gov/science-research/womens-health-research/regulations-guidance-and-reports-related-womens-health [https://perma.cc/9MX4-5NLA] (compiling regulatory documents addressing women's health throughout the history of FDA).

19 U.S. DEP'T OF HEALTH, EDUC. & WELFARE, PUB. HEALTH SERV., U.S. FOOD & DRUG ADMIN., GENERAL CONSIDERATIONS FOR THE CLINICAL EVALUATIONS OF DRUGS (1977), *available at* https://www.fda.gov/media/71495/download [https://perma.cc/AU38-YQ3P] [hereinafter "1977 Guidelines"].

20 *See id.* at iii; *see also* 21 C.F.R. §§ 10.115(d), (i), & (o) (2020).

21 The 1977 Guidelines defined a "woman of childbearing potential" broadly as "[a] premenopausal female capable of becoming pregnant. This includes women on oral, injectable, or mechanical contraception; women who are single; women whose husbands have been vasectomized or whose husbands have received or are utilizing mechanical contraceptive devices." 1977 Guidelines, *supra* note 19, at 10.

22 *Id.* at 10.

in early-phase studies,[23] a statement that implies that a large portion of the population—women of childbearing potential—is not "normal." The 1977 Guidelines then stated that women of childbearing potential "may be included" in Phase III studies "[i]f adequate information on efficacy and relative safety has been amassed during Phase II" studies and if animal reproductive studies have been completed.[24] For women of childbearing potential enrolled in a study, the 1977 Guidelines recommended that pregnancy tests be performed and that the women be advised about suitable methods of contraception.[25] In contrast, when animal reproductive studies suggest that a drug has a potential effect on the *male* reproductive system, the 1977 Guidelines merely stated that the inclusion of males in studies of that drug should "depend upon the nature of the abnormalities, the dosage at which they occurred, the disease being treated, the importance of the drug, and the duration of drug administration" and may require special written consent forms.[26] Unlike for women, the 1977 Guidelines did not recommend advising males about the use of contraception.

In 1993, FDA published new guidelines and withdrew the restrictions on the participation of women of childbearing potential in early clinical trials (*e.g.*, Phase I).[27] These revisions were a response to growing concerns that the drug development process did not produce adequate information about the safety and efficacy of drugs in women. FDA itself acknowledged that the 1977 Guidelines were viewed as "rigid," "paternalistic," and "overprotective"; left "virtually no room for the exercise of judgment by responsible female research subjects, physician investigators, and [Investigational Review Boards ("IRBs")]"; and denied "young women the opportunity available to young men and older women to participate in early drug development research."[28] FDA did not, however, require inclusion of women in general or women of childbearing potential, and recognized that drug companies and/or IRBs may not change their restrictions.[29]

In 1998, FDA further sought to address the problem by issuing a final rule amending its regulations pertaining to

---

23 *Id.* at 7. FDA regulations continue to use the term "normal" to describe the populations enrolled in Phase I studies. 21 C.F.R. § 312.21(a) (2020).

24 1977 Guidelines, *supra* note 19, at 10.

25 *Id.* at 11

26 *Id.* at 11

27 58 Fed. Reg. 39,406 (July 22, 1993).

28 *Id.* at 39,408.

29 *Id.*

investigational new drug applications ("INDs") and new drug applications ("NDAs").[30] Among other things, this final rule amended FDA regulations to require sponsors of NDAs to include in their applications analyses of safety and effectiveness data for certain subgroups, including gender.[31] FDA has the authority to refuse to file an NDA that lacks such data.[32] In 2000, FDA promulgated another final rule that gives the Agency the authority to place a trial for a life-threatening disease or condition on clinical hold if the sponsor excludes men or women only because of reproductive potential.[33] This rule only applies to trials for a life-threatening disease or condition in which the subjects have the disease or condition; it does not apply to trials only involving healthy volunteers or for diseases or conditions that are not considered "life-threatening."[34]

Then, in 2018, FDA issued draft guidance titled *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials*, which is intended to "support[] an informed and balanced approach to gathering data on the use of drugs and biological products during pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk."[35] In addition to these and other changes, the FDA Office of Women's Health ("OWH") was established by Congressional mandate in 1994, with a mission to "[p]romote the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and completion of sex/gender analysis."[36]

Examining recent data, women's enrollment in clinical trials that were used to support new drug approvals by FDA's

---

30 Investigational New Drug Applications and New Drug Applications, 63 Fed. Reg. 6854 (Feb. 11, 1998).

31 *Id.*

32 21 C.F.R. § 314.101(d)(3) (2020).

33 Investigational New Drug Applications: Amendment to Clinical Hold Regulations for Products Intended for Life-Threatening Diseases and Conditions, 65 Fed. Reg. 34,963 (June 1, 2000).

34 *Id.*

35 U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, PREGNANT WOMEN: SCIENTIFIC AND ETHICAL CONSIDERATIONS FOR INCLUSION IN CLINICAL TRIALS 1 (Apr. 2018).

36 U.S. FOOD & DRUG ADMIN., OFFICE OF WOMEN'S HEALTH (Dec. 2, 2019), https://www.fda.gov/about-fda/office-commissioner/office-womens-health [https://perma.cc/6CTY-PUAZ]; *see also* U.S. FOOD & DRUG ADMIN, WOMEN'S HEALTH RESEARCH (Feb. 7, 2020), https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research [https://perma.cc/8FUW-5ZLQ].

Center for Drug Evaluation and Research ("CDER") appears to be equal if not greater than men's enrollment.[37] There is some variation due, in part, to the diseases or conditions treated by the drugs approved and whether they disproportionately affect women. Nevertheless, many drugs on the market were studied and approved prior to the implementation of the previously discussed rules and guidance, and therefore may not have been adequately studied in women. Additionally, the reports do not indicate whether there were restrictions placed on pregnant women and/or women of childbearing potential.[38] Research suggests that many studies include fertility-related exclusion criteria and that there is a lack of human pregnancy data for many drugs.[39] And FDA itself acknowledges that "pregnant women are actively excluded from trials" and, as a result, there are frequently "no or limited human data to inform the safety of a drug or biological product taken during pregnancy."[40]

B. Women of Color as Unknowing or Unwilling Participants in Clinical Research

Traditionally, pregnant women and women of childbearing potential have faced exclusion from clinical trials and have

---

37 *See* U.S. FOOD & DRUG ADMIN., 2019 DRUG TRIALS SNAPSHOTS SUMMARY REPORT (Jan. 2020), https://www.fda.gov/media/135337/download [https://perma.cc/H6H9-TA7J] (average of 72% women); FOOD & DRUG ADMIN., 2018 DRUG TRIALS SNAPSHOTS SUMMARY REPORT (Jan. 2019), https://www.fda.gov/media/120253/download [https://perma.cc/6MZV-KPFR] (average of 56% women); U.S. FOOD & DRUG ADMIN., 2017 DRUG TRIALS SNAPSHOTS SUMMARY REPORT (Jan. 2018), https://www.fda.gov/media/112373/download [https://perma.cc/A8AG-55EF] (average of 55% women); U.S. FOOD & DRUG ADMIN., 2015–2016 DRUG TRIALS SNAPSHOTS SUMMARY REPORT (Jan. 2017), https://www.fda.gov/media/103160/download [https://perma.cc/VV57-HLEH] (average of 48% women).

38 FDA-approved labeling for a drug, however, includes a section (section 8.1 of the full prescribing information) that indicates whether the drug has been adequately studied in pregnant women. 21 C.F.R. § 201.57(c)(9)(i) (2020).

39 *See* sources cited *infra* note 102; *see also* Alannah L. Phelan, Allen R. Kunselman, Cynthia H. Chuang, Nazia T. Raja-Khan & Richard S. Legro, *Exclusion of Women of Childbearing Potential in Clinical Trials of Type 2 Diabetes Medications: A Review of Protocol-Based Barriers to Enrollment*, 39 DIABETES CARE 1004, 1004 (2016) (finding that 55% of trials of Phase II or III type 2 diabetes medications excluded pregnant women); Maryann Mazer-Amirshahi, Samira Samiee-Zafarghandy, George Gray & Johannes N. van den Anker, *Trends in Pregnancy Labeling and Data Quality for US-Approved Pharmaceuticals*, 211 AM. J. OBSTETRICS & GYNECOLOGY 690.e1 (2014) (reporting that of 213 new pharmaceuticals approved between 2003 and 2012, only 5.2% included any human pregnancy data).

40 U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, POSTAPPROVAL PREGNANCY SAFETY STUDIES 2 (May 2019).

been viewed as vulnerable populations that must be protected. Women of color have frequently not been treated with the same "concern." Indeed, rather than being "protected," all people of color—regardless of sex, gender, or age—have been subjected to dangerous and unethical research throughout history. The reasons for this are many, often rooted in racism, the view that people of color are "more expendable,"[41] and the utilitarian belief that the research was for the greater good and would advance scientific and medical knowledge.[42]

One of the most cited examples of such research is the Tuskegee syphilis experiment conducted by the U.S. Public Health Service from 1932 to 1972 on hundreds of poor Black sharecroppers in Macon County, Alabama. The study researched the effects of untreated syphilis on Black men, most of whom were not told they had the disease or whether they were being treated.[43] Although women themselves were not subjects of the study, the wives and partners of these men were also deceived, and at least forty were infected with syphilis by their untreated partners.[44] The Tuskegee experiment is one of the most noteworthy examples of unethical research that has exploited people of color, but if we unduly focus on that study, we fail to appreciate a much more extensive history of abuse, particularly the exploitation experienced by women of color specifically, often in the area of reproductive health.

1. *James Marion Sims: "The Father of Modern Gynecology"*

James Marion Sims was born in 1813 and entered the medical profession during a time when doctors underwent far less training than today.[45] He is recognized by many as the "father of modern gynecology," despite the questionable and problematic research and procedures he engaged in to secure his success and fame.[46]

After moving to Alabama, Sims began practicing as a plantation doctor for enslaved men, women, and children. He took a particular interest in women's health, despite having

---

41 *See* Baird, *supra* note 5, at 533.

42 Allan Gaw, *Beyond Consent: The Potential for Atrocity*, 99 J. ROYAL SOC'Y MED. 175, 175 (2006).

43 *See* WASHINGTON, *supra* note 3, at 157; *see generally id.* at 157–185.

44 *Id.* at 166.

45 *Id.* at 61.

46 *Id.* at 66; *see also* L. Lewis Wall, *The Medical Ethics of Dr. J Marion Sims: A Fresh Look at the Historical Record*, 32 J. MED. ETHICS 346, 346 (2006).

little experience and no specific gynecological training. Early on, he treated a slave with vesicovaginal fistula,[47] a condition that afflicted many women after difficult childbirths and that had a particularly high rate among enslaved women. Sims knew that white women would also be interested in a cure but that it would be "impossible" to test some of the potentially effective, yet extremely painful, procedures on white women.[48] Having a population of enslaved women at his disposal made it possible for him to begin his search for a cure. He thus found cases among enslaved women on whom he could perform these extremely painful experiments, which typically required the women to be restrained.[49] According to one historian, "it would have been most improbable that Sims and [his assistant] could have established so remarkable a surgical schedule without the slave system which provided the experimental subjects."[50] As Harriet Washington importantly notes, "[s]laves did not have to be recruited, persuaded, and cajoled to endure pain and indignity; they could not refuse."[51] The women were treated with no respect or dignity, forced to "undress completely, then kneel on hands and knees while [Sims] and several physicians took turns inserting a special speculum he had devised to open the women's vaginas fully to view."[52] Furthermore, despite the excruciating pain caused by these procedures, Sims refused to administer anesthesia to the women, even though its use was known at the time and Sims himself used it when performing surgery on white women a few

---

47 Vesicovaginal fistula is an abnormal opening between the bladder and vagina that results in continuous and unremitting urinary incontinence. There are a number of causes, the most common of which is obstructed labor. Today, it is relatively rare in developed countries but still relatively common in developing countries. Michael Stamatakos, Constantina Sargedi, Theodora Stasinou & Konstaninos Kontzoglou, *Vesicovaginal Fistula: Diagnosis and Management*, 76 INDIAN J. SURGERY 131, 131 (2014).

48 *See* WASHINGTON, *supra* note 3, at 64. The surgeries were extremely painful:

> Not only had Sims to close the unnatural openings in the ravaged vaginal tissues; he had to make the edges of these openings knit together. He opted to abrade, or 'scarify,' the edges of the vaginal tears every time he attempted to repair an opening. He then closed them with sutures and saw them become infected and reopen, painfully, every time.

Id. at 65.

49 *See id.* at 64, 65; Walter Fisher, *Physicians and Slavery in the Antebellum Southern Medical Journal*, 23 J. HIST. MED. & ALLIED SCI. 36, 48 (1968).

50 Fisher, *supra* note 49, at 48.

51 WASHINGTON, *supra* note 3, at 64.

52 *Id.*

years later.[53]

2. *Puerto Rico Contraception Trials*

Among the many things that have contributed to the fraught and often controversial history of the birth control pill are how and on whom it has been researched.[54] Clinical trials on the first birth control pill approved by FDA involved primarily poor, uneducated women in Puerto Rico in the 1950s and were led by Gregory Pincus.[55] Puerto Rico was seen as an ideal setting for the trials. After years of a government-sponsored sterilization campaign intended to reduce overpopulation, unemployment, and poverty,[56] there

---

53 *Id.*

54 *See generally* JONATHAN EIG, THE BIRTH OF THE PILL: HOW FOUR CRUSADERS REINVENTED SEX AND LAUNCHED A REVOLUTION (2014).

55 Jhoni Jackson, *How Puerto Rican Women Made Birth Control Possible–At the Expense of their Health*, BESE (Apr. 16, 2018), https://www.bese.com/how-puerto-rican-women-made-birth-control-possible-at-the-expense-of-their-health/ [https://perma.cc/JZJ3-2AYM]; Erin Blakemore, *The First Birth Control Pill Used Puerto Rican Women as Guinea Pigs*, HISTORY (updated Mar. 11, 2019), https://www.history.com/news/birth-control-pill-history-puerto-rico-enovid [https://perma.cc/C6VP-HATX]. Around this time, Pincus' team also conducted research on sixteen patients from the Worcester State Asylum—all classified as "psychotics"—who were not required to give their consent. *See* EIG, *supra* note 54, at 178–80.

56 Between the 1930s and 1970s, approximately one-third of women in Puerto Rico were sterilized. Family planning clinics were plentiful and provided free sterilization, which was presented as a free form of birth control. These women were not fully informed and some regretted being sterilized. Katherine Andrews, *The Dark History of Forced Sterilization of Latina Women*, PANORAMAS (Oct. 30, 2017), https://www.panoramas.pitt.edu/health-and-society/dark-history-forced-sterilization-latina-women [https://perma.cc/YSW5-LBEW]. There is also a long history of involuntary, forced, or coerced sterilization of women of color in the continental U.S. "Forced sterilization and welfare have been linked for decades" and many poor Black women have been sterilized in violation of the law and medical mores. WASHINGTON, *supra* note 3, at 209. American Indian women and girls were also sterilized without their knowledge or consent during the 1970s. Some were led to believe they would lose access to government services and benefits if they refused the procedure, and women under twenty-one were sterilized in violation of a court order prohibiting sterilization of women under that age. *See* Christina M. Pacheco et al., *Moving Forward: Breaking the Cycle of Mistrust Between American Indians and Researchers*, 103 AM. J. PUB. HEALTH 2152, 2153 (2013); Felicia Schanche Hodge, *No Meaningful Apology for American Indian Unethical Research Abuses*, 22 ETHICS & BEHAVIOR 431, 433–34 (2012). And, most recently in September of 2020, Dawn Wooten, a licensed practical nurse employed by the Irwin Country Detention Center ("ICDC"), alleged, among other things, that high rates of detained immigrant women at ICDC received hysterectomies without the women's full understanding or consent. *See* Letter from Project South, Georgia Detention Watch, Georgia Latino Alliance for Human Rights, & South Georgia Immigrant Support Network, to Joseph V. Cuffari, Inspector Gen., Office of the Inspector Gen., Dep't of Homeland Security, et al., at 18–19 (Sept. 14, 2020), *available at* https://projectsouth.org/wp-content/uploads/2020/09/OIG-ICDC-Complaint-

was general acceptance of family planning methods, unlike in the continental U.S., where cultural and religious opposition to contraception were generally still widespread.[57]

The government's support of contraception, Puerto Rico's lack of laws regulating contraceptive research, and its growing population and poverty also contributed to it being viewed as an ideal location to study the pill.[58] Furthermore, the numerous family planning clinics developed in Puerto Rico during the sterilization campaign provided a ready population of potential research participants.[59] The women, who were generally poor, uneducated, and "desperate to avoid both pregnancy and sterilization," were far more likely to try a contraceptive drug than wealthier, more educated women.[60] They were not, however, informed that the drug was experimental, given safety information about the drug, or told that they were participating in a clinical trial.[61] Thus, not only were they desperate to avoid pregnancy, they were not given sufficient information to make a fully informed choice. They were given pills that contained much higher doses of hormones than modern day birth control pills and that caused significant side effects, but women who reported side effects such as nausea, dizziness, headaches, and blood clots "were discounted as 'unreliable historians.'"[62] Three women died during the trial, but because their deaths were not investigated and no autopsies were performed, it is unknown whether the pill caused or contributed to their deaths.[63]

3. *Goldzieher Oral Contraceptive Study*

Another lesser-known example of ethically questionable contraception research is a study conducted during the 1960s led by Dr. Joseph Goldzieher. In the late 1960s, Dr. Goldzieher conducted a randomized, placebo-controlled, double-blind

---

1.pdf [https://perma.cc/965B-BEZW].

57 Jackson, *supra* note 55.

58 Darshi Thoradeniya, *Birth Control Pill Trials in Sri Lanka: The History and Politics of Women's Reproductive Health (1950–1980)*, 33 SOC. HIST. MED. 268, 273 (2018); *see also* Jackson, *supra* note 55; Blakemore, *supra* note 55. Pincus could not, for example, conduct trials in Massachusetts, where the pill was invented, because contraceptive research was illegal in Massachusetts at that time. Thoradeniya, at 272–73.

59 Blakemore, *supra* note 55.

60 *Id.*

61 *Id.*

62 Pamela Verma Liao & Janet Dollin, *Half a Century of the Oral Contraceptive Pill: Historical Review and View to the Future*, 58 CAN. FAM. PHYSICIAN e757, e757 (2012).

63 Blakemore, *supra* note 55.

trial designed to evaluate the side effects of four oral contraceptives.[64] Mexican-American women made up over 80% of the 398 women enrolled in the trial.[65] Seventy-six women were enrolled in the placebo arm, with the remaining women receiving one of four contraceptive drugs being tested. All women who received the placebo were required to use a contraceptive vaginal cream or foam.[66] Nevertheless, questions have been raised about whether these women were aware they were being enrolled in a clinical trial and that they might receive a placebo.[67] In fact, when asked why the women were not fully informed, Dr. Goldzieher stated "[i]f you think you can explain a placebo test to women like these, you've never met Mrs. Gomez from the west side,"[68] displaying not only prejudice but also a lack of respect for the women's autonomy.

4. *Henrietta Lacks*[69]

The bodies of women of color have also been exploited even when the woman herself was not a participant in a trial. Indeed, one of the most well-known examples of a woman's body being used "in the name of science" and "for the greater good" is that of Henrietta Lacks. Ms. Lacks, a poor Black mother of 5 who lived with her husband in Baltimore, sought care at Johns Hopkins Hospital in 1951 when she began experiencing gynecological bleeding.[70] She was diagnosed with and treated for an aggressive form of cervical cancer and died

---

64 Joseph W. Goldzieher, Louis E. Moses, Eugene Averkin, Cora Scheel & Ben Z. Taber, *A Placebo-Controlled Double-Blind Crossover Investigation of the Side Effects Attributed to Oral Contraceptives*, 22 FERTILITY & STERILITY 609 (1971) [hereinafter "Goldzieher, *Placebo-Controlled*"]; Joseph W. Goldzieher, Louis E. Moses, Eugene Averkin, Cora Scheel & Ben Z. Taber, *Nervousness and Depression Attributed to Oral Contraceptives: A Double-Blind Placebo-Controlled Study*, 111 AM. J. OBSTETRICS & GYNECOLOGY 1013 (1971) [hereinafter "Goldzieher, *Nervousness*"].

65 Goldzieher, *Placebo-Controlled, supra* note 64, at 610 (citing Joseph W. Goldzieher, Louis E. Moses & Lucy T. Ellis, *Study of Norethindrone in Contraception*, 180 J. AM. MED. ASS'N 359, 359 (1962), which describes the demographic make-up of the subjects); *see also* Goldzieher, *Nervousness, supra* note 64, at 1016.

66 Goldzieher, *Placebo-Controlled*, *supra* note 64, at 610–11.

67 JAEL SILLIMAN, MARLENE GERBER FRIED, ELENA R. GUTIERREZ & LORETTA ROSS, UNDIVIDED RIGHTS: WOMEN OF COLOR ORGANIZE FOR REPRODUCTIVE JUSTICE 228 (2004).

68 *Id.*

69 Unless other sources are cited, the information about Henrietta Lacks was obtained from THE IMMORTAL LIFE OF HENRIETTA LACKS. *See* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS 3 (2010).

70 *Id.* at 13–15, 26.

from the cancer that same year.[71]

As was common at the time, Ms. Lacks' invasive cervical cancer was treated with radium. During her first treatment, while unconscious on the operating table, a doctor retrieved two tissue samples from Ms. Lacks—one from her tumor and one from her healthy cervical tissue.[72] The tissue from the tumor was sent to a laboratory and would give rise to the "HeLa" cell line.[73] Ms. Lacks was never informed about and did not consent to the retrieval and use of her tissue samples or cells.[74] Then in 1985, extensive portions of her medical record were published in a book without her family's knowledge or consent.[75]

Unlike other cervical cancer cell lines, which tended to quickly die in the lab, Ms. Lacks' cells, referred to as the "HeLa" cells, doubled every twenty to twenty-four hours, making them ideal for use in experiments.[76] Ms. Lacks herself was not enrolled in a clinical trial, but her cells have been used in the research and development of countless medical advancements, including but not limited to the polio vaccine; chemotherapy; cloning; gene mapping; in vitro fertilization; drugs for herpes, leukemia, influenza, hemophilia, and Parkinson's diseases; and the study of lactose digestion, sexually transmitted diseases, appendicitis, human longevity, mosquito mating, and the negative cellular effects of working in sewers.[77] Her cells are considered one of the most important discoveries in medicine in the twentieth century and one of the most essential tools in medicine to this day.[78]

It is impossible to calculate the lives saved and profits earned by the medical advancements created, at least in part, through the use of Ms. Lacks' cells. Many would say they are invaluable. The HeLa cells continue to be used in research and development, including research on SARS-CoV-2, the virus

---

71 *Id.* at 3.

72 *Id.* at 33.

73 *Id.*

74 SKLOOT, *supra* note 69, at 33.

75 *Id.* at 210. At the time the records would have been released by a physician or medical institution and published, there was no federal law prohibiting the publication of medical records without permission. *Id.*

76 *Id.* at 30, 40–41.

77 *Id.* at 2, 4.

78 *Id.* at 4; HENRIETTA LACKS FOUND., http://henriettalacksfoundation.org/ [https://perma.cc/XY2L-VLKT] (last accessed Sept. 19, 2020); *The Legacy of Henrietta Lacks: The Importance of HeLa Cells*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/henriettalacks/importance-of-hela-cells.html [https://perma.cc/3FGB-H986] (last accessed Sept. 19, 2020).

that causes COVID-19.[79] To this day, Ms. Lacks' family has not received any direct compensation for the profits earned from her cells.[80] In fact, many of her ancestors have trouble affording basic health care, including the therapeutic and preventative medicines developed through the use of Ms. Lacks' cells.[81] Over the past decade, however, numerous scholarships, symposia, historical exhibits, and other grants have been established.[82] And Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*, founded the Henrietta Lacks Foundation, a non-profit that provides financial assistance to individuals and families "who were involved in historic research cases without their knowledge, consent, or benefit."[83] In addition to others, the Foundation has awarded over eighty grants to approximately thirty members of Henrietta Lacks' immediate family.[84]

---

79 *See, e.g.*, Xiuyuan Ou et al., *Characterization of Spike Glycoprotein of SARS-CoV-2 on Virus Entry and its Immune Cross-Reactivity with SARS-CoV*, 11 NATURE COMMUNICATIONS 1, 10 (2020) (noting use of HeLa cell cells lines); Jian Shang et al., *Cell Entry Mechanisms of SARS-CoV-2*, 117 PNAS 11727, 11733 (2020) (stating the same).

80 As noted *infra*, however, donations have been made to the Henrietta Lacks Foundation, which has provided financial support to members of the Lacks family, among others. *See infra* notes 82–84 and accompanying text.

81 According to Alfred Lacks Carter, Ms. Lacks' grandson, two of her sons have debilitating illnesses but cannot afford adequate care. *See* Andrea K. McDaniels, *Henrietta Lacks Family Calls for Inquiry into Johns Hopkins' Use of Her Cells*, BALT. SUN (Feb. 17, 2017), https://www.baltimoresun.com/maryland/baltimore-city/bs-hs-lacks-legacy-20170217-story.html [https://perma.cc/5922-XFQS]; s*ee also* Joyce Davis, *Stolen Cells: 'The Immortal Life of Henrietta Lacks'*, REP. HERALD (Apr. 21, 2017), https://www.reporterherald.com/2017/04/21/stolen-cells-the-immortal-life-of-henrietta-lacks-reposted/ [https://perma.cc/KR4C-2BRN (mentioning that many of Ms. Lacks' ancestors cannot afford health care); *Excerpt: 'The Immortal Life of Henrietta Lacks'*, ABC NEWS (Jan. 31, 2010), https://abcnews.go.com/WN/immortal-life-henrietta-lacks-excerpt/story?id=9712490 [https://perma.cc/C53G-2CUZ] (noting that despite the high profits earned from her cells, "her family – who often can't even afford health insurance – never saw any profits").

82 *See* Amy Dockser Marcus, *Henrietta Lacks and her Remarkable Cells Will Finally See Some Payback*, WALL ST. J. (Aug. 1, 2020), https://www.wsj.com/articles/henrietta-lacks-and-her-remarkable-cells-will-finally-see-some-payback-11596295285 [https://perma.cc/RZG2-Z8HL] (describing various financial contributions to honor Henrietta Lacks).

83 *About the Foundation*, HENRIETTA LACKS FOUND., http://henriettalacksfoundation.org/about/ [https://perma.cc/UD9Y-7EF5] (last accessed Sept. 19, 2020).

84 This includes grants for health care, dental assistance, tuition and books, job training, maintaining employment, and emergency relief. Educational grants have also been awarded to ancestors of those who were part of the Tuskegee syphilis studies. *Id.* In October 2020, the Howard Hughes Medical Institute ("HHMI") announced a six-figure gift to the Foundation. Various entities and individuals have donated to the Foundation. *See* Press Release, Henrietta Lacks

While some have defended the taking and using of Ms. Lacks' cells without her knowledge or consent because doing so was neither uncommon nor prohibited at the time,[85] her story raises important questions about race, gender, and the right to one's bodily integrity.[86] As stated by Ruth Faden, founder and former director of the Johns Hopkins Berman Institute of Bioethics,

> the Lackses' story is a sad commentary on how the biomedical research community thought about research in the 1950s. But it was not at all uncommon for physicians to conduct research on patients without their knowledge or consent. That doesn't make it right. It certainly wasn't right. It was also unfortunately common.[87]

This history—one in which some women have been excluded from research while others have been unwillingly forced into research—and its harms, which are discussed next, must be acknowledged and reckoned with when considering any path forward.

Found., Henrietta Lacks Foundation Receives Two Historic Gifts (Oct. 29, 2020) (mentioning gifts from HHMI, Abcam (a biotech company), and Francis Collins, current Director of the National Institutes of Health), https://henriettalacksfoundation.org/wp-content/uploads/2020/10/HLF-Press-Release-HHMI-Collins-Donations.pdf [https://perma.cc/5DPK-ZV5U].

85 *See, e.g.*, *The Legacy of Henrietta Lacks: Frequently Asked Questions*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/henriettalacks/frequently-asked-questions.html [https://perma.cc/9L7G-Z8Z3] (last accessed Sept. 19, 2020), (stating:

> In the 1950s, when Henrietta Lacks was hospitalized, there were no established practices for informing or obtaining consent from patients when retrieving cell or tissue samples for research purposes, nor were there any regulations on the use of patients' cells in research. It was common practice at Hopkins for extra samples to be collected from cervical cancer patients during biopsies to be used for research purposes, regardless of race or socio-economic status.).

86 It also raises questions regarding whether individuals should be compensated for profits earned through the use of research that they (or parts of their bodies) contribute to. The issue of whether individuals should be compensated for providing biological materials that result in profitable patents and/or medical products is an important question but beyond the scope of this Article. However, this Article is premised on the belief that individuals have a right to be informed of and consent to their participation and the use of their biological materials in clinical research and the development of medical products. *See, e.g.*, Allison M. Whelan, *That's My Baby: Why the State's Interest in Promoting Public Health Does Not Justify Residual Newborn Blood Spot Research Without Parental Consent*, 98 MINN. L. REV. 419 (2013).

87 Rebecca Skloot, *Henrietta's Dance*, JOHNS HOPKINS MAG. (Apr. 2000), https ://pages.jh.edu/~jhumag/0400web/01.html [https ://perma.cc/7YNE-Z3J5].

II
THE HARMS

A. Harms of Excluding Women from Clinical Research

The most obvious harm that results from inadequate representation of women in clinical trials is a lack of information about the safety and efficacy of medical products for women. It is now well known that there are important differences between men and women in the prevalence, diagnosis, severity, and outcomes of various diseases and that men and women may react differently to treatments. For example, a report by the U.S. General Accounting Office found that of 10 prescription drugs withdrawn from the market between January 1, 1997 and December 2000, 8 posed greater risks for women than men.[88] Four of the drugs may have led to more adverse events in women because they were prescribed more often to women, but the other four were widely prescribed to both women and men, and the differences may have been due to physiological differences.[89]

Conducting research only on men or a subset of women (if the treatment is also intended for use by women) can have important implications for women's health.[90] For example, the first randomized trial studying aspirin for cardiovascular disease prevention in the United States, published in 1989, enrolled only men.[91] The study found that taking aspirin every other day substantially reduced the risk of a first heart attack in men fifty years of age and older, but might increase the risk of stroke.[92] Not until 2005 was a similar study published on

---

88 U.S. GEN. ACCOUNTING OFFICE, DRUG SAFETY : MOST DRUGS WITHDRAWN IN RECENT YEARS HAD GREATER HEALTH RISKS FOR WOMEN 2 (Jan. 19, 2001), *available at* https://www.gao.gov/assets/100/90642.pdf [https://perma.cc/Z6BH-MMGC] [hereinafter "GAO, Drug Safety Report"].

89 *Id.* at 2, 4.

90 *See, e.g.*, INST. OF MED., EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH: DOES SEX MATTER? 3 (Theresa M. Wizeman & Mary-Lou Pardue eds., 2001) ("The incidence and severity of diseases vary between the sexes and may be related to differences in exposures, routes of entry and the processing of a foreign agent, and cellular responses."); Report, Marry Horrigan Connors Ctr. for Women's Health & Gender Biology at Brigham and Women's Hosp., Sex-Specific Medical Research: Why Women's Health Can't Wait (2014), *available at* https://www.brighamandwomens.org/assets/bwh/womens-health/pdfs/connorsreportfinal.pdf [https://perma.cc/Q4BC-97CQ] (describing diseases that affect men and women differently); Liu & DiPietro Mager, *supra* note 5, at 1–2 (discussing differences between men and women that implicate health).

91 Steering Committee of the Physicians' Health Study Research Group, *Final Report on the Aspirin Component of the Ongoing Physicians' Health Study*, 321 N. ENG. J. MED. 129 (1989).

92 *Id.*

women 45 years of age and older, which showed different results: taking aspirin every other day significantly *lowered* the risk of stroke for women 65 years of age and older but did *not* reduce the risk of heart attack in women under 65.[93] Women taking aspirin to prevent heart attacks were thus given a false sense of protection, believing they were taking measures to prevent heart attacks.

It is undeniably important to avoid immediate harm to a fetus or to a future fetus or child(ren), but by excluding pregnant women and/or women of childbearing potential—often categorically—from clinical research, we lose the opportunity to understand potential risks early in the development of a medical product, well before it becomes widely available on the market. Although FDA can inform patients and prescribers through drug labeling that a drug has not been studied in pregnant women, this does not eliminate the reality that pregnant women will need and will be prescribed prescription drugs. Indeed, data suggest that up to ninety percent of pregnant women will take a prescription drug during pregnancy.[94] In these situations, healthcare providers ("HCPs") must often decide whether to prescribe a drug off-label. Without clinical data, HCPs cannot adequately determine whether the benefits of a drug outweigh the potential harms for a particular patient. This could result in treatment with an unsafe or ineffective drug or cause the HCP not to treat the woman at all for the underlying condition, which itself may do more harm than good.[95] FDA itself has recognized this issue, stating that:

> some pregnant women need to use drugs to manage chronic disease conditions or treat acute medical problems . . . . [t]he frequent lack of information based on

---

93 Paul M. Ridker et al., *A Randomized Trial of Low-Dose Aspirin in the Primary Prevention of Cardiovascular Disease in Women*, 352 N. ENGL. J. MED. 1293, 1293 (2005).

94 Abi Millar, *ConcePTION: Tackling the Unknowns of Medication in Pregnancy*, PHARMACEUTICAL TECH. (Oct. 16, 2019), https://www.pharmaceutical-technology.com/features/unknowns-of-medication-in-pregnancy-conception/?utm_source=Army%20Technology&utm_medium=website&utm_campaign=Must%20Read&utm_content=Image [https://perma.cc/XY84-TZBJ].

95 This is a problem for other populations as well, such as children and the elderly. *See* Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J. L. & MED. ETHICS 476 (2009); *see also* Marry Horrigan Connors Ctr., *supra* note 90, at 14 ("[L]ack of parity in enrollment in trials of treatment for cardiovascular disease leaves holes in our knowledge of the risk and benefits of treatment for coronary artery disease in women.").

> clinical data often leaves the [HCP] and the patient reluctant to treat the underlying condition, which in some cases may result in more harm to the woman and the fetus than if she had been treated. In addition, pregnant women often use medically necessary drugs without a clear scientific understanding of the risks and benefits to themselves or their developing fetuses.[96]

This issue is extremely important in the context of COVID-19.[97] Infectious diseases "can severely—and at times uniquely—affect the health interests of pregnant women and their offspring."[98] There is still much to learn about COVID-19 generally and how it affects women of childbearing potential and pregnant women specifically. But data suggest that pregnancy makes a woman's body more vulnerable to severe COVID-19.[99] And the Centers for Disease Control and Prevention ("CDC") has found that the proportion of preterm births among women with SARS-CoV-2 infections during pregnancy is higher than that in the general population.[100]

---

96 U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, PREGNANT WOMEN: SCIENTIFIC AND ETHICAL CONSIDERATIONS FOR INCLUSION IN CLINICAL TRIALS 2 (Apr. 2018), *available at* https://www.fda.gov/media/112195/download [https://perma.cc/MH62-54SK]; *see also* Carleigh B. Krubiner et al., *Pregnant Women & Vaccines Against Emerging Epidemic Threats: Ethics Guidance for Preparedness, Research, and Response*, 39 VACCINE 85 (2019) ("[T]remendous evidence gaps about the appropriate dosing and use of drugs and biologics in pregnancy persist . . . . the vast majority of drugs that have come to market have little to no data on their safe and effective use in pregnancy."); Anne Drapkin Lyerly, Margaret Olivia Little & Ruth Faden, *The Second Wave: Toward Responsible Inclusion of Pregnant Women in Research*, 1 INT'L J. OF FEMINIST APPROACHES TO BIOETHICS 5, 7 (2008) (noting that most medications used to treat diseases or conditions during pregnancy will be used off label).

97 *See generally* Ruth Farrell, Marsha Michie & Rachel Pope, *Pregnant Women in Trials of COVID-19: A Critical Time to Consider Ethical Frameworks of Inclusion in Clinical Trials*, 42 ETHICS & HUMAN RES. 17 (2020).

98 Krubiner, *supra* note 96, at 3.

99 *See* Sascha Ellington et al., *Characteristics of Women of Reproductive Age With Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–June 7, 2020*, 69 MORBIDITY & MORTALITY REP. WKLY. 769, 769, 775 (June 26, 2020); Meredith Wadman, *Why Infection Poses a Special Risk to Pregnant Women*, 369 SCI. 606 (Aug. 2020), *available at* https://science.sciencemag.org/content/sci/369/6504/606.full.pdf [https://perma.cc/5FY8-2E2E]; CTRS. FOR DISEASE CONTROL & PREVENTION, DATA ON COVIC 19 DURING PREGNANCY (updated Feb. 8, 2021), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/special-populations/pregnancy-data-on-covid-19.html [https://perma.cc/F2QZ-JJNU]; CTRS. FOR DISEASE CONTROL & PREVENTION, PREGNANCY, BREASTFEEDING, AND CARING FOR NEWBORNS (updated Dec. 28, 2020), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html [https://perma.cc/T296-5EGN].

100 *See* Kate R. Woodworth et al., *Birth and Infant Outcomes Following Laboratory-Confirmed SARS-CoV-2 Infection in Pregnancy — SET-NET, 16 Jurisdictions, March 29–October 14, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP.

Thus, it is imperative to study potential treatments and vaccines for COVID-19 in pregnant women, and FDA is encouraging sponsors to enroll pregnant and lactating individuals in Phase III clinical trials.[101] Nevertheless, a number of studies listed on clinicaltrials.gov that are evaluating COVID-19 treatments and vaccines exclude pregnant and breastfeeding women.[102] One review of 371 interventional trials registered on clinicaltrials.gov related to COVID-19 found that 75.8% of drug trials declared pregnancy as an exclusion criteria.[103]

In addition to physical harms, there are also dignitary harms. Treating pregnant women and women of childbearing potential as vulnerable and incapable of making fully informed decisions about enrolling in a clinical trial violates respect for persons—one of three basic ethical principles set forth in The Belmont Report.[104] This principle incorporates two sub-principles: that individuals should be treated as

---

1635, 1636 (Nov. 6, 2020); Miranda J. Delahoy et al., *Characteristics and Maternal and Birth Outcomes of Hospitalized Pregnant Women with Laboratory-Confirmed COVID-19—COVID-NET, 13 States, March 1–August 22, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1347, 1353 (Sept. 16, 2020) (finding that preterm deliveries were 25% higher among women who tested positive for COVID-19 compared to the rate of preterm delivery in the general U.S. population, with preterm deliveries 3 times more common in symptomatic patients than asymptomatic patients).

101 U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, COVID 19: DEVELOPING DRUGS AND BIOLOGICAL PRODUCTS FOR TREATMENT OF PREVENTION at 4–5 (May 2020).

102 *See, e.g.*, *A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19, NCT04470427*, U.S. NAT'L LIBR. OF MED., https://clinicaltrials.gov/ct2/show/NCT04470427 [https://perma.cc/M37R-N5DP]; *Trial of Imatinib for Hospitalized Adults With COVID-19, NCT04394416*, U.S. NAT'L LIBR. OF MED., https://clinicaltrials.gov/ct2/show/NCT04394416?recrs=ab&cond=covid-19&cntry=US&phase=2&draw=2&rank=5 [https://perma.cc/CW36-59JE]; *Azithromycin for COVID-19 Treatment in Outpatients Nationwide (ACTION), NCT04332107*, U.S. NAT'L LIBR. OF MED., https://clinicaltrials.gov/ct2/show/NCT04332107?recrs=ab&cond=covid-19&cntry=US&phase=2&draw=2 [https://perma.cc/B9FU-R25E]; *A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE), NCT04505722*, U.S. NAT'L LIBR. OF MED., https://clinicaltrials.gov/ct2/show/NCT04505722?recrs=ab&cond=covid-19&cntry=US&phase=2&draw=2&rank=73 [https://perma.cc/87FD-N8X9]; *Adaptive COVID-19 Treatment Trial (ACTT-3), NCT04492475*, U.S. NAT'L LIBR. OF MED., https://clinicaltrials.gov/ct2/show/NCT04492475?recrs=ab&cond=covid-19&cntry=US&phase=2&draw=2&rank=41 [https://perma.cc/E7PC-GD3U].

103 Sharon Einav, Mariachiara Ippolito & Andrea Cortegiani, *Inclusion of Pregnant Women in Clinical Trials of COVID-19 Therapies: What Have We Learned?*, BRIT. 125 J. OF ANAESTHESIA e326, e326 (2020).

104 The Belmont Report, *supra* note 10.

autonomous agents and that persons with diminished autonomy are entitled to protection. There is no reason to presume that pregnant women and women of childbearing potential have diminished autonomy or are incapable of self-determination. As such, their actions should not be obstructed and weight should be given to their "considered opinions and choices."[105] Refusing to do so perpetuates the infantilization of women, particularly pregnant women, as well as the notion that women do not have the right to control their own bodies.

B. Harm of Unethical Research on Women of Color

As discussed above, recent data indicate that women's representation in clinical trials has improved.[106] However, there is still much progress to be made, particularly among pregnant women[107] and women of color. For example, although Black women and white women are diagnosed with breast cancer at similar rates, data published in 2016 found that breast cancer death rates were 40% higher among Black women than white women.[108] Nevertheless, of the 4 novel drugs for breast cancer approved by FDA between 2016 and 2019, none involved clinical trials with more than 3% Black participants.[109] And data from trials on 15 different types of

---

105 *Id.*

106 *See supra* note 37; *see also, e.g.*, Geert Labots, Aubrey Jones, Saco J. de Visser, Robert Rissmann & Jacobus Burggraaf, *Gender Differences in Clinical Registration Trials: Is there a Real Problem?*, 84 BRIT. J. OF CLINICAL PHARMACOLOGY 700, 705 (2018) (finding no evidence of systemic under-representation of women in clinical trials based on cross-sectional, structured research into publicly available registration dossiers of FDA-approved drugs that are prescribed frequently); Pamela E. Scott et al., *Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs*, 71 J. AM. COLL. CARDIOLOGY 1960, 1967 (2018) (finding that women were well represented in trials of drugs for hypertension and atrial fibrillation, and over-represented for pulmonary arterial hypertension); *see generally* INST. OF MED., WOMEN'S HEALTH RESEARCH: PROGRESS, PITFALLS, AND PROMISE 97–143 (2010) (describing various conditions on which research has contributed to progress in women's health research).

107 *See* sources cited *supra*, note 102; *see also* Phelan, *supra* note 39; Mazer-Amirshahi, *supra* note 39.

108 Lisa C. Richardson, S. Jane Henley, Jacqueline W. Miller, Greta Massetti & Cheryll C. Thomas, *Patterns and Trends in Age-Specific Black-white Differences in Breast Cancer Incidence and Mortality – United States, 1999–2014*, 65 MORBIDITY & MORTALITY WKLY. 1093, 1095 (2016).

109 *See* Max Blau, *Black Women More Likely to Die of Breast Cancer – Especially in the South*, STATELINE (May 15, 2019), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/05/15/black-women-more-likely-to-die-of-breast-cancer-especially-in-the-south [https://perma.cc/CU2V-F6BZ].

cancer found that while Black people made up 12.1% of those with the cancers, the proportion of Black patients was only 2.9% in trials sponsored by pharmaceutical companies and 9.0% for trials conducted by the National Cancer Institute's National Clinical Trial's Network ("NCTN") (*i.e.*, government-sponsored trials).[110] Similarly, another study of 61,763 patients enrolled in clinical trials between 2014 and 2018 for cancer drugs subsequently approved by FDA found that African Americans were markedly underrepresented when compared to the prevalence of the cancers among African Americans.[111]

Intentionally *excluding* women from clinical trials or failing to recruit and enroll them in adequate numbers is of course problematic, but *including* a subset of women in ways that are unethical, exploitative, and knowingly harmful is just as problematic, if not more so. Efforts to increase women's participation in clinical trials must ensure diverse representation at every stage of drug development, but such efforts will not succeed if women of color do not, and perhaps *cannot*, trust those responsible for drug research, development, and distribution.

There are many potential sources of the distrust felt by women of color toward clinical research and the medical system more generally.[112] The reasons for distrust of clinical trials may include, *inter alia*: (1) fear that physicians will not be honest about the risks associated with a study; (2) fear of being a "guinea pig"; (3) fear that physicians will allow participation in a study even if serious harm is anticipated; and (4) general distrust of the medical system and, more

---

110 Joseph M. Unger et al., *Representativeness of Black Patients in Cancer Clinical Trials Sponsored by the National Cancer Institute Compared with Pharmaceutical Companies*, 4 JNCI CANCER SPECTRUM (2020).

111 Samer Al Hadidi, Martha Mims, Courtney N. Miller-Chism & Rammurti Kamble, *Participation of African American Persons in Clinical Trials Supporting U.S. Food and Drug Administration Approval of Cancer Drugs*, 173 ANNALS OF INTERNAL MED. 320 (2020). The percentage of African American participants in the trials was divided by the percentage of the population of people with any specific cancer who were African American (the "participation-to-prevalence ratio (PPR)"). If the PPR was between 0.8 and 1.2, this would indicate that African Americans were represented in clinical trials at a proportion similar to that seen in the real-world cancer population. Overall, 7.44% of the clinical trial participants were African American, resulting in a PPR of only 0.31 for all types of cancer combined. The PPR for breast cancer was 0.29, 0.18 for prostate cancer, 0.15 for lung cancer, and 0.12 for blood cancers. *Id.*

112 *See* Jill A. Fisher & Corey A. Kalbaugh, *Challenging Assumptions About Minority Participation in Clinical Research*, 101 AM. J. PUB. HEALTH 2217, 2218–19 (2011) (describing some of this research).

broadly, the white majority.[113] Distrust can pose an important barrier to research participation. For example, African American participants in a qualitative study exploring barriers to research participation stated, among other things:

- "One of the reasons most Black people are reluctant to get involved [in clinical research] is suspicion. We've been kind of brainwashed, and we're guinea pigs."[114]
- "You don't know what they are giving you and what they're experimenting on you. They are very secretive. They say one thing and might do another."[115]
- "[P]articipating in something else that might be like [Tuskegee], why would I do that to myself?"[116]
- "I know as a Black American that we are not told all the time the correct truth."[117]

Given the long history of abuse, exploitation, and racism that continues to this day—both in the context of clinical research and more generally (slavery, Jim Crow, police brutality, structural racism, etc.)—these fears are not baseless and should not be dismissed as "paranoia."[118]

The consequences of this history go beyond clinical trial participation and may affect whether women of color will actually seek medical care and use the medical products

---

113 *Id.*; *see also* Tovia G. Freedman, *"Why Don't They Come to Pike Street and Ask Us"?: Black American Women's Health Concerns*, 47 SOC. SCI. & MED. 941(1998); Giselle M. Corbie-Smith, *Minority Recruitment and Participation in Health Research*, 65 N.C. MED. J. 385 (2004); Giselle M. Corbie-Smith, Stephen B. Thomas, Mark V. Williams & Sandra Moody-Ayers, *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 J. GEN. INTERNAL MED. 537 (1999); Electra D. Paskett et al., *Recruitment of Minority and Underserved Populations in the United States: The Centers for Population Health and Health Disparities Experience*, 29 CONTEMP. CLINICAL TRIALS 847 (2008).

114 Darcell P. Scharff et al., *More than Tuskegee: Understanding Mistrust about Research Participation*, 21 J. HEALTH CARE FOR THE POOR & UNDERSERVED 879, 883 (2010).

115 *Id.* at 886.

116 *Id.*

117 *Id.* at 880 (highlighting several factors that affect African American's research participation).

118 WASHINGTON, *supra* note 3, at 21; *see also* Willie M. Abel & Jimmy T. Efird, *The Association Between Trust in Health Care Providers and Medication Adherence Among Black Women with Hypertension*, 1 FRONTIERS IN PUB. HEALTH 1, 4 (Dec. 2013) (discussing how injustices such as the Tuskegee experiment, "along with issues such as racism, discrimination, access to care, financial barriers, thoughts of being experimented on, and substandard health care" all influence Black people's trust in the medical system).

developed.[119] As noted by Washington, "the history of ethically flawed medical experimentation with African Americans . . . . has played a pivotal role in forging the fear of medicine that helps perpetuate our nation's racial gulf."[120] Several studies have cited distrust of the medical community as a reason for non-adherent health behaviors, such as non-adherence to treatment regimens among women of color, which can have negative consequences that contribute to a vicious cycle of racial disparities in health in the United States.[121] Moreover, distrust may not only affect whether *women* of color seek and adhere to medical care, but can also

---

[119] This assumes, of course, that they have *access* to and can *afford* healthcare, which is a problematic assumption to make. Access to healthcare is a serious issue faced by people of color, which can have profound impacts on their overall health and well-being. *See generally* Jamila Taylor, *Racism, Inequality, and Health Care for African Americans*, THE CENTURY FOUND. (Dec. 19, 2019), https://production-tcf.imgix.net/app/uploads/2019/12/19172443/AfAmHealth_Jamila_PDF.pdf [https://perma.cc/RY9D-HPP3] (examining the state of health care coverage for African Americans and the social factors that impact health outcomes); Samantha Artiga & Kendal Orgera, *Key Facts on Health and Health Care by Race and Ethnicity*, HENRY J. KAISER FAM. FOUND. 9, 11–12 (Nov. 2019), https://www.kff.org/report-section/key-facts-on-health-and-health-care-by-race-and-ethnicity-coverage-access-to-and-use-of-care/ [https://perma.cc/B2LX-N6ZQ] (finding continued disparities in access to care between people of color and whites, despite some improvements after passage of the Affordable Care Act).

[120] WASHINGTON, *supra* note 3, at 21; *see also* Maria J. Ferrera, Rebecca T. Feinstein, William J. Walker & Sarah J. Gehlert, *Embedded Mistrust Then and Now: Findings of a Focus Group Study on African American Perspectives on Breast Cancer and its Treatment*, 26 CRITICAL PUB. HEALTH 455, 456 (2016) ("Deep-rooted beliefs and perceptions regarding mistrust of the health care system and fear of deficient treatment become personally mediated. In tandem with internalized messages of being devalued and unworthy of quality of care, these beliefs potentially lead to a lack of engagement in treatment and continuity of care.").

[121] *See* Abel & Efird, *supra* note 118, at 4 ("[P]articipants in this study who reported the most trust in their health care providers were more adherent to their prescribed hypertensive medications."); Seth C. Kalichman, Lisa Eaton, Moira O. Kalichman & Chauncey Cherry, *Medication Beliefs Mediate the Association Between Medical Mistrust and Antiretroviral Adherence Among African Americans Living with HIV/AIDS*, 22 J. HEALTH PSYCHOL. 269, 275 (2017) (finding that mistrust of HCPs was associated with medication beliefs and antiretroviral therapy ("ART") adherence); Cynthia Prather, Taleria R. Fuller, Khiya J. Marshall & William L. Jeffries, *The Impact of Racism on the Sexual and Reproductive Health of African American Women*, 25 J. WOMEN'S HEALTH 664 (2016) (describing how racism and cultural mistrust can affect sexual and reproductive health outcomes among African American women); Michael V. Relf et al., *Discrimination, Medical Distrust, Stigma, Depressive Symptoms, Antiretroviral Medication Adherence, Engagement in Care, and Quality of Life Among Women Living With HIV in North Carolina: A Mediated Structural Equation Model*, 81 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 328, 333 (2019) (finding, among women with HIV, that everyday discrimination, distrust in the medical system and its personnel, and internalized HIV stigma adversely affect depressive symptoms, ART adherence, and engagement of care, which collectively influence quality of life).

influence whether *children* of color are enrolled in research[122] and/or receive medical care, particularly immunizations.[123]

Inadequate representation of women of color in clinical trials is exacerbated by other barriers, such as limited access to trials (*e.g.*, lack of trial sites in close proximity to where they live); costs of participation (*e.g.*, for travel to a trial site); lack of information; and inadequate recruitment efforts by trial sponsors and investigators, including the simple fact that people of color may not be asked to participate in research in the first place.[124] Indeed, it is imperative to not focus solely on distrust and fear as the reasons for low participation rates. Doing so risks a "blame the victim" mentality by dismissing the distrust and fear as unfounded. Such a mindset suggests that it is women of color who must change rather than society as a whole, such as through broader systemic and structural changes like improving recruitment and enrollment strategies, increasing accessibility to clinical trials, and combating the widespread explicit and implicit racism that continues to plague our society in all areas of life.

Notably, although fear and distrust are frequently cited as

---

122 *See* Jennifer Cunningham-Erves, Jason Deakings, Tilicia Mayo-Gamble, Kendria Kelly-Taylor, Stephania T. Miller., *Factors Influencing Parental Trust in Medical Researchers for Child and Adolescent Patients' Clinical Trial Participation*, 24 PSYCHOL., HEALTH & MED. 691 (2019) (describing how parental distrust toward medical research is more common among African American parents and can be a barrier to enrollment of children in clinical research); Kumaravel Rajakumar, Stephen B. Thomas, Donald Musa, Donna Almario & Mary A. Garza, *Racial Differences in Parents' Distrust of Medicine and Research*, 163 ARCHIVES OF PEDIATRIC & ADOLESCENT MED. 108 (2009) (discussing similar findings).

123 *See generally* Jennifer D. Allen et al., *Decision-Making About the HPV Vaccine Among Ethnically Diverse Parents: Implications for Health Communications*, 2012 J. ONCOLOGY 1 (2012) (describing parents' knowledge, attitudes, and decisions about the human papillomavirus ("HPV") vaccine for their daughters and finding that a common theme was mistrust of HCPs and pharmaceutical companies); Charlotte Lee, Kathryn Whetten, Saad Omer, William Pan & Daniel Salmon, *Hurdles to Herd Immunity: Distrust of Government and Vaccine Refusal in the US, 2002–2003*, 34 VACCINE 3972 (2016) (discussing the influence of parental distrust of the government and HCPs on rates of nonmedical exemptions from required childhood vaccines).

124 *See* Sheba George, Nelida Duran & Keith Norris, *A Systemic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders*, 104 AM. J. PUB. HEALTH e16, e17 (2014); Scharff, *supra* note 114, at 881 (citing several studies suggesting that investigators are less likely to ask minority patients to enroll in trials); Mary A. Garza et al., *The Influence of Race and Ethnicity on Becoming a Human Subject: Factors Associated with Participation in Research*, 7 CONTEMP. CLINICAL TRIALS COMMS. 57, 57–58 (2017) (noting that "researchers are documenting that there *are* significant differences in the number of minorities being asked to participate" in clinical trials, "far lower than would be expected based on minority representation in the country").

barriers to research participation, studies have also found that people of color are, in fact, often willing to participate in clinical trials. For example, one study found that although Blacks and Puerto Rican Hispanics were more likely to report fear of participating in clinical trials than whites, they were just as likely to be willing to participate.[125] And another study found only small differences by race or ethnicity in consent to participate in a study but did find substantial differences in the number of individuals asked to participate, with individuals from minority groups less likely to be offered a chance to enroll.[126]

C. Harms in the Context of COVID-19

Scholars have long documented the distrust of clinical research, the medical system, and the government among people of color and the role that distrust plays in the representation of people of color in clinical trials. Thus, the concerns raised here and reiterated in other works are not new—even while they seem to be systemically undervalued and ineffectively addressed. This may leave some asking: Why another article discussing this issue? Why now? The answers to those questions are easy and point to the lingering, unresolved inequities in healthcare.

First, until and unless we are able to better address and mitigate the consequences of history, these problems will always matter, continue to plague society, and must continue to be discussed. And second, the COVID-19 pandemic has brought these issues to the fore given the virus's disproportionate effects on people of color and concerns about whether COVID-19 clinical trials are sufficiently diverse.

Data from the CDC as of March 12, 2021 indicate that compared to non-Hispanic whites, rates of COVID-19 cases, hospitalizations, and deaths are higher among Blacks,

---

125 Ralph V. Katz et al., *Willingness of Minorities to Participate in Biomedical Studies: Confirmatory Findings From a Follow-Up Study Using the Tuskegee Legacy Project Questionnaire*, 99 J. NAT'L MED. ASS'N 1052, 1057 (2007); *see also* Ralph V. Katz et al., *Awareness of the Tuskegee Syphilis Study and the US Presidential Apology and Their Influence on Minority Participation in Biomedical Research*, 98 AM. J. PUB. HEALTH 1137, 1139 (2008) (finding that despite knowledge of the Tuskegee study, Black people were nearly three times more likely to indicate a willingness to participate in clinical research); Ralph V. Katz et al., *Exploring the "Legacy" of the Tuskegee Syphilis Study: A Follow-Up Study From the Tuskegee Legacy Project*, 101 J. NAT'L MED. ASS'N 179 (2009) (finding that African Americans were not less likely than whites to participate in a clinical trial when asked to do so, regardless of prior knowledge of the Tuskegee study).

126 David Wendler et al., *Are Racial and Ethnic Minorities Less Willing to Participate in Health Research?*, 3 PLOS MED. 0201, 0207 (2006).

American Indians, Alaskan Natives, Hispanics, and Latinos.[127] The exact reasons for these disparities are not yet known, but contributing factors likely include socioeconomic status; access to healthcare; increased occupational exposure (*e.g.*, frontline, essential, and critical infrastructure workers); underlying health conditions that increase the risk of serious illness; living conditions (*e.g.*, living in crowded conditions and densely populated parts of cities); and lack of access to products such as personal protective equipment.[128]

In light of these disparities, the U.S. government has increased efforts to promote clinical trial participation among people of color, such as through the COVID-19 Prevention Network ("CoVPN"), formed by the National Institute of Allergy and Infectious Diseases ("NIAID") at the National Institutes of Health ("NIH"),[129] and has informed pharmaceutical companies that it expects their COVID-19 clinical trials to be sufficiently diverse.[130] And while recognizing that this is a "goal" and not

---

127 *SEE* CTRS. FOR DISEASE CONTROL & PREVENTION, COVID-19 CASES, HOSPITALIZATION, AND DEATH BY RACE/ETHNICITY (Mar. 12, 2021), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html [https://perma.cc/2AJD-TSUH].

128 *See id.*; Alireza Hamidian Jahromi & Anahid Hamidianjahromi, *Why African Americans are a Potential Target for COVID-19 Infection in the United States*, 22 J. MED. INTERNET RES. E19934 (2020). It has also been suggested that genetics/biology may play a role, but this is subject to debate and future research. *See, e.g.*, Eyad Abuelgasim, Li Jing Saw, Manasi Shirke Mohamed Zeinah & Amer Harky, *COVID-19: Unique Public Health Issues Facing Black, Asian and Minority Ethnic Communities,* 45 CURRENT PROBS. IN CARDIOLOGY 1, 2–5 (Aug. 2020); Monica Webb Hopper, Anna Maria Napoles & Eliseo J. Perez-Stable, *COVID-19 and Racial/Ethnic Disparities*, 323 J. AM. MED. ASS'N 2466, 2467 (2020); Mike Stobbe, *U.S. Reports Show Racial Disparities in Kids with COVID-19*, AP NEWS (Aug. 7, 2020), https://apnews.com/277772d59418c8bc79e0aff3fef946e6#:~:text=The%20report%20found%20that%2013,still%20learning%20about%20the%20condition [https://perma.cc/6DHK-XS9H] ("Experts say genetics has nothing to do with why some racial and ethnic groups are more likely to be infected by the virus, get seriously sick from it or die from it.").

129 *About Us*, COVID-19 PREVENTION NETWORK, https://www.coronaviruspreventionnetwork.org/about-covpn/ [https://perma.cc/D4V8-ZKZW] (last accessed Sept. 19, 2020).

130 *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, COVID-19: DEVELOPING DRUGS AND BIOLOGICAL PRODUCTS FOR TREATMENT OF PREVENION, *supra* note 101, at 4 ("Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population."); *see also* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, DEVELOPMENT AND LICENSURE OF VACCINES TO PREVENT COVID-19, 11 (June 2020) ("FDA encourages the inclusion of diverse populations in all phases of vaccine clinical development. This inclusion helps to ensure that vaccines are safe and effective for everyone in the indicated populations.").

a requirement, Dr. Anthony Fauci, director of NIAID, stated that Phase III vaccine trials should aim to enroll minorities at levels that are at least double their representation in the population and should aim to match the burden of disease.[131] Nevertheless, people of color continue to be underrepresented in COVID-19 studies.[132] As noted, the reasons for this are many, including fear and distrust. In the context of COVID-19, there are a number of factors likely exacerbating fear and distrust of clinical trials, the medical system, and the government.

Throughout the pandemic, the Trump Administration pushed for fast development of COVID-19 drugs and vaccines. "Operation Warp Speed" was established with the primary goal of delivering 300 million doses of a safe and effective vaccine by January 1, 2021,[133] a much faster timeline than is typical for the development of a vaccine, which is typically a 7–10 year process.[134] Pharmaceutical companies have stated that they have not accomplished, or do not intend to accomplish, this speed by cutting corners or sacrificing safety or efficacy. Rather, shorter timelines are made possible by doing certain steps in parallel, such as scaling up manufacturing capacity before it is known whether a vaccine works. The risk, therefore, is financial—companies and the government are expending time and money to manufacture doses that

---

131 Elizabeth Cohen, *Fauci Says Pharma Companies Should Aim for Higher Minority Enrollment in Vaccine Trials*, CNN (Aug. 20, 2020), https://www.cnn.com/world/live-news/coronavirus-pandemic-08-20-20-intl/h_7161d63767b4e937f63049d2d3002d46 [https://perma.cc/5NDD-5NGG].

132 *See* Daniel B. Chastain et al., *Racial Disproportionality in COVID Clinical Trials*, 383 NEW ENG. J. MED. e59 (Aug. 27, 2020); *see also* Samantha Artiga, Jennifer Kates, Josh Michaud & Latoya Hill, *Racial Diversity Within COVID-19 Vaccine Clinical Trials: Key Questions and Answers*, KAISER FAM. FOUND. (Jan. 26, 2021), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/ [https://perma.cc/4WH5-68TP] (reporting that people of color were underrepresented in late-stage clinical trials for the two vaccines that had been authorized for emergency use as of January 26, 2021, with the largest disparity among the Black population).

133 U.S. DEP'T OF DEFENSE, OPERATION WARP SPEED: ACCELERATED VACCINE PROCESS, https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.jpg [https://perma.cc/ZC2H-MBTD] (last accessed Feb. 12, 2021).

134 *See* Patrick Boyle, *Here's Why We Can't Rush a COVID-19 Vaccine*, AM. ASS'N OF MED. COLL. (Mar. 31, 2020), https://www.aamc.org/news-insights/here-s-why-we-can-t-rush-covid-19-vaccine [https://perma.cc/MLB7-22UM]; *New Era of Medicine: Vaccines*, PHRMA, https://www.phrma.org/en/Media/New-Era-of-Medicine-Vaccines [https://perma.cc/MQ43-37SM] (last accessed Sept. 19, 2020).

ultimately could be of no use if the vaccine is not proven safe and effective and not approved or authorized for use.[135] FDA has also been adamant that it "will not cut corners" when reviewing data and making decisions about COVID-19 products.[136] And Dr. Peter Marks, director of FDA's Center for Biologics Evaluation and Research ("CBER") stated that he "would feel obligated" to resign if a vaccine were approved before it is shown to be safe and effective.[137]

Nevertheless, public trust and confidence in the government and the agencies tasked with the development and review of COVID-19 medical products have been shaken in light of frequent disagreement among government officials about development timelines and the safety and efficacy of COVID-19 medical products, as well as concerns about the Trump Administration's interference with, among other things, the drug development and review process and CDC reports on COVID-19.[138] President Trump frequently touted the safety

---

135 *See* U.S. GOV'T ACCOUNTABILITY OFF., OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES at 3–4 n.b (Feb. 2021) (noting that "in some cases, the federal government is taking on the financial risk to enable large-scale manufacturing to start while clinical trials are ongoing"); Jaimy Lee, *Race for a COVID-19 Vaccine has Drug Makers Scaling Up Manufacturing — Before One is Developed*, MARKETWATCH (June 29, 2020), https://www.marketwatch.com/story/race-for-a-covid-19-vaccine-has-drug-makers-scaling-up-manufacturing-before-one-is-developed-2020-06-25 [https://perma.cc/YQ6E-NSGT] (quoting Dr. Fauci's description of how the development of a COVID-19 vaccine is being accelerated).

136 *AMA, FDA Video Update: The Critical Role of Health Care Professionals During COVID-19,* AM. MED. ASS'N (Aug. 14, 2020), https://www.ama-assn.org/delivering-care/public-health/ama-fda-video-update-critical-role-health-care-professionals-during [https://perma.cc/Z646-QKKM] (providing a transcript of the August 10, 2020 video conversation with Dr. Stephen Hahn, Commissioner of FDA, and Susan R. Bailey, President of the American Medical Association).

137 Dan Levine & Marisa Taylor, *Exclusive: Top FDA Official Says Would Resign if Agency Rubber-Stamps an Unproven COVID-19 Vaccine*, REUTERS (Aug. 20, 2020), https://www.reuters.com/article/us-health-coronavirus-vaccines-fda-exclu/exclusive-top-fda-official-says-would-resign-if-agency-rubber-stamps-an-unproven-covid-19-vaccine-idUSKBN25H03H [https://perma.cc/L3CA-Q9Y5].

138 *See, e.g.*, Letter from James E. Clyburn, Chairman, Select Subcomm. on the Coronavirus Crisis, to Norris Cochran, Acting Sec'y, Dep't of Health & Hum. Servs., , at 8, 10 (Feb. 8, 2020), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021-02-08.Clyburn%20to%20Cochran%20re%20WH%20Failures%20on%20Pandemic%20.pdf [https://perma.cc/XSX8-5GTD] (noting concerns about the Trump Administration's "pattern of political interference in coronavirus treatments and vaccines" and requesting documents to "understand the full scope and impact of the Trump Administration's political interference in vaccine and treatment approvals and its failure to implement an effective national plan to procure and distribute vaccines"); Hannah Kuchler, *Covid-19 Vaccine Trials Worry US Minority*

and efficacy of various treatments and suggested that a vaccine could be ready prior to the November election, often in direct contradiction of top health officials. For example, although FDA revoked the emergency use authorization ("EUA")[139] for hydroxychloroquine and chloroquine for the treatment of COVID-19 on June 15, 2020 after concluding that the drugs are unlikely to be effective in treating COVID-19,[140] President Trump continued to post tweets suggesting their effectiveness.[141] Then, after being diagnosed with COVID-19 and treated with an unapproved antibody drug in October 2020, President Trump touted it and other investigational treatments as "miracles coming down from God."[142]

Communities, FINANCIAL TIMES (Aug. 24, 2020), https://www.ft.com/content/07c5d878-0edd-4d01-982d-b130445306af [https://perma.cc/VY4Y-U8MQ] (quoting Mitchell Warren, executive director of the AIDS Vaccine Advocacy Coalition: "I'm worried about that name [Operation Warp Speed] . . . . We have to work with the hand we are dealt and the hand we are dealt is a politically charged environment where there's mistrust in government and there's mistrust in science.").

139 Under section 564 of the FD&C Act, FDA may authorize the use of an unapproved medical product (drugs, biologics, vaccines, devices) or an unapproved use of an approved medical product in the context of a public health emergency such as the COVID-19 pandemic. FDA may only issue an EUA following a determination of a particular type of threat or public health emergency by the Secretary of HHS (or certain other Cabinet members), which was made for COVID-19 on February 4, 2020, *see* 85 Fed. Reg. 7316 (Feb. 7, 2020), and a declaration that the circumstances exist justifying EUAs for a particular type of medical product (which has been made for various types of medical products for COVID-19, including, among others, in vitro diagnostics, 85 Fed. Reg. 7316 (Feb. 7, 2020), medical devices, 85 Fed. Reg. 17335 (Mar. 27, 2020), and drugs and biologics (including vaccines), 85 Fed. Reg. 18250 (Apr. 1, 2020)). An EUA is not a full approval and may only be issued if the following criteria are met: (1) the pathogen (*e.g.*, SARS-CoV-2) is capable of causing a serious or life-threatening disease or condition; (2) based on the totality of the scientific evidence available, it is reasonable to believe that (a) the drug "may be effective" in treating or preventing the disease or condition caused by the pathogen; and (b) the known and potential benefits of the product, when used to treat or prevent the disease or condition, outweigh the known and potential risks of the product; and (3) there are no "adequate, approved, and available" alternatives to the emergency use of the product. FD&C Act § 564(c).

140 Letter from RADM Denise M. Hinton, Chief Sci., Food & Drug Admin., to Gary L. Disbrow, Deputy Ass't Sec'y, Dir., Med. Countermeasure Programs, Biomedical Advanced Res. & Dev't Auth., Office of Ass't Sec'y for Preparedness & Response, U.S. Dep't of Health & Human Servs. (July 15, 2020), *available at* https://www.fda.gov/media/138945/download [https://perma.cc/D826-P7U5] (revoking the EUAs for hydroxychloroquine and chloroquine).

141 Donald Trump (@realDonaldTrump), TWITTER (July 6, 2020), https://twitter.com/realDonaldTrump/status/1280209143127773184?s=20.

142 Jonathan Lemire, Jill Colvin, & Zeke Miller, *Trump Said to be Improving but Next 48 Hours 'Critical'*, AP NEWS (Oct. 3, 2020, https://apnews.com/article/election-2020-virus-outbreak-donald-trump-elections-campaigns-08fcfd3778ca3bbabd011307cf23dc8d

Officials have also disagreed about the efficacy of convalescent plasma in treating COVID-19. For example, FDA authorized the emergency use of convalescent plasma, concluding that it "may be effective in treating COVID-19,"[143] with President Trump touting it as an "historic breakthrough."[144] The EUA was issued less than a week after being put on hold when government health officials—including Dr. Francis Collins, Director of NIH, and Dr. Fauci—intervened, asserting that the data were too weak to support the EUA.[145] Then, a week after the EUA was issued, the NIH's COVID-19 Treatment Guidelines Panel issued a statement concluding, among other things, that based on the available evidence, "[t]here are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of COVID-19 convalescent plasma for the treatment of COVID-19."[146]

With respect to vaccines, President Trump frequently suggested that a vaccine could be available by October or November 2020. For example, during a September 4, 2020 press briefing, President Trump stated that there could be a vaccine "before the end of the year and maybe even before

---

[https://perma.cc/EZ3L-N8FN].

143 Letter to Robert P. Kadlec, Ass't Sec'y for Preparedness & Response, Office of the Ass't Sec'y for Preparedness & Response, Office of the Sec'y, U.S. Dep't of Health & Human Servs. (Aug. 23, 2020), *available at* https://www.fda.gov/media/141477/download [https://perma.cc/VK7C-CDX6].

144 Remarks by President Trump in Press Briefing (Aug. 23, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/ [https://perma.cc/6CKR-HGAW].

145 Noah Weiland, Sharon LaFraniere & Sheri Fink, *F.D.A.'s Emergency Approval of Blood Plasma Is Now on Hold*, N.Y. TIMES (Aug. 19, 2020), https://www.nytimes.com/2020/08/19/us/politics/blood-plasma-covid-19.html [https://perma.cc/JB34-U2HZ]. Furthermore, the EUA was issued one day after President Trump tweeted that the "deep state" at FDA was slowing down the development of COVID-19 treatments and vaccines. Donald Trump (@realDonaldTrump), TWITTER (Aug. 22, 2020, 7:49 AM), https://twitter.com/realDonaldTrump/status/1297138862108663808?s=20; *Mark Meadows Defends Trump's "Deep State" Attacks on FDA*, AXIOS (Aug. 23, 2020), https://www.axios.com/trump-fda-mark-meadows-98349bcd-6e21-478a-a1c3-e8a307b071b4.html [https://perma.cc/TV3S-9B6Y] (quoting Mark Meadows, White House Chief of Staff, who said that the plasma EUA should have been issued "several weeks ago" and that "sometimes you have to make them feel the heat if they don't see the light.").

146 NAT'L INST. OF HEALTH, THE COVID 19 TREATMENT GUIDELINES PANEL'S STATEMENT ON THE EMERGENCY USE AUTHORIZATION OF CONVALESCENT PLASMA FOR THE TREATMENT OF COVID-19 (last updated Oct. 9, 2020), https://www.covid19treatmentguidelines.nih.gov/statement-on-convalescent-plasma-eua/ [https://perma.cc/5ZRL-CTKY].

Nov. 1, I think we can probably have it sometime in October."[147] Yet, on September 3, 2020, Moncef Slaoui, then head of Operation Warp Speed, stated that although "not impossible," the government was "very unlikely" to approve or authorize a vaccine by early November, because "[t]here is a very, very low chance that the trials that are running as we speak could [provide the necessary data] before the end of October."[148] President Trump's suggestions about the timeline for a vaccine raised concerns that politics would play a role in the authorization or approval of a vaccine at the expense of safety and efficacy, which could undermine public confidence in not just the COVID-19 vaccine, but all vaccines.[149]

Then, on September 11, 2020, Politico reported that politically appointed communication aides in the Department of Health and Human Services ("HHS") requested and received the ability to review and seek changes to, or delay, studies published in the CDC's Morbidity and Mortality Weekly Reports ("MMWR") that discussed trends in COVID-19 data that could be unflattering to President Trump or otherwise

---

147 Sarah Owermohle, *Trump Contradicts Health Officials, Says 'Probably' a Covid-19 Vaccine in October*, POLITICO (Sept. 4, 2020), https://www.politico.com/news/2020/09/04/trump-coronavirus-vaccine-october-409248 [https://perma.cc/UB2Z-DYKJ].

148 *Id. See also Unlikely That a COVID-19 Vaccine Will Be Ready in October, But Note Impossible, Fauci Says*, REUTERS (Sept. 3, 2020) https://www.reuters.com/article/us-health-coronavirus-vaccine-fauci/unlikely-that-a-covid-19-vaccine-will-be-ready-in-october-but-not-impossible-fauci-says-idUSKBN25U2B0 [https://perma.cc/L57P-FXGQ].

149 *See* Letter from Thomas M. File, Pres., Infectious Diseases Soc'y of Am. & Judith Feinberg, Chair, HIV Med. Ass'n, to Stephen M. Hahn, Cmm'r, U.S. Food & Drug Admin. & Peter Marks, Dir., Ctr. for Biologics Evaluation & Research (Aug. 26, 2020), https://www.idsociety.org/globalassets/idsa/public-health/covid-19/vaccine-eua-letter.pdf [https://perma.cc/P8HE-WT3Y] ("[M]aking a vaccine available before sufficient safety and efficacy data are available could significantly undermine COVID-19 vaccination efforts and seriously erode confidence in all vaccines . . . ."); Sharon LaFraniere, Katie Thomas, Noah Weiland, Peter Baker & Annie Karni, *Scientists Worry About Political Influence Over Coronavirus Vaccine Project*, N.Y. TIMES (updated Sept. 1, 2020), https://www.nytimes.com/2020/08/02/us/politics/coronavirus-vaccine.html [https://perma.cc/DUC8-JEKH] ("

> There are a lot of people on the inside of this process who are very nervous about whether the administration is going to reach their hand into the Warp Speed bucket, pull out one or two or three vaccines, and say 'We've tested it on a few thousand people, it looks safe, and now we are going to roll it out,' . . . . They are really worried about that, ... And they should be.

" (quoting Dr. Paul A. Offit, member of FDA's vaccine advisory committee)); Joe Palca, *COVID-19 Vaccine May Pit Science Against Politics*, NAT'L PUB. RADIO (Aug. 27, 2020), https://www.npr.org/sections/health-shots/2020/08/27/906240454/covid-19-vaccine-may-pit-science-against-politics [https://perma.cc/KJ49-7SVC].

"undermine [his] optimistic messages about the outbreak."[150] MMWRs are written by career scientists, largely for scientists and public health experts. They have been referred to as "the go-to place for the public health community to get information that's scientifically vetted."[151] An investigation conducted by the House Select Subcommittee on the Coronavirus Crisis[152] has "revealed that efforts to interfere with scientific work at CDC were far more extensive and dangerous than previously known," with Trump Administration employees particularly seeking to alter or block reports with evidence of the virus's "early spread" in the United States and "massive spread" during the summer of 2020, "which they believed sent 'the wrong message' about the Administration's policies."[153] Although it is not clear whether any of the reports were substantially changed as a result,[154] the interference and possibility that the reports were altered further undermine the government's credibility and the public's ability to trust the

---

150 Dan Diamond, *Trump Officials Interfered with CDC Reports on COVID-19*, POLITICO (updated Sept. 12, 2020), https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809 [https://perma.cc/7Y65-5X8K].

151 *Id.*

152 The House Select Subcommittee on the Coronavirus Crisis was established on April 23, 2020 to provide congressional oversight of the Trump Administration's response to the COVID-19 pandemic. *See* SELECT SUBCOMM. ON THE CORONAVIRUS CRISIS, ABOUT, https://coronavirus.house.gov/about [https://perma.cc/HGN8-EY2P] (last accessed Feb. 13, 2021). On September 14, 2020, the Select Subcommittee launched an investigation into the potential political inference in CDC scientific reports. *See* Press Release, Select Subcomm. on the Coronavirus Crisis, Select Subcommittee Launches Investigation into Political Interference in CDC Scientific Reports on Coronavirus (Sept. 14, 2020), https://coronavirus.house.gov/news/press-releases/select-subcommittee-launches-investigation-political-interference-cdc-scientific [https://perma.cc/W6A6-PKL9].

153 Letter from James E. Clyburn, Chairman, Select Subcomm. on the Coronavirus Crisis, to Alex M. Azar II, Sec'y, Dep't of Health & Hum. Servs., and Robert R. Redfield, Dir., Ctrs. For Disease Control & Prevention, at 1 (Dec. 21, 2020), https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-12-21.Clyburn%20to%20Redfield%20and%20Azar%20re%20Subpoena%20FINAL%20_0.pdf [https://perma.cc/RU7V-WE6L].

154 *See* Letter from James E. Clyburn, Chairman, Select Subcomm. on the Coronavirus Crisis, to Norris Cochran, Acting Sec'y, Dep't of Health & Hum. Servs., at 3 (Feb. 8, 2021), (https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021-02-08.Clyburn%20to%20Cochran%20re%20WH%20Failures%20on%20Pandemic%20.pdf [https://perma.cc/V52D-9M64] (suggesting that CDC career staff were successful at "fend[ing] off" attempts by the Trump Administration to influence CDC publications).

government and its response to the COVID-19 pandemic. Evidence obtained by the Select Subcommittee, including emails from political appointees, further underscores the possibility that the Trump Administration bullied, retaliated against, and tried to silence career science officials and their staff. For example, a June 30, 2020 email from Paul Alexander, science adviser at HHS (who was dismissed from HHS), to Michael Caputo, assistant secretary for public affairs at HHS (who subsequently went on leave from HHS), accused Dr. Anne Schuchat, Principal Deputy Director and thirty-two year veteran of the CDC, of trying to "embarrass the president" when, among other things, she appealed to Americans to wear masks.[155] And in July 2020, after Caputo learned that a CDC scientist was interviewed by NPR about the Administration's decision to strip CDC of its well-established role in collecting hospital data, Caputo demanded to know the name of the CDC press officer who arranged the interview and warned CDC senior staff that if they "disobeyed" his directions, they would "be held accountable."[156]

The political and social atmosphere in which the development of COVID-19 drugs and vaccines has taken place has undermined Americans' trust in the process, particularly among people of color. Racism, discrimination, inequality, and health are colliding in ways that cannot be ignored. We must acknowledge the killings of Breonna Taylor, George Floyd, Ahmaud Arbery, and many others; concerns about police brutality; subsequent protests throughout the nation; and the increasing loss of trust and confidence in the people and institutions that are supposed to protect and govern us, particularly among people of color.[157] All of these issues play a role in whether, and to what extent, people of color feel they can trust COVID-19 research, treatments, and vaccines, as well as the government's overall response to the pandemic.

---

155 Noah Weiland, *Emails Detail Effort to Silence C.D.C. and Question its Silence*, N.Y. TIMES (Sept. 18, 2020), https://www.nytimes.com/2020/09/18/us/politics/trump-cdc-coronavirus.html [https://perma.cc/EA35-WYMD]; *see also* Letter from James E. Clyburn, *supra* note 154.

156 Letter from James E. Clyburn, *supra* note 154, *at* 13.

157 In Gallup's 2020 "Confidence in Institutions" poll, 56% of white adults said they have a "great deal" or "quite a lot" of confidence in the police, compared to only 19% of Black adults, and 47% of white adults versus 13% of Black adults expressed confidence in the presidency. Both Blacks and whites expressed little confidence in Congress (11% versus 15%, respectively). Jeffrey M. Jones, *Black, White Adults' Confidence Diverges Most on Police*, GALLUP (Aug. 12, 2020), https://news.gallup.com/poll/317114/black-white-adults-confidence-diverges-police.aspx [https://perma.cc/BP4J-8AB3].

Deidra Sorrell, for example, recognizes the importance of diverse study populations, but would not herself participate, stating that she has "an extreme distrust of anything associated with COVID-19. The origin of this virus is very sketchy in my opinion."[158] And Reverend Rob Newells, an African American minister in Oakland, California, believed it was too late to encourage more people of color to participate in vaccine trials, and that the focus should instead shift to helping people understand the research process and mitigating fears of being "guinea pigs" so they will trust a vaccine once authorized or approved.[159] This requires trust in multiple parties, including pharmaceutical companies, individual researchers, the medical profession, and the government.

In the context of a COVID-19 therapy or vaccine, the government's role extends beyond its review, authorization, or approval of the product. Initially, the federal government is largely controlling the distribution of the COVID-19 vaccines, overseeing a centralized system for ordering, distributing, and tracking COVID-19 vaccines.[160] Given the government's significant role, public trust in the government's ability to handle the rollout of the COVID-19 vaccine in an efficient and equitable manner is imperative.

Given COVID-19's disproportionate impact on people of

---

158 Candace Y.A. Montague, *Recruiting Black Volunteers for COVID-19 Vaccine Trials Means Overcoming Mistrust*, CTR. FOR HEALTH JOURNALISM (Aug. 3, 2020), http://centerforhealthjournalism.org/2020/07/30/recruiting-african-american-volunteers-covid-19-vaccine-trials-means-overcoming-mistrust [https://perma.cc/2SKV-PCRD].

159 Kuchler, *supra* note 138.

160 Government control over distribution is particularly likely when a product is initially made available through an EUA rather than regular approval, which is the case for COVID-19 vaccines. Under sections 564(e)(1) and (2) of the FD&C Act, FDA has the obligation and the authority to establish certain conditions on an EUA, including limitations on distribution and administration. Of relevance here, FDA may impose conditions on "which entities may distribute the product . . . (including limitation to distribution by government entities), and on how distribution is to be performed." FD&C Act §§ 564(e)(1)(B)(i) & (e)(2)(A). As of March 21, 2021, the EUAs for the Moderna, Pfizer/BioNTech, and Janssen Biotech, Inc. vaccines, for example, all provide that the vaccine will be distributed "as directed by the U.S. government." *See* Letter from RADM Denise Hinton, Chief Scientist, Food & Drug Admin., to Carlota Vinals, ModernaTX, Inc., at 3 (Feb. 25, 2021), *available at* https://www.fda.gov/media/144636/download [https://perma.cc/P3C7-K2BY]; Letter from RADM Denise Hinton, Chief Scientist, Food & Drug Admin., to Elisa Harkins, Pfizer Inc., at 3 (Feb. 25, 2021), *available at* https://www.fda.gov/media/144412/download [https://perma.cc/4UWW-8UUE]; Letter from RADM Denise Hinton, Chief Scientist, Food & Drug Admin., to Ruta Walawalkar, Janssen Biotech, Inc., at 3 (Feb. 27, 2021), *available at* https://www.fda.gov/media/146303/download [https://perma.cc/H5PF-QG8S].

color, some have debated whether people of color should be among those prioritized to receive the COVID-19 vaccine.[161] The intent of such a policy is admirable—to ensure those hit hardest by the virus have access to a vaccine—but there are potential unintended consequences and serious questions remain. First, there is the possibility that prioritizing people of color could be stigmatizing. Georges Benjamin, executive director of the American Public Health Association, stated that prioritizing based on race and ethnicity "says that people are at risk because of their skin color, which isn't the case—they're at risk because they have public-facing jobs, chronic diseases, and other social determinants that put them at risk . . . . this is not a Black disease . . . . [I]t's stigmatizing to the African-American community to say we're more risky because of who we are than what we do."[162] Second, for those concerned that the vaccines may have been authorized based on politics rather than science, prioritizing people of color may exacerbate skepticism and fears among people of color that they are being used as "guinea pigs."[163] Dr. Benjamin, for

---

161 *See, e.g.*, Megan Twohey, *Who Gets a Vaccine First? U.S. Considers Race in Coronavirus Plans*, N.Y. TIMES (updated July 16, 2020), https://www.nytimes.com/2020/07/09/us/coronavirus-vaccine.html [https://perma.cc/7QNX-X4VZ]; Jamie Ducharme, *Melinda Gates Lays Out Her Biggest Concern for the Next Phase of the COVID-19 Pandemic*, TIME (June 4, 2020), https://time.com/5847483/melinda-gates-covid-19/ [https://perma.cc/4GDA-L2K5] (quoting Melinda Gates, who said that people of color should be among one of the priority groups to receive a vaccine due to COVID-19's disproportionate effects on people of color).

162 Meera Jagannathan, *Should Black and Latino People Get Priority Access to a COVID-19 Vaccine?*, MARKETWATCH (July 19, 2020), https://www.marketwatch.com/story/should-black-and-latino-people-get-priority-access-to-a-covid-19-vaccine-2020-07-16 [https://perma.cc/JK79-TGHD]; *see also* Ariel Hart & Jeremy Redmon, *Distrust of Health Care System Adds to Toll in Rural Black Communities Gutted by COVID*, ATL. J. CONST. (Aug. 14, 2020), https://www.ajc.com/news/coronavirus/distrust-of-healthcare-system-adds-to-toll-in-rural-black-communities-gutted-by-covid/SOO6UWMIBZHPTN7DMK3ZHCNQMI/ [https://perma.cc/DJW6-GPT4] ("You kind of can see it or feel it; there's almost like a COVID shame.").

163 Some may even believe it is a method of population control or cultural genocide. Louis Farrakhan, Minister of the Nation of Islam, stated that Black people should be skeptical of a COVID-19 vaccine and that Dr. Fauci and other vaccine proponents are more interested in population control than public health. He also warned that "You're sure to die now. They [just] want a quicker death." NewsOne Staff, *Farrakhan Warns Black People Against COVID-19 Vaccine and 'Their Medications'*, NEWSONE (July 6, 2020), https://newsone.com/3971438/farrakhan-warns-black-people-covid-19-vaccine/ [https://perma.cc/3CF2-3NL9]; *see also WARNING: Do Not Take the Experimental COVID-19 Vaccine*, NATION OF ISLAM, https://www.noi.org/vaccine/ [https://perma.cc/EFC6-RXSW] (last accessed Feb. 13, 2021). The Nation of Islam is well-known for its anti-vaccine positions. *See, e.g.*, Anna Merlan, *The Anti-Vaccination Movement is Working with the Nation of Islam to Scare Black*

example, saw flyers mentioning the Tuskegee study that encouraged Black people not to get tested or get a vaccine.[164] Thus, even if COVID-19 vaccine policies prioritized people of color, there is still some question as to whether this would increase vaccine uptake among people of color, particularly among those who express the greatest hesitancy or distrust.

One thing, however, is clear: that regardless of the reason, Black Americans have been vaccinated at much lower rates than white Americans during the initial rollout of the vaccine. Approximately one month after a COVID-19 vaccine became available, roughly three percent of Americans had received at least one dose of the vaccine. But in sixteen states that released data by race, white residents were vaccinated at significantly higher rates than Black residents, often two to three times higher.[165] There are numerous potential reasons for these disparities, with mistrust being cited as one key factor.[166] As discussed below in Part III, because there is no single cause, there will not be a single solution.

III
WHERE DO WE GO FROM HERE?

It is clear that there are many converging factors that affect (1) women's representation in clinical trials generally, (2) women of color's participation in clinical trials specifically, and (3) women of color's ability to access medical care and likelihood of seeking that care. So how can we solve these problems, or at least begin to mitigate their harmful consequences? While proposing a specific solution is beyond

---

Families, JEZEBEL (June 26, 2017), https://jezebel.com/the-anti-vaccination-movement-is-working-with-the-natio-1796021231 [https://perma.cc/295Q-PU5S]; *see also* Ethan A. Huff, *Why Vaccine Mandates Racially Discriminate Against African Americans*, GLOBAL RES. (June 16, 2015), https://www.globalresearch.ca/why-vaccine-mandates-racially-discriminate-against-african-americans/5455987 [https://perma.cc/8UQJ-E8JM]; Isabelle Z., *Black People Are the First Targets of the Bill Gates Vaccines. . . Ever Wonder Why?*, GENOCIDE.NEWS (June 30, 2020), https://genocide.news/2020-06-30-black-people-are-first-targets-bill-gates-vaccines.html [https://perma.cc/H2S8-7CQ4] (asserting that Melinda Gates' suggestion that Black people be prioritized to receive a COVID-19 vaccine is part of the Gates Foundation's "comprehensive and frighteningly well-funded efforts to accelerate the depopulation of black people"); Hart & Redmon, *supra* note 162 "We still feel on some level like lab rats.").

164 Hart & Redmon, *supra* note 162.

165 Hannah Recht & Lauren Weber, *Black Americans are Getting Vaccinated at Lower Rates than White Americans*, KAISER HEALTH NETWORK (Jan. 17, 2021), https://khn.org/news/article/black-americans-are-getting-vaccinated-at-lower-rates-than-white-americans/ [https://perma.cc/C386-VZ5A].

166 *Id.*

the scope of this Article, this Part offers some suggestions that law and policymakers, government officials, pharmaceutical companies, private and public researchers/investigators, HCPs, patient advocates, and society as a whole should consider as we move forward.

Just as the problems do not have a single cause, there will not and cannot be a single solution. For example, it is clear that legal and regulatory requirements and guidance,[167] such as FDA's regulations requiring NDA sponsors to include analyses of safety and effectiveness data based on gender,[168] have improved women's overall representation in clinical trials.[169] But women are not a homogenous group and not all women are treated similarly in the context of clinical trials and the medical system in general. We cannot look at the data on the surface and become complacent because they suggest that women are now more equally represented in clinical trials. As this Article has discussed, pregnant women, women of childbearing potential, and women of color have had, and continue to have, very different experiences with clinical research and the broader medical system. Pregnant women continue to be excluded from most clinical trials, including those related to COVID-19.[170] And women of color remain underrepresented in clinical trials for many disease areas, including conditions that disproportionately affect people of color (such as COVID-19); continue to distrust clinical research, the medical system, and the government after a long history of exploitation, explicit and implicit racism, and abuse (much of which continues); and continue to face barriers when seeking access to clinical trials and/or medical care.

Given the relevance of these issues in the context of the COVID-19 pandemic, there is no time like the present to face them head-on and work toward solutions that will last beyond the pandemic. In moving forward, the following should all be considered:

- **Statutory and Regulatory Mandates**. As noted, statutory and regulatory requirements can help improve representation in clinical trials.[171] FDA should consider additional requirements, such as requiring a level of representation in clinical trials that is proportionate to the burden of the disease

167 *See supra* notes 27–36 and accompanying text.
168 *See supra* notes 30–34 and accompanying text.
169 *See supra* notes 37 & 38 and accompanying text.
170 *See* sources cited *supra* notes 102 & 107.
171 *See supra* notes 30–34 and accompanying text.

being studied in specific populations. For example, if Black women represent 20% of those with the disease being studied, clinical trials to support approval of a drug to treat that disease should be required to enroll a subject population that includes 20% Black women. If enrolling specific populations is deemed unethical, infeasible, or unnecessary, sponsors should be required to (1) justify why such enrollment is unethical, infeasible, or unnecessary; and (2) conduct post-market studies that will collect real-world data ("RWD") and real-world evidence ("RWE") on the populations not studied in clinical trials.[172] Liability protection for pharmaceutical companies that enroll pregnant women in their trials, in conjunction with a government-funded injury compensation fund, could be considered to reduce pharmaceutical companies' hesitancy to enroll pregnant women.

- **FDA Guidance**. Instead of or in addition to statutory requirements, FDA could issue guidance recommending the requirements suggested above. Although FDA guidance is not considered mandatory, in practice it is generally followed by those to whom it is directed (*e.g.*, industry) and thus would likely have a similar effect as laws or regulations.
- **Private and Public Funding to Support Recruitment, Enrollment, and Education/Outreach.** To improve recruitment and enrollment of diverse populations in clinical trials, funding will be needed. This funding should come from both private and public sources and efforts should extend beyond recruitment and enrollment in a specific trial. With regard to recruitment and enrollment, trial sponsors should ensure they include geographically and demographically diverse trial sites that are accessible by individuals of all socioeconomic classes. This will be key because

---

172 RWD "are data relating to patient health status and/or the delivery of health care that are routinely collected from a variety of sources," such as electronic health records, medical claims and billing data, data from product and disease registries, patient-generated data, and data from other sources such as mobile devices. RWE "is the clinical evidence regarding usage and potential benefits or risks of a medical product derived from analysis of RWD," which "can be generated, for example, by collecting information about effectiveness or safety outcomes from an RWD source in randomized clinical trials or in observation studies." U.S. FOOD & DRUG ADMIN., SUBMITTING DOCUMENTS USING REAL WORLD DATA AND REAL WORLD EVIDENCE TO FDA FOR DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY (May 2019).

although fear and distrust may dissuade people of color from participating in clinical trials, other barriers frequently include a lack of access to clinical trials and the fact that people of color are frequently never asked to participate in trials.

- There must also be much broader education and community outreach to increase transparency and improve public understanding of the clinical research and drug development processes. Prior to initiating a clinical trial in any community, trial sponsors should consider offering informational sessions about the research and development process in general as well as the specific trial to be conducted. People of color and members of the communities being targeted should have a key role in developing and implementing these educational initiatives and recruitment and enrollment efforts.[173] This, of course, will require that people of color are represented in relevant positions in government, research and development, and the medical profession.
- The content of this outreach and precisely how it would be done are beyond the scope of this Article and should be discussed further in future work. Indeed, a workable solution cannot be developed by one person, it must involve a multi-disciplinary group that can ensure diverse professional and personal experiences are represented and reflected.
- **De-Politicization of the Drug Approval Process.** As discussed in this Article, concerns about the politicization of the drug development and approval processes, particularly during a public health emergency, have come to the fore during the COVID-19 pandemic. The review of safety and efficacy data and subsequent decisions about whether to authorize or approve the use of medical products should not be made or influenced by political appointees. Rather, FDA, CDC, NIH, and other relevant agencies should ensure there are laws, regulations, and policies in place that require career scientists, whose positions are more insulated from the executive branch, to make such decisions. Their review of the data and the reasoning behind their decisions should be made

---

173 However, research also suggests that potentially more important than the race of researchers/trial recruiters are characteristics such as honesty, openness, and shared values. *See, e.g.*, Garza et al., *supra* note 124, at 58.

public and subject to external, impartial review. Such a process is particularly important during a public health emergency, when medical products are being reviewed and authorized or approved on shorter timelines and, at times, based on less data than a typical drug approval (*e.g.*, in the context of an EUA). Greater transparency is an important component of efforts to improve trust in the industries, agencies, and institutions tasked with researching, developing, reviewing, and authorizing or approving medical products during the COVID-19 pandemic and beyond.

- **Broader Societal/Structural Changes**. With respect to improving the representation of women of color in clinical trials, solving that problem cannot focus solely on clinical trials. The harms caused by the exploitation and abuse that women of color have experienced throughout history in the "name of science" go far beyond distrust in clinical trials. Attempts to mitigate these harms will not be successful if they do not simultaneously acknowledge and address broader societal and structural issues. The COVID-19 pandemic is coinciding with pandemics of racism, inequality, and violence, all of which have their own health consequences and affect women of color's trust in government, research institutions, and the medical system.[174] There are many valid reasons for women of color to feel such distrust, and no statutory mandates or amount of money will heal the wounds of this long history if the broader issues plaguing our society are not also addressed.

CONCLUSION

The COVID-19 pandemic has given renewed importance and urgency to diversity in clinical trials and brought this issue into the public domain like never before. This Article has argued that while women in general are now better represented in clinical trials, certain subgroups of women remain vastly underrepresented, such as pregnant women and women of color, with the potential for adverse health consequences, particularly in the context of COVID-19. This Article has only

---

174 *See, e.g.*, Press Release, Am. Pscyhol. Ass'n, 'We Are Living in a Racism Pandemic,' Says APA President (May 29, 2020) (statement of Sandra L. Shullman, President, Am. Psychol. Ass'n), https://www.apa.org/news/press/releases/2020/05/racism-pandemic [https://perma.cc/B6F9-YX89].

scratched the surface of the significance of this issue and potential solutions to consider. Any solution must be multifaceted and include changes that target clinical trials specifically as well as much broader societal changes. These issues are not new, but the COVID-19 pandemic has made them all the more salient. There is no time like the present to revisit these issues with a renewed sense of passion, purpose, and urgency.