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Diversity's Pandemic Distractions

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DIVERSITY'S PANDEMIC DISTRACTIONS

Jonathan Kahn, JD, PhD[†]

ABSTRACT

Pandemic diseases have a nasty history of racialization. COVID-19 is no exception. Beyond the obvious racist invocations of the “China virus” or the “Wuhan Flu” are subtler racializing dynamics that are often veiled in more benign motives but are nonetheless deeply problematic. The racialization of COVID-19 proceeded along two distinct trajectories each of which threatened to reinforce inaccurate biologized conceptions of race while diverting attention from the social, legal, and political forces historically structuring race-based health disparities. First, early on as significant racial disparities in disease incidence and mortality became evident, a frame of race-based genetic difference came to the fore as a possible explanation.

Second, as vaccine development ramped up there came widespread calls for racially “diversifying” clinical trials for the vaccines being tested. The rationales for such diversification were varied but tended to reinforce genetic frames of racial difference. Most common was the assertion (without substantial evidence) that vaccines might work differently in Black or Brown bodies and so racial diversity in trials was imperative for reasons of safety and efficacy.

Derrick Bell cautioned 20 years ago that “the concept of diversity . . . is a serious distraction in the ongoing efforts to achieve racial justice.” (Derrick Bell, *Diversity's Distractions*, 103 COLUM. L. REV. 1622, 1622 (2003).) This article explores the dynamics of how the concept of “diversity” racialized responses to COVID-19 and considers their broader implications for understanding and responding to racial disparities in the face of pandemic emergencies and beyond. In the short term, vaccine developers did a decent job of enrolling minorities in their clinical trials and the vaccines have proven to have the same safety and efficacy across races. In the long term, diversity in the biomedical context of pandemic response not only distracts attention from important structural causes of health injustice, but it also focuses attention on the genetics of disparities in a manner that has the potential to reinforce pernicious and false ideas of essential biological difference among racial groups.

This article argues that an uncritical embrace of the idea of diversity in analyzing and responding to emergent health crises has the potential to distract us from considering deeper historical and structural formations contributing to racial health disparities. It proceeds first by exploring the dynamics through which initial responses to racial

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disparities in COVID-19 became geneticized. It will then move on to unpack the rationales for such racialization, examine their merits (or lack thereof), and consider their implications for developing an equitable response to pandemic emergencies. The next section will examine the subsequent racialization of clinical trials for COVID-19 vaccines through the concept of “diversity.” It then moves on to explore how the geneticization of COVID-19 racial disparities laid the foundations for a similar geneticization of race in vaccine development. It will argue that in failing to clearly distinguish social and biological rationales for diversity, such framings, while generally well-intentioned, are poorly supported and work in tandem with the geneticization of racial disparities in COVID-19 morbidity and mortality to locate the causes of disparities in the minds and bodies of minoritized populations; again this distracts attention from the historical and structural forces contributing to such disparities. The article concludes by recognizing a certain intractability to the problems of using race in biomedical research and practice, particularly in the context of public health emergencies. It offers modest suggestions for improvement that could have significant practical effects if taken to heart by researchers, clinicians, and policy makers.

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INTRODUCTION

Pandemic diseases have a nasty history of racialization,¹ and COVID-19 is no exception. In 2020, as SARS-Cov-2 took hold and spread through the United States, race quickly entered the narrative framing of those seeking to identify, understand, and respond to the virus.² In some ways, the racialization of COVID-19 sadly and predictably echoed older racist tropes of some foreign “other” being responsible for the spread of disease.³ Invocations of the “China virus” or the “Wuhan Flu” were common, particularly among President Trump and other prominent Republicans, and thereby came to circulate widely among the public.⁴ The tropes have persisted, giving rise to increased anti-Asian violence throughout the United States.⁵

The racialization of COVID-19, however, has also proceeded along two other distinct and perhaps more subtly problematic trajectories. First, significant racial disparities in disease incidence and mortality became evident early on. This was not particularly surprising given long-standing disparities in underlying comorbidities and related socioeconomic factors affecting exposure and response to the disease. Nonetheless, as these disparities became evident, a frame of race-based genetic differences emerged as a possible explanation. This is problematic for many reasons, not least of which being the simple fact that racial categories are variable and do not map onto any clearly identifiable genetic groupings.⁶ To simply invoke the mantra “race is

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1. See, e.g., PRISCILLA WALD, *CONTAGIOUS: CULTURES, CARRIERS, AND THE OUTBREAK NARRATIVE* (Duke Univ Press ed., 2008); Susan Craddock, *City of Plagues: Disease, Poverty, and Deviance in San Francisco*, 56 *J. HIST. MED.* 302, 302 (2001).
 2. See Keith Wailoo, *Spectacles of Difference: The Racial Scripting of Epidemic Disparities*, 94 *BULL. HIST. MED.* 602, 602 (2020).
 3. *Id.* at 607-08.
 4. Tyler T. Reny & Matt A. Barreto, *Xenophobia in the Time of a Pandemic: Othering, Anti-Asian Attitudes, and COVID-19*, TAYLOR & FRANCIS ONLINE: POL., GROUPS, & IDENTITIES (May 28, 2020), <https://www.tandfonline.com/doi/full/10.1080/21565503.2020.1769693> [<https://perma.cc/B8DR-XDL6>].
 5. See, e.g., Weiyi Cai, Audra D. S. Burch, & Jugal K. Patel, *Swelling Anti-Asian Violence: Who Is Being Attacked Where*, *N.Y. TIMES* (Apr. 3, 2021), <https://www.nytimes.com/interactive/2021/04/03/us/anti-asian-attacks.html> [<https://perma.cc/72SJ-AVL9>].
 6. The literature on this is voluminous. For a brief overview, see e.g., Jonathan Kahn et al., *How Not To Talk About Race And Genetics*, BUZZFEEDNEWS (Mar. 30, 2018), <https://www.buzzfeednews.com/article/bfopinion/race-genetics-david-reich> [<https://perma.cc/48SR-Q7JY>].

socially constructed” is not enough.⁷ As anthropologist Alan Goodman recently put it: “Race is real, but it’s not genetic.”⁸ There are, perhaps, crude correlations that can be observed between racial groups and certain biological characteristics.⁹ However, as Jonathan Marks has observed, “to the extent that class differences may correlate with biological differences, we can see that the reality of race is as a bio-cultural category – the intersection of natural human differences and the culturally classificatory decisions about what kinds and what amounts of differences matter.”¹⁰ In the specific realm of health disparities, it is useful to consider epidemiologist Nancy Krieger’s formulation that race-based health differences can be conceptualized as “biologic expressions of race relations.”¹¹ The genetic frame diverts attention from the social, environmental or historical conditions that account for COVID-19 disparities, focusing instead on the incorrectly racialized genetic makeup of the affected groups to locate responsibility at the molecular level. Such diversion is not merely incidental. It can have a critical and wide-ranging impact upon how we marshal and deploy resources in the short term; and in the long term it can impede efforts to address the deeper structural issues that COVID-19 disparities have so powerfully brought to light.

Second, following readily upon the heels of this biologization of racial disparities, as vaccine development ramped up there came widespread calls for racially “diversifying” clinical trials for the vaccines being tested. The rationales for such diversification were varied, but tended to reinforce genetic frames of racial difference.¹² Most common

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7. As sociologists, Michael Omi and Howard Winant have argued, race is perhaps best understood as “an unstable and ‘decentered’ complex of social meanings constantly being transformed by political struggle.” MICHAEL OMI & HOWARD WINANT, *RACIAL FORMATION IN THE UNITED STATES: FROM THE 1960S TO THE 1990S* 55 (2d ed. 1994).
 8. Alan Goodman, *Race Is Real, But It’s Not Genetic*, SAPIENS (Mar. 13, 2020), <https://www.sapiens.org/biology/is-race-real/> [<https://perma.cc/8BBX-7ZY3>].
 9. See, e.g., Vence L. Bonham, Eric D. Green, & Eliseo J. Pérez-Stable, *Examining How Race, Ethnicity, and Ancestry Data Are Used in Biomedical Research*, 320 JAMA 1513, 1533-34 (2018); Agustin Fuentes, *Race is Real, But Not in the Way Many People Think*, PSYCHOL. TODAY: BLOG (Apr. 9, 2012), https://www.psychologytoday.com/us/blog/busting-myths-about-human-nature/20_1204/race-is-real-not-in-the-way-many-people-think [<https://perma.cc/QQ68-TCG2>].
 10. JONATHAN MARKS, *IS SCIENCE RACIST?* 58 (Polity Press ed., 2017).
 11. Nancy Krieger, *If “Race” is the Answer, What is the Question?—On “Race,” Racism, and Health: A Social Epidemiologist’s Perspective*, SOC. SCI. RES. COUNCIL (June 7, 2006), <http://raceandgenomics.ssrc.org/Krieger/#31> [<https://perma.cc/3DM4-357R>].
 12. See discussion *infra* Part II regarding “The Racialization of Vaccine Trials.”

was the assertion that vaccines might work differently in Black or Brown bodies, and so racial diversity in trials was imperative for reasons of safety and efficacy.¹³ The idea behind racial diversification was that results from trials enrolling predominantly White subjects might not be generalizable to other “populations.” Related to this was a more politically-inflected concern that equitable distribution of vaccines would more readily follow from diversified trials, especially because such diversity would encourage trust among vaccine hesitant groups, particularly African-Americans. Safety, Efficacy, Generalizability, Equity, and Trust thus rapidly came to frame the drive toward racializing vaccine development.¹⁴

Of course, it is appropriate, indeed, imperative, to be concerned about the racially disparate impact of COVID-19 and also to work to make sure that vaccines are safe, effective, and accessible to all. The problem is not with these overarching concerns, but rather with their being framed in geneticized conceptions of racial difference. Such geneticization is enabled, indeed fueled, by the blurring, conflation, and confusion of biological and social conceptions of diversity. While many stories about race and COVID-19 have emerged and circulated during the pandemic, the dominant narrative located responsibility for racial disparities—both in disease impact and vaccine uptake—on the bodies and minds of those suffering disproportionately from COVID-19. This necessarily diverts attention from the historical and on-going structural factors driving racial inequities in health, and has profound implications both for biomedical understandings of race and for socio-political approaches to addressing issues of racial justice in health.

In the 2003 Affirmative Action case of *Grutter v. Bollinger*, the Supreme Court affirmed “diversity” as a constitutional rationale for considering race as a factor in higher education admissions.¹⁵ Responding to the decision, Derrick Bell wrote a foundational article titled “Diversity’s Distractions.”¹⁶ While acknowledging the importance of increasing minority enrollment colleges and graduate schools, Bell cautioned that “the concept of diversity . . . is a serious distraction in the ongoing efforts to achieve racial justice.”¹⁷ For Bell, diversity itself was not a bad thing; however, as a rationale for affirmative action it “enable[d] courts and policymakers to avoid addressing directly the barriers of race and class that adversely affect so many applicants.”¹⁸ Additionally, Bell argued, “[t]he tremendous attention directed at

13. *Id.*

14. *Id.*

15. *Grutter v. Bollinger*, 539 U.S. 306, 343 (2003).

16. Derrick Bell, *Diversity’s Distractions*, 103 COLUM. L. REV. 1622, 1622 (2003).

17. *Id.*

18. *Id.*

diversity programs diverts concern and sources from the serious barriers of poverty that exclude far more students from entering college than are likely to gain admission under an affirmative action program.”¹⁹ Similar dynamics have been at play in the invocation of diversity to address disparities that have come to light during the COVID-19 pandemic. In the biomedical context of the pandemic response, however, there is the added problem, not confronted by Bell, that diversity not only distracts attention from important structural causes of health injustice, it also focuses attention on genetics in a manner that has the potential to reinforce pernicious and false ideas of essential biological difference among racial groups.

This article argues that an uncritical embrace of the idea of diversity in analyzing and responding to emergent public health crises has the potential to distract us from considering deeper historical and structural formations contributing to racial health disparities. First, in Part I, it proceeds by exploring the dynamics through which initial responses to racial disparities in COVID-19 became geneticized and will then move on to unpack the rationales for such racialization, examine their merits (or lack thereof), and consider their implications for developing an equitable response to pandemic emergencies. Part II will examine the subsequent racialization of clinical trials for COVID-19 vaccines through the concept of “diversity” and will then move on to explore how the geneticization of COVID-19 racial disparities laid the foundations for a similar geneticization of race in vaccine development. In Part III, it will argue that in failing to clearly distinguish social and biological rationales for diversity, such framings are poorly supported; those framings also work in tandem with the geneticization of racial disparities in COVID-19 morbidity and mortality to locate the causes of disparities in the minds and bodies of minoritized populations. This distracts attention from the historical and structural forces contributing to such disparities. Finally, in Part IV, this article concludes by recognizing a certain intractability to the problems of using race in biomedical research and practice, particularly in the context of public health emergencies. It offers modest suggestions for improvement that could have significant practical effects if taken to heart by researchers, clinicians, and policymakers.

I. GENETICIZING RACIAL IMPACT

When COVID-19 gained a foothold in the United States in early 2020, President Trump and other prominent Republican law makers wasted little time in racializing the disease itself, repeatedly referring to it as the “Wuhan Virus,” “Chinese Virus,” and “Kung Flu.”²⁰ Similar recent examples of racialization of disease can be seen the responses to

19. *Id.*

20. Reny & Barretto, *supra* note 4.

the 2013-2016 Ebola outbreak in Africa²¹ and in invocations of “African AIDS” during the 1980s.²² This is hardly a new phenomenon. Historian Keith Wailoo has explored how epidemics have long given rise to “distinctive, recurring racial scripts about bodies and identities.”²³ He argues that the opening act of such scripts, from yellow fever epidemics in the 18th century to cholera in the 19th century and influenza, tuberculosis, and AIDS in the 20th, up to COVID-19 today, has created a moment of “racial revelation” where “health experts and authorities take note of Black people’s experiences, illnesses, or mortality as a specific object of curiosity and social commentary.”²⁴ He argues that “whether the moment of racial revelation focused on supposed Black immunity or Black susceptibility, the revelation became material for an ur-script . . . a plotline framed as a mystery of racial difference.”²⁵

President Trump declared COVID-19 to be a public health emergency on January 31, 2020 and issued two national emergency declarations on March 13.²⁶ Before long, the racially disparate impact of the virus became evident. On April 12, 2020, the COVID Tracking Project started collecting race and ethnicity data from every state that reported such data. On April 15, it launched the first iteration of the COVID Racial Data Tracker using that dataset.²⁷ Three days later, Fordham law professor Catherine Powell coined the term “Color of Covid” in an opinion piece for CNN, stating that people of color were being hit particularly hard by the pandemic.²⁸ The COVID Racial Data Tracker and other subsequent studies would go on to document massive racial disparities in morbidity and mortality from COVID-19 in the United States. For example, one study found that as of June 17, 2020,

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21. *Id.* at 20.
 22. Lisa Betty, “Black Death”: Race and Representations of the Ebola Epidemic and COVID-19 Pandemic, MEDIUM (May 30, 2020), <https://lbetty1.medium.com/black-death-race-and-representations-of-the-ebola-epidemic-and-covid-19-pandemic-479195d590> [https://perma.cc/XJ89-D4KF].
 23. Wailoo, *supra* note 2, at 604.
 24. *Id.* at 605.
 25. *Id.* at 606.
 26. *President Trump Declares State of Emergency for COVID-19*, NAT’L CONF. ST. LEG. (Mar. 25, 2020), <https://www.ncsl.org/ncsl-indc/publications-and-resources/president-trump-declares-state-of-emergency-for-covid-19.aspx> [https://perma.cc/27S3-BC9M].
 27. *About the Racial Data Tracker*, THE ATLANTIC: THE COVID TRACKING PROJECT, <https://covidtracking.com/race/about> [https://perma.cc/K97D-ZYJP] (last visited May 21, 2021).
 28. Catherine Powell, *Color of Covid: The Racial Justice Paradox of Our New Stay-at-Home Economy*, CNN (Apr. 18, 2020), <https://www.cnn.com/2020/04/10/opinions/covid-19-people-of-color-labor-market-disparities-powell/index.html> [https://perma.cc/3R3D-LJ2P].

“[a]mong older adults, Blacks and Latinxs have death rates approximately three and two times higher than Whites, respectively.”²⁹ By September one report found that the infection rate for Hispanic patients was over three times higher than the rate in White patients (143 vs. 46 per 10,000), and the rate among Black patients was over two times as high (107 per 10,000).³⁰ Some targeted studies, such as one in New York City, found that Blacks were five times more likely to develop COVID-19 than Whites.³¹

As such racial differences became more evident, they also became geneticized. Anthropologist Lance Gravlee flagged some of the crudest forms of geneticizing COVID-19 racial disparities in a June 2020 blog post for *Scientific American*. Gravlee noted that:

Louisiana Sen. Bill Cassidy, who was a medical doctor before entering politics, claimed, without providing evidence, that “genetic reasons,” among other factors, put African Americans at risk of diabetes and, therefore, of serious complications from COVID-19. Scientists writing in the *Lancet*, one of the world’s leading medical journals, suggested—also without evidence—that ethnic disparities in COVID-19 mortality may be partly attributable to “genetic make-up” and speculated on a “genomically determined response to viral pathogens.” Epidemiologists writing in *Health Affairs* noted that “there may be some unknown or unmeasured genetic or biological factors that increase the severity of this illness for African Americans.”³²

This last reference to “some unknown or unmeasured genetic or biological factors” is particularly notable as it is a rhetorical move repeatedly deployed to create a space for geneticizing disparities without evidence. It is always available because one can never know *all* of the causes of any given racial disparity. Much more reasonable and

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29. Marc A. Garcia et al., *The Color of COVID-19: Structural Racism and the Pandemic's Disproportionate Impact on Older Racial and Ethnic Minorities*, GERONTOLOGICAL SOC'Y AM., 2020, at 1, 5.
 30. Lily Rubin-Miller et al., *COVID-19 Racial Disparities in Testing, Infection, Hospitalization, and Death: Analysis of Epic Patient Data*, KAISER FAM. FOUND. (Sept. 16, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/> [<https://perma.cc/3CMV-EBR4>].
 31. Charles DiMaggio et al., *Black/African American Communities Are at Highest Risk of COVID-19: Spatial Modeling of New York City ZIP Code-Level Testing Results*, 51 ANNALS EPIDEMIOLOGY 7, 9 (2020).
 32. Clarence Gravlee, *Racism, Not Genetics, Explains Why Black Americans Are Dying of COVID-19*, SCI. AM.: VOICES (June 7, 2020), <https://blogs.scientificamerican.com/voices/racism-not-genetics-explains-why-black-americans-are-dying-of-covid-19/> [<https://perma.cc/TYS4-7VMC>].

responsible would be to assume a null hypothesis: racial disparities are *not* due to genetics until proven otherwise.

Ironically, some of the earliest discussions of racialized genetic difference involved spurious reports of Black immunity to the virus. On March 10, Reuters reported about false claims circulating on social media that “African Skin” resists the coronavirus.³³ Around the same time, a columnist with the *Chicago Tribune* noted similar rumors and referenced a Twitter Live video posted by actor Idris Elba (who had recently contracted the virus) pleading “with black people to stop spreading the ‘scary’ rumor that they are immune,” calling it “the quickest way to get more black people killed . . . around the world.”³⁴ These examples do not address disparities per se, but they nonetheless play into the moment of “racial revelation” where early on in the pandemic race was becoming geneticized in relation to the virus. While these early rumors of Black resistance to the virus were quickly challenged, the search for genetic bases of COVID-19 susceptibility by seemingly more reputable and prestigious biomedical researchers rapidly became racialized in new and problematic ways.

Social media was not the only platform that began looking to genetics to explain this observed phenomenon. In a September 2020 article published in the prestigious journal *Nature*, researchers claimed to have identified a genetic risk locus for respiratory failure after infection with SARS-CoV-2 that was inherited from Neanderthals and present at much higher frequencies in people from South Asia and Europe than Africa.³⁵ Similarly, a published report from the direct-to-consumer genetics company, 23andMe found a “strong association between blood type and COVID-19 diagnosis.”³⁶ Specifically, it found “that the O blood group was protective when compared to other blood

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33. *See generally False Claim: African Skin Resists the Coronavirus*, REUTERS (Mar. 10, 2020), <https://www.reuters.com/article/uk-factcheck-coronavirus-ethnicity/false-claim-african-skin-resists-the-coronavirus-idUSKBN20X27G> [<https://perma.cc/5RNV-ZGBU>].
 34. Dahleen Glanton, *Column: Let's Stop the Spread – of the Myth Black People Are Immune to the Coronavirus*, CHI. TRIB. (Mar. 18, 2020), <https://www.chicagotribune.com/columns/dahleen-glanton/ct-dahleen-glanton-coronavirus-black-immunity-myth-idris-elba-20200319-5auoqjzrmbcsphitbhpoch3qa-story.html> [<http://archive.today/mNBxI>].
 35. Hugo Zeberg & Svante Pääbo, *The Major Genetic Risk Factor for Severe COVID-19 is Inherited From Neanderthals*, 587 NATURE 610, 610-12 (2020).
 36. Janie F. Shelton et al., *Trans-Ethnic Analysis Reveals Genetic and Non-Genetic Associations with COVID-19 Susceptibility and Severity*, MEDRXIV (Sept. 7, 2020), <https://www.medrxiv.org/content/10.1101/2020.09.04.20188318v1> [<https://perma.cc/QM8Z-Y3J7>].

groups.”³⁷ O type blood is found the world over but is more common in Africa than elsewhere.³⁸

Subsequent research revealed a much more complex picture of possible genetic bases for variable COVID-19 susceptibility. For example, later studies cast into doubt the significance of ABO blood group variation,³⁹ and the same researchers who published the Neanderthal study in September 2020 published a second study in January 2021. In the second study, those researchers identified yet another Neanderthal genetic risk locus, this time finding it to be protective against severe COVID-19.⁴⁰ Based on these studies, there were apparently some genetic variants inherited from Neanderthals that could make populations outside of Africa more susceptible to COVID-19, and others than could make them less so. In any event, given that only 2-3% of modern humans’ DNA derives from Neanderthals,⁴¹ it seems likely that most genetic variations of relevance to COVID-19 susceptibility have nothing to do with our Neanderthal ancestry.

One of the factors contributing to early rumors of Black immunity to contracting COVID-19 was the relatively low incidence rates in sub-Saharan African as COVID-19 spread in 2020. There were, however, very clear non-genetic reasons explaining the much lower case-fatality rate for Africa as compared to the rest of the world at that time. One BBC report from October 2020 noted five reasons in particular.⁴² First, “Quick Action:” this included the swift introduction of public health measures such as avoiding handshakes, frequent hand-washing, social distancing and wearing of face masks. Second, “Public Support:” for example, in a survey conducted in 18 African countries, 85% of

37. *Id.*

38. See Jon Entine & Patrick Whittle, *What’s ‘Race’ Got to Do with it? Sub-Saharan Africa Emerges as Coronavirus ‘Cold Spot’, Offering Clues to Develop COVID-19 Vaccines*, GENETIC LITERACY PROJECT (Mar. 31, 2020), <https://geneticliteracyproject.org/2020/03/31/whats-race-got-to-do-with-it-most-of-sub-saharan-africa-emerges-as-coronavirus-cold-spot-which-may-offer-clues-to-finding-covid-19-vaccine/> [https://perma.cc/N7NJ-MM74].

39. Erola Pairo-Castineira et al., *Genetic Mechanisms of Critical Illness in COVID-19*, 591 NATURE 92, 96 (2021).

40. Hugo Zeberg & Svante Pääbo, *A Genomic Region Associated with Protection Against Severe COVID-19 is Inherited from Neandertals*, PROC. NAT’L ACAD. SCI., 2021, at 1, 1-2, 4.

41. See Nathaniel Sharping, *How Much Neanderthal DNA Do Humans Have?*, DISCOVER MAG. (Apr. 28, 2020), <https://www.discovermagazine.com/planet-earth/how-much-neanderthal-dna-do-humans-have> [https://perma.cc/X9BE-PVRP].

42. Anne Soy, *Coronavirus in Africa: Five reasons Why Covid-19 Has Been Less Deadly Than Elsewhere*, BBC (Oct. 8, 2020), <https://www.bbc.com/news/world-africa-54418613> [https://perma.cc/4MWG-QTRX].

respondents said they wore masks in the previous week.⁴³ Third, a “Young Population” — and few old-age homes. Fourth, a “Favorable Climate,” And fifth, “Good Community Health Systems:” particularly those that were familiar with outbreaks of viruses such as Ebola and methods of containing them.⁴⁴

Many of these measures are similar to those taken by countries such as New Zealand, which also had very low rates of COVID-19.⁴⁵ But, of course, no one was conducting any genetic studies of predominantly European descended New Zealanders to try to understand why they seemed so resistant to the ravages of the virus. When the unmarked racial category of “White” was involved, it was assumed that political and social interventions must have made the difference because other “Western” (read “predominantly White”) countries without those interventions still suffered from COVID-19.

The search for genes to explain disparities did not end with Neanderthals and blood groups. As racial disparities became more evident, studies of possible candidate genes to explain the difference proliferated. Prominent among these were studies of genotypes encoding for the Human Leukocyte Antigen (HLA) system,⁴⁶ the angiotensin-converting enzyme-2 (ACE2) receptor,⁴⁷ transmembrane serine protease

43. *Id.*

44. *Id.*

45. Anna Jones, *How Did New Zealand Become Covid-19 Free?*, BBC (July 10, 2020), <https://www.bbc.com/news/world-asia-53274085> [<https://perma.cc/HRQ8-F8T8>].

46. *See generally* Austin Nguyen et al., *Human Leukocyte Antigen Susceptibility Map for Severe Acute Respiratory Syndrome Coronavirus 2*, J. VIROLOGY, 2020, at 1; Monojit Debnath et al., *Genetic Gateways to COVID-19 Infection: Implications for Risk, Severity, and Outcomes*, 34 FASEB J. 8787 (2020); David J. Langton et al., *The Influence of HLA Genotype on Susceptibility to, and Severity of, COVID-19 Infection*, MEDRXIV (Jan. 4, 2021), <https://www.medrxiv.org/content/10.1101/2020.12.31.20249081v1.full> [<https://perma.cc/EEE8-Z9XX>].

47. *See* Debnath et al., *supra* note 46. *See generally* Yanan Cao et al., *Comparative Genetic Analysis of the Novel Coronavirus (2019-nCoV/SARS-CoV-2) Receptor ACE2 in Different Populations*, CELL DISCOVERY, 2020, at 1.

2 (TMPRSS2) nasal gene expression,⁴⁸ ion channel genetic variants,⁴⁹ and prothrombin genetic mutations.⁵⁰

HLA variants encode for the production of cell-surface proteins that are responsible for the regulation of the immune system and are known to vary significantly geographically across the globe.⁵¹ There are three major histocompatibility complex (MHC) class 1 genes: HLA-A, HLA-B, and HLA-C.⁵² These genes do not directly correlate with any racial groups, but they (and their various alleles) do vary in their relative frequencies in different populations across geographic space.⁵³ Thus, for example, one 2020 study identified global allele frequency distributions by country for three representative alleles (HLA-A*02:02, HLA-B*15:03, and HLA-C*12:03) thought likely to be protective for SARS-CoV-2 and for three other three representative alleles (HLA-A*25:01, HLA-B*46:01, and HLA-C*01:02) with the lowest predicted levels of protection based on an *in silico* analysis.⁵⁴ While all of the alleles were found across the globe (*i.e.*, none were race-specific), the study did generally find a higher prevalence of the protective alleles in Africa and a higher prevalence of less protective alleles in Europe.⁵⁵ Whether or not this *in silico* analysis actually plays out *in vivo*, it certainly cannot be used to explain racial disparities because, like the ABO blood group study and the first Neanderthal gene study, the results of this HLA study would indicate a protective advantage on average for African descended populations. Additionally, there is tremendous allelic diversity in all major classes of the HLA system among populations *within* Africa, so variable immune response is not simply of matter of HLA diversity based on so-called continental populations.⁵⁶

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48. See Supinda Bunyavanich, Chantal Grant, & Alfin Vicencio, *Racial/Ethnic Variation in Nasal Gene Expression of Transmembrane Serine Protease 2 (TMPRSS2)*, 324 JAMA 1567, 1567 (2020). See generally J.M. Carethers, *Insights into Disparities Observed with COVID-19*, 289 J. INTERNAL MED. 463 (2020).
49. See generally John R. Giudicessi et al., *Genetic Susceptibility for COVID-19-Associated Sudden Cardiac Death in African Americans*, 17 HEART RHYTHM 1487 (2020).
50. See generally Rahul Chaudhary et al., *Race-Related Disparities in COVID-19 Thrombotic Outcomes: Beyond Social and Economic Explanations*, 29 ECLINICALMEDICINE, 2020, at 1.
51. See Nguyen et al., *supra* note 46.
52. *Id.* at 1.
53. See Debnath et al., *supra* note 46, at 4.
54. See Nguyen et al., *supra* note 46, at 6-7.
55. *Id.* at 7.
56. K. Cao et al., *Differentiation Between African Populations is Evidenced by the Diversity of Alleles and Haplotypes of HLA Class I Loci*, 63 TISSUE ANTIGENS 293, 293-94 (2004).

One obvious molecular candidate for possible race-specific variable response to COVID-19 was the ACE2 gene encoding the angiotensin-converting enzyme-2, which had been proved to be the receptor for the SARS-CoV-1 and so was naturally looked to as a possible host receptor for SARS-CoV-2.⁵⁷ One study published in February 2020, just as COVID-19 was taking hold, observed variable frequencies of certain possible significant alleles across “East Asian,” “European,” “African,” “South Asian,” and “Ad-Mixed American,” groups but also found “no direct evidence supporting the existence of coronavirus S-protein binding-resistant ACE2 mutants in different populations.”⁵⁸ A later study, published in May 2020, looked at both ACE2 and HLA loci hypothesizing that “genetic variations within these gateways could be key in influencing geographical discrepancies of COVID-19.”⁵⁹ However, the study concluded that “currently, there are no genetic data to support ethnic/geographical variation of COVID-19 on global basis.”⁶⁰ A study published in September continued to look at ACE2 and other genes as possible contributors to COVID-19 disparities and similarly acknowledged that “it is unknown how these genetic polymorphisms contribute to the disparate mortality rates.”⁶¹ Nonetheless, the authors of this study hypothesized that “genetic and biological risk for highly relevant COVID-19 comorbid conditions may be critical to our ability to understand and therefore address the observed health disparities in the COVID-19 pandemic affecting US NHBs [non-hispanic blacks].”⁶² In pursuing this geneticized approach to disparities, the authors tellingly wrote:

Population-specific risk in Black communities is clearly multifactorial; however, recent research on the prevalence and risk in the UK indicates that comorbidity and social determinants of health only tell part of the story when it comes to accounting for disease risk and mortality in vulnerable populations. Naturally, biological risk likely fills the void, at least in some part.⁶³

In noting that “population-specific risk” is “multifactorial,” the authors acknowledged social determinants of health but went on to assert that those determinants tell “only part of the story.” The other

57. Cao, *supra* note 47.

58. *Id.*

59. Debnath et al., *supra* note 46, at 8787.

60. *Id.*

61. Nicole Phillips et al., *The Perfect Storm: COVID-19 Health Disparities in US Blacks*, 8 J. RACIAL & ETHNIC HEALTH DISPARITIES, 2020, at 1, 1.

62. *Id.*

63. *Id.*

part of that story, it seems, must be biological; this implied despite the fact that they present no hard evidence to support the claim.

Certainly, “biological risk” plays a role in COVID-19 prevalence, but the authors conveniently blurred the distinction between biological risk and *race-specific* biological risk and strangely reconfigured the absence of evidence of such racialized risk into evidence of presence. This is a common rhetorical move in biomedical studies seeking to establish race-specific biological difference as an explanation for disparities: authors often note that the social determinants they have identified as contributing to disparities fail to explain the entirety of the disparity, and they therefore assert that the residual disparities *must* be caused by underlying (yet unidentified) race-specific biological differences.⁶⁴

In this case, the authors posited “ancestral variations” in ACE2 as a source of race-specific “biological risk.”⁶⁵ They framed their discussion of ACE2 with a reference to research from the UK which purported to indicate that “social determinants only tell part of the story.”⁶⁶ The study was published in September 2020. Its reference for the UK claim came from a news story from May 2020, which offered this striking claim as its opening sentence:

People from Asian and black ethnic backgrounds are at increased risk of dying from covid-19 and, contrary to speculation, this can only be partly explained by comorbidity, deprivation, or other risk factors, according to data from the largest study to date.⁶⁷

Yet, the barely one-page-long news story from May 2020 also stated in the fourth paragraph that:

[M]ore research was needed on whether some of the increased risk [of dying from COVID-19] is from greater occupational exposure with proportionally more people from black and minority ethnic (BAME) backgrounds working in sectors such as healthcare or transport. Research is also needed into a range of factors throughout the disease pathway including access to testing, treatment, and intensive care.⁶⁸

This assertion is hardly a convincing argument as to the likely genetic basis for such disparities.

64. For an extended discussion of this phenomenon, see JONATHAN KAHN, *RACE IN A BOTTLE: THE STORY OF BiDiL AND RACIALIZED MEDICINE IN A POST-GENOMIC AGE* 157-92 (2012).

65. Phillips et al., *supra* note 61, at 4.

66. *Id.*

67. Jacqui Wise, *Covid-19: Known Risk Factors Fail to Explain the Increased Risk of Death Among People from Ethnic Minorities*, *BMJ*, 2020, at 1, 1.

68. *Id.*

In October 2020, just one month after this article referenced research in the UK to support the idea that race-specific “biological risk” likely plays a role in disparities, the UK government issued its first quarterly report on COVID-19 health inequalities.⁶⁹ At that time, the UK government report found that “existing research suggests that biological factors such as genetics are unlikely to explain the inequalities in ethnic groups from COVID-19.”⁷⁰ As Reuters described, the report found that “the increased risk to ethnic minorities from COVID-19 is largely driven by factors such as living circumstances and profession and not the genetics of different groups.”⁷¹

Nonetheless, another study published in March 2021, well after the UK report, deployed now-common rhetorical frames to perpetuate the idea that genes, not social determinants, *might* be responsible for COVID-19 disparities.⁷² To support its observation that “both biological and nonbiological factors *seem to* contribute to racial disparities in COVID-19,” this article referenced a study purportedly finding that African Americans “are *likely* more susceptible” due to a polymorphism in the androgen receptor gene.⁷³ It also went on to reference yet another study finding that “that African populations are genetically predisposed to lower expression of ACE2 and TMPRSS2 and *may* therefore be less susceptible to the coronavirus.”⁷⁴

Putting aside the fact that these two studies (like the Neanderthal gene studies) would seem to cancel each other out in terms of explaining disparities, the authors’ strategic use of words such as “might,” “likely,” and “seem to” is notable. On the one hand, such terminology is common in scientific papers seeking to explore possible hypotheses. Here, however, they are doing a different sort of work. For example, the phrase “seem to” makes it appear that non-biological explanations for disparities exist in the same speculative realm as biological explanations. This is clearly not the case. The October UK report is just one of many studies powerfully demonstrating the impact of “non-biological” (*i.e.*, social) factors causing race-based health disparities.

69. *See generally* U.K. CABINET OFF., RACE DISPARITY UNIT, QUARTERLY REPORT ON PROGRESS TO ADDRESS COVID-19 HEALTH INEQUALITIES (Oct. 2020).

70. *Id.* at 53.

71. *Socioeconomic Factors Drive COVID Risks for Minorities – UK Government Report*, REUTERS (Oct. 21, 2020), <https://www.reuters.com/article/us-health-coronavirus-britain-ethnicity/socioeconomic-factors-drive-covid-risks-for-minorities-uk-government-report-idUSKBN2763CF> [<https://perma.cc/RAJ7-4AWT>].

72. Geetanjali Saini et al., *Disentangling the Coronavirus Disease 2019 Health Disparities in African Americans: Biological, Environmental, and Social Factors*, OPEN FORUM INFECTIOUS DISEASES, 2021, at 1, 9.

73. *Id.* (emphasis added).

74. *Id.* (emphasis added).

Only the studies of purported racial biological differences “seem to” show some possible correlations between certain allele frequencies and higher levels of morbidity or mortality. In the end, the authors deploy these speculative terms not simply to further scientific exploration but to create a space for geneticizing racial disparities.

The above-noted study referenced “African populations” differential expressions of *ACE2* and *TMPRSS2* and speculated that “these data suggest that a genetic component might contribute to lower numbers of reported COVID-19 cases in Africa.”⁷⁵ Yet, it also went on to note that “it remains likely that non-genetic factors such as age and comorbidities might play a more important role than host genetic elements, especially in determining disease severity and outcome in infected individuals.”⁷⁶ In other words, even when identifying possible genetic contributors to disparities, the authors of the cited study carefully noted that the significance of genetic contributors likely paled in comparison to non-genetic factors. Moreover, this study was of variable “gene expression,” not of genetic variation itself.

As a different study of *TMPRSS2* expression and COVID-19 stated, “although this study suggests one factor that may partially contribute to COVID-19 risk . . . many additional factors are likely, especially because gene expression and race/ethnicity reflect multiple social, environmental, and geographic factors.”⁷⁷ In other words, study of the impact of variable *TMPRSS2* expression on COVID-19 disparities cannot be separated from social and environmental factors. In the hands of those arguing for strong genetic contributions to disparities, however, such caveats tend to fall by the wayside. As Merlin, Chowkwanyun and Adolph L. Reed Jr. cautioned in a May 2020 article, when such context is lost, “data in a vacuum can give rise to biologic explanations for racial health disparities.”⁷⁸

Another study looking for possible genetic bases for COVID-19 racial disparities hypothesized that certain common ion-channel-regulating genetic variants might be “contributing to the spike in sudden deaths and racial health disparities observed in COVID-19 epicenters.”⁷⁹ These variants occurred at higher frequencies in “individuals of African origin” and had been linked to “an increased risk of ventricular arrhythmia (VA) and sudden cardiac death (SCD)

75. Lourdes Ortiz-Fernández & Amr H. Sawalha, *Genetic Variability in the Expression of the SARS-CoV-2 Host Cell Entry Factors Across Populations*, 21 GENES & IMMUNITY 269, 271 (2020).

76. *Id.*

77. Bunyavanich et al., *supra* note 48, at 1568.

78. Merlin Chowkwanyun & Adolph L. Reed, Jr., *Racial Health Disparities and Covid-19 – Caution and Context*, 383 NEW ENG. J. MED. 201, 202 (2020).

79. Giudicessi et al., *supra* note 49, at 1491.

in African Americans across the age spectrum.”⁸⁰ The authors of this study also deployed the common rhetorical move of opening with an acknowledgement that “this phenomenon is likely explained by the convergence of multiple cultural and socioeconomic factors” before moving on to hypothesize that “an underlying genetic susceptibility to SARS-CoV-2 infection . . . could also contribute.”⁸¹ Yet even on its own terms, after creating this space for geneticizing racial disparities, this study concluded that its hypothesis “remains to be proven” and, strikingly, “may not even be testable.”⁸²

In contrast, the authors of a similar study looked at possible relations between COVID-19 outcomes and purported genetic bases to racial “thrombotic outcome disparities” (*i.e.* negative blood clotting events) chose to subtitle their article “Beyond social and economic explanations.”⁸³ In this study, the authors hypothesized that “differences in mortality and thromboembolic event occurrences in COVID-19 may also be, in part, explained by important, but comparatively unrecognized, race-related disparities in intrinsic thrombogenicity.”⁸⁴ The word “intrinsic” is critical here as it biologizes the disparities of the affected racialized group. By way of comparison, a systemic review of 68 studies exploring possible genetic contributions to racial disparities in cardiovascular disease published in 2015 found little evidence to support any purported genetic connection, concluding that “most associations reported from genome-wide searches were small, difficult to replicate, and in no consistent direction that favored one racial group or another.”⁸⁵

It has not been just the individual researchers foregrounding genetic explanations of racial disparities, but major journals themselves. In the wake of a major controversy surrounding a JAMA podcast that effectively denied the existence of racism in the medical profession, former New York City Health Commissioner Dr. Mary Bassett asserted that “the biomedical literature just has not embraced racism as more than a topic of conversation, and hasn’t seen it as a construct that should help guide analytic work . . . But it’s not just JAMA — it’s all of them.”⁸⁶ With specific reference to COVID-19, Bassett lamented the

80. *Id.* at 1490.

81. *Id.* at 1487.

82. *Id.* at 1491.

83. Chaudhary et al., *supra* note 50.

84. *Id.*

85. Jay S. Kaufman et al., *The Contribution of Genomic Research to Explaining Racial Disparities in Cardiovascular Disease: A Systematic Review*, 187 AM. J. EPIDEMIOLOGY 464, 464 (2015).

86. Apoorva Mandavilli, *Medical Journals Blind to Racism as Health Crisis*, *Critics Say*, N.Y. TIMES (June 2, 2021), <https://www.nytimes.com/>

telling example of JAMA rejecting her analysis of COVID-19 mortality rates by race and age, while publishing another paper proposing that a racial variation in a cellular receptor for the coronavirus might be an explanation for the pandemic's disproportionate toll on Black people.⁸⁷

The above discussion is a representative sampling of the wide range of articles published in major biomedical journals. Reviewing them is important for several reasons. First, they set a narrative frame that could have real impacts on understandings of and substantive responses to the observed phenomenon of COVID-19 racial disparities. Second, they play into and reinforce pre-existing dynamic of racialized care with potential implications for triage and treatment in a time of public health emergency. Third, they set the stage for racializing clinical trials for vaccines in a manner that further reinforced the narrative that races are genetically distinct groups, and these differences must play a role in our response to COVID-19 (and other) health disparities.

A. Unpacking the Geneticization of Racial Disparities in COVID-19

Perhaps the most remarkable thing about the almost reflexive search for genetic bases to COVID-19 health disparities was the mountain of evidence that such disparities were profoundly and overwhelmingly due to historical, social, environmental, legal, and political (*i.e.*, *not* genetic) factors. Even if some possible genetic correlations to racial disparities were to be uncovered, the chances were minimal that they would explain more than a tiny fraction of such difference relative to the impact of non-genetic factors. This must have been obvious to anyone with the slightest familiarity with the history of racial disparities in the United States. As Lance Gravlee put it: “[h]uman biology is more than the genome. Our environments, experiences and exposures have profound impacts on how our bodies develop, turning genetic potential into whole beings.”⁸⁸ But if your idea of looking at gene-environment interactions is considering how methyl groups affect gene expression, perhaps you never develop a feel or appreciation for considering the power forces beyond the genome to shape health.

The non-genetic factors contributing to COVID-19 disparities were myriad. Minoritized populations already bear a disproportionate burden of underlying comorbidities that can place them at greater risk of higher mortality from COVID-19. Moreover, not everyone is in an equal position to manage their risk of encountering others with COVID-19. As cardiologist Clyde Yancy notes, social distancing is a form of

2021/06/02/health/jama-racism-bauchner.html [https://perma.cc/SLY4-265G].

87. *Id.*

88. Gravlee, *supra* note 32.

privilege.⁸⁹ Many of the conditions that have structured access to such privilege along racial lines are the result of decades-long legal and political actions, such as mortgage red-lining, employment discrimination, and urban transportation policies.⁹⁰ Such policies have led to the reality that ethnic and racial minorities are more likely to live in sub-standard crowded housing, be exposed to toxic environmental pollutants, be forced to rely on public transportation, and have reduced access to health care.⁹¹ They are also more likely to work in settings that have been deemed “essential” such as healthcare facilities, farms, factories, grocery stores, and public transportation,⁹² not to mention that these populations had, and have, higher rates of incarceration in prisons where COVID-19 ran rampant.⁹³

In their analysis of the legal underpinning of COVID-19 disparities, Yearby and Mohapatra noted that “structural racism in employment causes disparities in exposure; structural racism in housing causes disparities in susceptibility; and structural racism in healthcare causes disparities in treatment.”⁹⁴ Moving from the structural to the interpersonal, another study published in November 2020 found a strong correlation between levels of implicit anti-Black bias among non-Hispanic Whites and higher overall COVID-19 mortality rates and larger Black-White incidence rate gaps. In that study, the authors concluded that racism may not merely aggravate disparities, but may actually be “harmful for everyone’s health.”⁹⁵

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89. Clyde W. Yancy, *COVID-19 and African Americans*, 323 JAMA 1891, 1891 (2020).
90. *Id.* at 1891-92.
91. Ruqaiyah Yearby & Seema Mohapatra, *Law, Structural Racism, and the COVID-19 Pandemic*, 7 J. L. & BIOSCIENCES 2, 4 (2020); Harriet A. Washington, *How Environmental Racism is Fuelling the Coronavirus Pandemic*, NATURE (May 19, 2020), <https://www.nature.com/articles/d41586-020-01453-y> [<https://perma.cc/9TNA-HKW2>].
92. *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, HEALTH EQUITY CONSIDERATIONS AND RACIAL AND ETHNIC MINORITY GROUPS, <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html> [<https://perma.cc/GRF8-M5ZU>] (Nov. 30, 2021); Monia Webb Hooper, Anna Maria Nápoles & Eliseo J. Pérez-Stable, *COVID-19 and Racial/Ethnic Disparities*, 323 JAMA 2466, 2466 (2020).
93. Eddie Burkhalter et al., *Incarcerated and Infected: How the Virus Tore Through the U.S. Prison System*, N.Y. TIMES (Apr. 10, 2021), <https://www.nytimes.com/interactive/2021/04/10/us/covid-prison-outbreak.html>? [<https://perma.cc/7NC2-24ZY>].
94. Yearby & Mohapatra, *supra* note 91.
95. Marilyn D. Thomas et al., *Whites’ County-Level Racial Bias, COVID-19 Rates, and Racial Inequities in the United States*, INT’L J. ENVTL. RES & PUB. HEALTH (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7700363/pdf/ijerph-17-08695.pdf> [<https://perma.cc/MVG4-T8AG>].

As a September 2020 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded:

”This disproportionate burden [of COVID-19 morbidity, mortality, and transmission] largely reflects the impacts of systemic racism and socioeconomic factors that are associated with increased likelihood of acquiring the infection (e.g., frontline jobs that do not allow social distancing, crowded living conditions, lack of access to personal protective equipment, inability to work from home) and of having more severe disease when infected (as a result of a higher prevalence of comorbid conditions or other factors).”⁹⁶

All of these factors combined to offer up a decidedly non-genetic menu of contributors to health disparities. Yet, as we saw above, the search for genetic causes was widespread and on-going.

Not only were there many studies documenting the myriad non-genetic contributors to COVID-19 disparities, but there were also studies explicitly concluding that genetics were *not* contributing to COVID-19 disparities. In addition to the UK report mentioned above finding that “biological factors such as genetics are unlikely to explain the inequalities in ethnic groups from COVID-19,”⁹⁷ NASEM similarly declared in September 2020 that “currently there is little evidence that this is biologically mediated, but rather reflects the impact of systemic racism.”⁹⁸ Further, longtime health and science reporter Gina Kolata authored a December 2020 article in the *New York Times* with the unequivocal title “‘Nothing to do with genes’: Racial gaps in pandemic stem from social inequities, studies find.”⁹⁹ One of the studies discussed in Kolata’s article had recently been published in JAMA Network Open.¹⁰⁰ That study assessed racial disparities in hospitalization and mortality in patients with COVID-19 in New York City hospitals. It

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96. NAT’L ACAD. SCI., ENG’G, & MED., FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE 9 (2020).
 97. U.K. CABINET OFF., RACE DISPARITY UNIT, *supra* note 69.
 98. *National Academies Release Draft Framework for Equitable Allocation of a COVID-19 Vaccine, Seek Public Comment*, NAT’L ACAD. SCI., ENG’G & MED. (Sept. 1, 2020), <https://www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-seek-public-comment> [https://perma.cc/6F8E-PADP].
 99. Gina Kolata, ‘*Nothing to Do with Genes’: Racial Gaps in Pandemic Stem from Social Inequities, Studies Find.*, N.Y. TIMES (Dec. 9, 2020), <https://www.nytimes.com/2020/12/09/world/nothing-to-do-with-genes-racial-gaps-in-pandemic-stem-from-social-inequities-studies-find.html> [https://perma.cc/68CF-88XM].
 100. Gbenga Ogedegbe et al., *Assessment of Racial/Ethnic Disparities in Hospitalization and Mortality in Patients with COVID-19 in New York City*, JAMA NETWORK OPEN, 2020, at 1, 1.

found that “[a]lthough Black patients were more likely than White patients to test positive for COVID-19, after hospitalization they had lower mortality, suggesting that neighborhood characteristics may explain the disproportionately higher out-of-hospital COVID-19 mortality among Black individuals.”¹⁰¹ Ultimately, this led to the conclusion that “existing structural determinants pervasive in Black and Hispanic communities may explain the disproportionately higher out-of-hospital deaths due to COVID-19 infections in these populations.”¹⁰² In commenting on the study for the *Times* story, its lead author Dr. Gbenga Ogedegbe noted that “[w]e hear this all the time — ‘Blacks are more susceptible’ . . . It is all about the exposure. It is all about where people live. It has nothing to do with genes.”¹⁰³

A similar study of hospitalization and mortality in Louisiana, published in June 2020 in the *New England Journal of Medicine*, likewise found that “Black race was not associated with higher in-hospital mortality than white race.”¹⁰⁴ That is, once they were admitted, Black patients fared no worse than White patients. Therefore, the study concluded, differences in clinical presentation and mortality likely reflected social factors such as risk of community exposure or “longer wait to access care.”¹⁰⁵ In a larger study of 92 hospitals across 12 states, Yehia and colleagues found that “there was no statistically significant difference in all-cause, in-hospital mortality between White and Black patients after adjusting for other factors.”¹⁰⁶ This study again indicated that once Black patients actually obtained access to comparable care, the disparities in mortality disappeared.

Now contrast these studies with those discussed earlier that looked, for example, “beyond social and economic explanations”¹⁰⁷ for genetic bases to explain COVID-19 disparities. The former are based on empirical observations of existing conditions informed by historical understandings of the social structures shaping those conditions. The latter tend to be abstract hypotheses of possible genetic pathways that *might* involve differing certain alleles that occur at different frequencies in certain socially identified racial groups. Such studies almost always involve trying to explain conditions that disproportionately impact

101. *Id.*

102. *Id.* at 2.

103. Kolata, *supra* note 99.

104. Eboni G. Price-Haywood et al., *Hospitalization and Mortality among Black Patients and White Patients with Covid-19*, 382 *NEW ENG. J. MED.* 2534, 2534 (2020).

105. *Id.*

106. Baligh R. Yehia et al., *Association of Race with Mortality Among Patients Hospitalized With Coronavirus Disease 2019 (COVID-19) at 92 US Hospitals*, *JAMA NETWORK OPEN*, 2020, at 1, 6.

107. Chaudhary et al., *supra* note 50.

social groups that have experienced a history of social dispossession and injustice.

On the one hand, it is quite reasonable to want to explore how genes contribute to the spread and severity of COVID-19. Such analysis was central to the development of the mRNA vaccines by Pfizer and Moderna.¹⁰⁸ However, looking for a genetic explanation of the structure and functioning of SARS-COV-2 is not the same thing as using genes to explain racial disparities in morbidity and mortality in those suffering from COVID-19. Epidemiologist Jon Zelner at the University of Michigan lead another of the studies discussed in the Kolata article.¹⁰⁹ He asserted that the toll on Black and Hispanic Americans “could easily have been ameliorated in advance of the pandemic by a less threadbare and cruel approach to social welfare and health care in the U.S.”¹¹⁰ Trying to find race-specific genetic differences to explain such disparities not only has little scientific basis, it also diverts attention exactly from these sorts of historical and social inequities that pre-dated the pandemic and structured its racialized impact.

Misconceiving the relationship between race and biological difference can also negatively impact medical treatment. Racism in medical treatment and research has a long and sordid history in this country.¹¹¹ In 1966, Martin Luther King Jr. is said to have declared that “[o]f all the forms of inequality, injustice in health care is the most shocking and inhumane.”¹¹² Incidents of racial bias in access to and delivery of health care have been glaringly evident at least since the publication in 2002 of *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*.¹¹³ This major study, sponsored by the Institute of Medicine, considered racial inequities in quality of care

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108. U.S. FOOD & DRUG ADMIN., FDA BRIEFING DOCUMENT PFIZER-BIONTECH COVID-19 VACCINE 7 (Dec. 10, 2020); Tal Zaks, Chief Medical Officer at ModernaTX, Presentation to FDA, Emergency Use Authorization (EUA) Application for mRNA-1273 (Dec. 17, 2020).
109. Jon Zelner et al., *Racial Disparities in Coronavirus Disease 2019 (COVID-19) Mortality Are Driven by Unequal Infection Risks*, 72 CLINICAL INFECTIOUS DISEASE e88, e88 (2021).
110. Kolata, *supra* note 99.
111. HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* (2006).
112. Amanda Moore, *Tracking Down Martin Luther King, Jr.'s Words on Health Care*, HUFFPOST (Jan. 18, 2013), https://www.huffpost.com/entry/martin-luther-king-health-care_b_2506393 [<https://perma.cc/3VVZ-LN27>].
113. INST. MED. NAT'L ACAD. *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* (Brian D. Smedley, Adrienne Y. Stith, & Alan R. Nelson, eds., 2002).

within multiple facets of the health infrastructure.¹¹⁴ *Unequal Treatment* focused on social factors but following the completion of the Human Genome Project in 2003, genetic studies of racial disparities seemed to proliferate.¹¹⁵

As COVID-19 was ravaging the country in the summer of 2020, Vyas et al. published a major study in the *New England Journal of Medicine* documenting the problems created by the “subtle insertion of race into medicine [through] diagnostic algorithms and practice guidelines that adjust or ‘correct’ their outputs on the basis of a patient’s race or ethnicity.”¹¹⁶ The authors stated:

Physicians use these algorithms to individualize risk assessment and guide clinical decisions. By embedding race into the basic data and decisions of health care, these algorithms propagate race-based medicine. Many of these race-adjusted algorithms guide decisions in ways that may direct more attention or resources to white patients than to members of racial and ethnic minorities.¹¹⁷

Such disparate allocation of attention and resources might be justified if there were a true genetic basis to the racial algorithms, but the Vyas study found that developers of such algorithms often had either no clearly articulated rationale for using race as they did, or used rationales based on faulty or outdated data.¹¹⁸

This is problematic both for immediate concerns of quality of care and also because, as the authors noted:

Most race corrections implicitly, if not explicitly, operate on the assumption that genetic difference tracks reliably with race. If the empirical differences seen between racial groups were actually due to genetic differences, then race adjustment might be justified: different coefficients for different bodies.

Such situations, however, are exceedingly unlikely. Studies of the genetic structure of human populations continue to find more variation within racial groups than between them.¹¹⁹

114. *Id.*

115. See Lundy Braun et al., *Racial Categories in Medical Practice: How Useful Are They?*, 4 PLOS MED. 1423, 1424 (2007); KAHN, *supra* note 64, at 293.

116. Darshali A. Vyas, Leo G. Eisenstein, & David S. Jones, *Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms*, 383 NEW ENG. J. MED. 874, 874 (2020).

117. *Id.*

118. *Id.* at 879.

119. *Id.*

This study looked at race-adjusted algorithms in such areas as cardiology, nephrology, and obstetrics. It concluded that “by embedding race into the basic data and decisions of health care, these algorithms propagate race-based medicine. Many of these race-adjusted algorithms guide decisions in ways that may direct more attention or resources to white patients than to members of racial and ethnic minorities.”¹²⁰ This study was conducted largely before COVID-19 had taken hold in the United States, but it speaks directly to how the biologization of racial difference can affect access to and delivery of care.

As the nature of COVID-19 became better understood, doctors began looking to measure levels of oxygen in the blood using devices known as pulse oximeters to diagnose hypoxemia, or low blood oxygen, as indicative of the presence and severity of the disease. A pulse oximeter is a clamp-like device that clips onto a finger. As a Michigan study published in the *New England Journal of Medicine* in December 2020 noted, “[o]xygen is among the most frequently administered medical therapies, with a level that is commonly adjusted according to the reading on a pulse oximeter that measures patients’ oxygen saturation.”¹²¹ Yet this study of two large cohorts determined that

Black patients had nearly three times the frequency of occult hypoxemia that was not detected by pulse oximetry as White patients. Given the widespread use of pulse oximetry for medical decision making, these findings have some major implications, especially during the current coronavirus disease 2019 (Covid-19) pandemic. Our results suggest that reliance on pulse oximetry to triage patients and adjust supplemental oxygen levels may place Black patients at increased risk for hypoxemia.¹²²

The reason for this particular technologically mediated disparity is fairly simple. Pulse oximeters work by sending two types of red light through the finger from one arm of the clamp which is then picked up by a sensor of the other side to detect the color of your blood. The redder the blood, the more highly oxygenated it is. But pulse oximeters were developed using algorithms calibrated to detect oxygen levels in lighter skinned people; so they often mis-read blood levels of darker skinned people. This has nothing to do with the genetics of blood oxygen levels, it has to do with using a white norm to develop diagnostics.

Following the publication of the *New England Journal of Medicine* study, Senators Ron Wyden, Cory Booker, and Elizabeth Warren wrote

120. *Id.* at 874.

121. Michael W. Sjoding et al., *Racial Bias in Pulse Oximetry Measurement*, 383 NEW ENG. J. MED. 2477, 2477 (2020).

122. *Id.* at 2478.

to the acting director of the FDA requesting it “conduct a review of the interaction between a patient’s skin color and the accuracy of pulse oximetry measurements.”¹²³ The following month, the FDA issued a public warning about the devices, acknowledging they had limitations but pointedly not using the word “race.” Instead, the FDA alert cautioned that “a recent report . . . suggests that the devices may be less accurate in people with dark skin pigmentation.”¹²⁴ On the one hand, this alert appropriately decoupled dark skin pigmentation (a biological attribute) from race (a social attribute). On the other hand, the original report explicitly mentioned race in part because it noted that the inaccuracies in pulse oximeter readings could have racially disproportionate impacts that might aggravate already existing health disparities. This is one of the great tensions in using race in medicine—sometimes taking race out of the picture obscures the impact of racism.

A February 2021 Comment published in *The Lancet Respiratory Medicine* similarly asked: “Could routine race-adjustment of spirometers exacerbate racial disparities in COVID-19 recovery?”¹²⁵ Spirometers are devices that originated in the 19th century, used to measure lung function. As Lundy Braun has shown in her masterful study of the development and application of spirometry, the use of the device has long been plagued by the use of highly problematic and inaccurate “race-corrections” that often lead to the misdiagnosis of Black patients.¹²⁶ The authors of the 2021 Comment cautioned that “these race adjustments could potentially cause clinicians to miss important diagnoses” in Black COVID-19 patients and “influence treatment plans” to their detriment.¹²⁷

Biologized racial difference in relation to COVID-19 has also been invoked under very different circumstances, for example, in trying to obtain compassionate release from prison. In such instances, courts have embraced the idea of race as social rather than genetic construct in order to deny those compassionate release requests. In one federal case, a prisoner seeking COVID-19-related compassionate release from prison cited a number of physiological conditions which he alleged placed him at higher risk for severe COVID-19. Among them: simply that he was

123. Letter from Elizabeth Warren, Ron Wyden, & Cory A. Booker, Senators, to Dr. Janet Woodcock, Acting Comm’r, U.S. Food & Drug Admin. (Jan. 25, 2021) (on file with the U.S. Senate).

124. U.S. FOOD & DRUG ADMIN., SAFETY COMMUNICATION ON PULSE OXIMETER ACCURACY AND LIMITATIONS (2021).

125. Meredith A. Anderson et al., *Could Routine Race-Adjustment of Spirometers Exacerbate Racial Disparities in COVID-19 Recovery?*, 9 LANCET RESPIRATORY MED. 124, 124 (2021).

126. LUNDY BRAUN, BREATHING RACE INTO THE MACHINE: THE SURPRISING CAREER OF THE SPIROMETER FROM PLANTATION TO GENETICS 204-05 (2014).

127. Anderson et al., *supra* note 125.

an “African-American male” and that “the virus has hit the African-American community particularly hard and is killing men at a higher rate than women.”¹²⁸ The court refused his release plea, noting that “[w]hile some have suggested that genetic factors might explain these differences, defendant concedes that the reasons remain unknown.”¹²⁹ Similarly, in the case of *United States v. Alexander*, the court denied the defendant prisoner’s application for compassionate release, stating that:

[I]t is not clear that being African-American increases Defendant’s risk of complications from the COVID-19, in the same manner as one’s underlying medical conditions. Indeed, although African Americans are overrepresented in data regarding COVID-19 hospitalizations and deaths in America as a whole, this overrepresentation may result from other systemic economic and social issues affecting the African American community, including access to health care, higher prevalence of underlying conditions, and lack of access to health insurance.¹³⁰

In response to a similar claim from a prisoner in Colorado, federal district court Judge Robert Blackburn cited anthropologist Lance Gravlee’s *Scientific American* post to support his contention that “[a]lthough some researchers suggest there also may be a biological component to African Americans’ observed susceptibility to the disease . . . that idea is neither proven nor uncontested It thus is entirely speculative whether Mr. Billings’s race, in and of itself, increases his risks of contracting the virus or experiencing a more severe course of the virus. This consideration therefore cannot be considered compelling.”¹³¹

In light of the legal underpinnings to COVID-19 disparities identified by Yearby and Mohapatra,¹³² the irony of federal courts embracing the idea that race is not genetic is palpable. While these courts certainly get the science right, this position stands in marked contrast to the ways in which representatives from other federal agencies, pharmaceutical corporations, and academic research centers discussed [referred to] race and biological difference in relation to COVID-19 during the same period of time. Specifically, those representatives, agencies, and corporations made repeated and

128. *United States v. Johnson*, No. 17-CR-162, 2020 U.S. Dist. WL 2770266, at *5 (E.D. Wis. May 28, 2020).

129. *Id.* at *1, *5.

130. *United States v. Alexander*, No. CV 19-32, 2020 U.S. Dist. WL 2507778, at *4 (D.N.J. May 15, 2020).

131. *United States v. Billings*, No.19-CR-00099-REB, U.S. Dist. WL 4705285, at *3 n. 5 (D. Colo. Aug. 13, 2020) (citing Gravlee, *supra* note 32).

132. Yearby & Mohapatra, *supra* note 91.

widespread calls to “diversify” clinical trials for COVID-19 vaccines by enrolling more Black bodies as subjects. One might well wonder why it is that some agents of the federal government were so willing to embrace ideas about the social construction of race when it served to keep Black bodies in detention while under different circumstances other agents of the federal government were so ready to invoke biological racial difference as grounds for enrolling Black bodies in clinical trials. Such divergence points up the importance of examining the work that a given conceptualization of race is doing in different contexts, and in whose interests such conceptualizations are being deployed. This is the subject of the next section of this article.

II. THE RACIALIZATION OF VACCINE TRIALS

The broad discussions of biological difference framing COVID-19 disparities created a powerful rationale for racializing emergent vaccine trials by calling for inclusion of “diverse” bodies as a scientific imperative. At the same time that discourses of biological difference were being used by some to *explain* disparities, others were using biological difference as a purported basis for *addressing* disparities. As sociologist Steven Epstein showed over a decade ago in his masterful book, *Inclusion: The Politics of Difference in Medical Research*, diversifying the racial composition of clinical trials has been a growing concern of researchers and the federal government since the 1980s.¹³³ A key transitional moment in this story was the passage of the 1993 NIH Revitalization Act, which required that women and members of “minority groups” be included as research subjects in NIH-funded studies unless a valid reason for non-inclusion was articulated. The Act also established an Office of Research on Minority Health within the NIH.¹³⁴

Despite the passage of the Act, some of those working on health disparities expressed discomfort at the implicit geneticization of racial differences encompassed in such calls for inclusion. Otis Brawley, then director of NCI’s Office of Special Populations Research, worried that implementation of the NIH Revitalization Act Guidelines “may eventually do more harm than good for the minority populations that it hopes to benefit. The legislation’s emphasis on potential racial differences fosters the racism that its creators want to abrogate by establishing government-sponsored research on the basis of the belief that there are significant biological differences among the races.”¹³⁵

133. STEVEN EPSTEIN, *INCLUSION: THE POLITICS OF DIFFERENCE IN MEDICAL RESEARCH* 1-2 (2008).

134. *Id.* at 82.

135. Otis W. Brawley, *Response to “Inclusion of Women and Minorities in Clinical Trials and the NIH Revitalization Act of 1993 – The Perspective*

Moreover, Brawley opined, it might “distract from truly important health care issues[] . . . [by] encourag[ing] scientists to waste time and resources looking for minute, insignificant biological differences and to ignore social and environmental influences.”¹³⁶

Yet since 1994, diversity in clinical trials has been a mantra of the industry even as racial disparities have persisted and in some cases deepened. In 1997 Congress passed the FDA Modernization Act, which called upon pharmaceutical companies to include racial data in their new drug approval submissions.¹³⁷ The FDA itself followed up with official guidance papers in 1999,¹³⁸ 2005,¹³⁹ and 2016,¹⁴⁰ each of which encouraged and provided direction for the collection of race-specific data in the drug development and approval process.

This is not to say that such calls for diversity in clinical trials were nefarious or wholly without merit. Certainly, racial inclusion, when understood as related to variable social, environmental, and historical conditions along with differential rates of comorbidities, can be very relevant for clinical trials and a potential way to address issues of racial equity. However, it is very difficult, though not impossible, to maintain the use of racial categories as social variables once introduced into biomedical contexts. This is especially true where the researchers involved are generally not trained to understand or appreciate the complexities of race as a bio-cultural construct – that is, a social construct with very real biological implications for individuals whose bodies are being racialized. The general foundations for racializing COVID-19 clinical trials were thus broad and deep, but the proximate context and frame for racializing specific vaccine trials in 2020 was clearly conditioned by the racialization of the disease itself.

Calls for racial inclusion and diversity in clinical trials for COVID-19 vaccines came early and persistently from a wide variety of sources, ranging from industry and government to media, civil rights groups, and the biomedical community itself. As early as April 2020, a group of sixteen U.S. Democratic Senators sent an open letter to the CEOs of major pharmaceutical corporations requesting that “that any vaccine

of NIH Clinical Trialists,” 16 CONTROLLED CLINICAL TRIALS 293, 293 (1995).

136. *Id.*

137. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified as amended in scattered sections of 21 U.S.C.).

138. Guidance for Industry on Population Pharmacokinetics, 64 Fed. Reg. 6663 (Feb. 10, 1999).

139. Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials, 70 Fed. Reg. 54,946 (Sept. 19, 2005).

140. U.S. FOOD & DRUG ADMIN., COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2016).

or therapeutic drug trials related to COVID-19 include women, minorities, and LGBTQ+ persons.”¹⁴¹ The letter noted various social factors contributing to already-observed racial disparities in COVID-19 morbidity and mortality and noted that “alarming research shows that although ‘African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.’”¹⁴²

In July 2020, NIH Director Francis Collins and CDC Director Robert Redfield appeared before a Senate subcommittee with other top government scientists, they emphasized the importance of diversifying COVID-19 vaccine trials. Redfield insisted that “[t]he last thing we want is to be trying to recommend who gets the vaccine and we don’t have any data on how the vaccine works in the population’ that needs it.”¹⁴³ Similarly, in August, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, expressed his desire “to see minorities enrolled in coronavirus vaccine trials at levels at least double their percentages in the population, because COVID-19 has hit those groups especially hard.”¹⁴⁴

By June 2020, the FDA had already issued a “Guidance for Industry on the Development and Licensure for Vaccines to Prevent COVID-19,” which “encourage[d] the inclusion of diverse populations in all phases of vaccine clinical development.”¹⁴⁵ In November, it followed up with another Guidance, this time specifically on “Enhancing the Diversity of Clinical Trial Populations” wherein it elaborated on issues of eligibility criteria, enrollment practices and trial design and noted that the FDA had been steadily working to diversify clinical trials over the past few decades.¹⁴⁶

Prominent academic and non-profit organizations such as the Henry Ford Health System and the Kaiser Family Foundation similarly emphasized the importance of racially diversifying COVID-19 vaccine

141. Letter from Robert Menendez et al., Senators, to David A. Ricks, Chief Exec. Officer, Eli Lilly & Co. (Apr. 20, 2020) (on file with the U.S. Senate).

142. *Id.*

143. Mary Chris Jaklevic, *Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials*, 324 JAMA 826, 827 (2020).

144. Elizabeth Cohen, *Moderna Increases Minority Numbers in Its Vaccine Trial, But Still Not Meeting Fauci’s Goal*, CNN (Aug. 29, 2020), <https://www.cnn.com/2020/08/29/health/moderna-coronavirus-vaccine-minorities-goal/index.html> [<https://perma.cc/V2TX-UQFC>].

145. U.S. FOOD & DRUG ADMIN., DEVELOPMENT AND LICENSURE OF VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY (2020) [hereinafter GUIDANCE FOR INDUSTRY].

146. Enhancing the Diversity of Clinical Trial Populations – Eligibility, Criteria, Enrollment Practices, and Industry, 85 Fed. Reg. 71,654 (Nov. 10, 2020).

trials. They released statements purporting to explain “Why [] Diversity [Is] So Important In Vaccine Trials[]”¹⁴⁷ and declared that “[e]nsuring racial and ethnic diversity in clinical trials for development of COVID-19 vaccines is particularly important[.]”¹⁴⁸ Especially resonant were the calls from prominent Black leaders in the medical community, such as the National Medical Association (the largest and oldest national organization representing African-American physicians) and leaders at Historically Black Colleges and Universities (HBCUs). In June, the National Medical Association and the Alliance of Multicultural Physicians urged Congress and the FDA “to make diversity in clinical trials a greater priority.”¹⁴⁹ Similarly, the Presidents of Dillard and Xavier Universities issued a joint statement in September 2020, declaring that “[i]t is of the utmost importance that a significant number of black and brown subjects participate” in COVID-19 vaccine trials.¹⁵⁰ That same month, representatives of four historically Black medical schools (Meharry Medical College, Howard University, Morehouse School of Medicine, and Charles Drew University of Medicine and Science) stated their commitment “to the inclusion of Black, Indigenous and people of color (BIPOC) as we engage in research initiatives focused on the novel coronavirus, SARS CoV-2.”¹⁵¹

Popular media reported widely on the calls for clinical trial diversity. In August, National Public Radio aired an interview with Renee Mahaffey Harris, president of the Center for Closing the Health Gap, which was titled “More People of Color Needed in COVID-19 Vaccine Trials.”¹⁵² That same month, *STAT News* published a story

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147. *Why Is Diversity So Important In Vaccine Trials?*, HENRY FORD HEALTH SYSTEM (Nov. 24, 2020), <https://www.henryford.com/blog/2020/11/diversity-in-vaccine-trials> [<https://perma.cc/F3BD-SWZT>].
 148. Samantha Artiga et al., *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/FYY3-VTHC>].
 149. *COVID-19 Treatments Must Work for Communities of Color*, NAT’L MED. ASS’N (June 11, 2020), <https://www.nmanet.org/news/512553/COVID-19-Treatments-Must-Work-for-Communities-of-Color.htm> [<https://perma.cc/MV3S-326B>].
 150. Walter M. Kimbrough & C. Reynold Verret, *A Message From the Presidents of Dillard and Xavier*, DILLARD UNIV. (Sept. 2, 2020), <https://dillard.edu/communications/news/xavier-dillard-vaccine-trials.php> [<https://perma.cc/GP66-G7YU>].
 151. Wayne A. I. Frederick et al., *Joint Statement on the Integrity of Vaccine Trials and the Inclusion of Black, Indigenous and People of Color*, HOW. NEWSROOM (Sept. 17, 2020), <https://newsroom.howard.edu/newsroom/article/13236/joint-statement-integrity-vacc> [<https://perma.cc/MM7C-ZPN6>].
 152. *More People of Color Needed In COVID-19 Vaccine Trials*, NAT’L PUB. RADIO (Aug. 23, 2020), <https://www.npr.org/2020/08/23/905181731/>

noting “Covid-19 clinical trials are failing to enroll diverse populations, despite awareness efforts.”¹⁵³ In June, NBC National News ran a story on the importance of diversifying clinical trials asserting that “[a] COVID-19 vaccine will work only if trials include Black participants[.]”¹⁵⁴ Many other major news outlets, including the *Wall Street Journal*,¹⁵⁵ *The New York Times*,¹⁵⁶ and *The Washington Post*¹⁵⁷ published stories and opinion pieces on the importance of diversifying COVID-19 vaccine trials.

The pharmaceutical industry was responsive to these calls. In May 2020, the Chief Diversity Officer and the Head of U.S. Medical Affairs for Genentech issued a “call for more inclusive COVID-19 research.”¹⁵⁸ Testifying before a U.S. House Subcommittee in July 2020, a representative from Johnson & Johnson declared that it “is committed to robust representation of diverse populations in our studies.”¹⁵⁹ The

more-people-of-color-needed-in-covid-19-vaccine-trials [https://perma.cc/HJL6-YCGW].

153. Adam Feuerstein, Damian Garde, & Rebecca Robbins, *Covid-19 Clinical Trials Are Failing to Enroll Diverse Populations, Despite Awareness Efforts*, STAT (Aug. 14, 2020), <https://www.statnews.com/2020/08/14/covid-19-clinical-trials-are-are-failing-to-enroll-diverse-populations-despite-awareness-efforts/> [https://perma.cc/4PZ8-FRVV].
154. Curtis Bunn, *A COVID-19 Vaccine Will Work Only if Trials Include Black Participants, Experts Say*, NBC NEWS (June 7, 2020), <https://www.nbcnews.com/news/nbcblk/covid-19-vaccine-will-only-work-if-trials-include-black-n1228371> [https://perma.cc/56BN-K2GZ].
155. Brian Gormley, *Researchers Look for Ways to Make Drug Trials More Diverse*, WALL ST. J. (Mar. 28, 2021), <https://www.wsj.com/articles/researchers-look-for-ways-to-make-drug-trials-more-diverse-11616885108> [https://perma.cc/K3SE-6ZEP].
156. Wayne A.I. Frederick et al., *We Need to Recruit More Black Americans in Vaccine Trials*, N.Y. TIMES (Sept. 11, 2020), <https://www.nytimes.com/2020/09/11/opinion/vaccine-testing-black-americans.html> [https://perma.cc/K6S7-AC8Z].
157. Karen Bass, *People of Color Are Disproportionately Affected By Covid-19. Yet They Are Underrepresented in Vaccine Trials*, WASH. POST (Sept. 1, 2020), https://www.washingtonpost.com/opinions/karen-bass-covid-trials-people-of-color-underrepresented-/2020/09/01/9f5c8502-ebae-11ea-ab4e-581edb849379_story.html [https://perma.cc/RBH6-CXBD].
158. Quita Highsmith & Jamie Freedman, *A Call For More Inclusive COVID-19 Research: Tackling Disparities During a Pandemic*, GENENTECH (May 22, 2020), <https://www.gene.com/stories/a-call-for-more-inclusive-covid-19-research> [https://perma.cc/V5Q9-RMAQ].
159. *Pathway to a Vaccine: Efforts to Develop a Safe, Effective, and Accessible COVID-19 Vaccine Virtual Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. (2020) (statement of Macaya Douoguih, Head of Clinical Development and Medical Affairs, Janssen Vaccines and Prevention, Johnson & Johnson).

major trade group PhRMA issued a statement in October, recognizing that “achieving clinical trials that include diverse populations presents an ongoing challenge[,]” and affirmed its commitment “to enhance the diversity of clinical trial participants[.]”¹⁶⁰ In presenting data on its COVID-19 vaccine to the FDA for approval in December, Pfizer emphasized “the importance of conducting the study in people of color,”¹⁶¹ and asserted that “from the very start [it was] focused on targeting in recruitment from racial and ethnic minorities.”¹⁶² Moderna was so responsive to these concerns that it actually paused its clinical trial in October in order to increase minority enrollment.¹⁶³ By April 2021, the industry trade publication *Scrip* was even promoting the Twitter hashtag “#ClinicalTrialsSoWhite.”¹⁶⁴

Concerns for clinical trial diversity were also evident throughout the FDA review process for both the Pfizer and the Moderna vaccines. Pfizer reported that, of a total clinical trial population of 40,277 subjects, 3929, or 9.8%, were Black and 10553 or 26.2% were Hispanic/Latino.¹⁶⁵ Moderna similarly reported that of its 30,351 clinical trial subjects approximately 10% were Black and 21% Hispanic or Latino.¹⁶⁶ A number of people and organizations submitting

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160. *Principles on Conduct of Clinical Trials Communication of Clinical Trial Results*, PhRMA (Oct. 14, 2020), <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMAPrinciples-of-Clinical-Trials-FINAL.pdf>.
161. U.S. FOOD & DRUG ADMIN., 162ND VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING OF THE U.S. FOOD AND DRUG ADMIN. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (2020) [hereinafter 162ND MEETING OF VACCINES], <https://www.fda.gov/media/144859/download> [<https://perma.cc/G8LX-YBYJ>] (transcript of the statement of William Gruber, Pfizer Senior Vice President of Vaccine Clinical Research & Development available at 211).
162. *Id.* (available at 352).
163. Julie Steenhuysen, *Moderna Vaccine Trial Contractors Fail to Enroll Enough Minorities, Prompting Slowdown—Sources*, REUTERS (Oct. 6, 2020), <https://www.reuters.com/article/idUSL1N2GW1F0> [<https://perma.cc/HFY2-FUJT>].
164. @PharmaScrip, TWITTER (Apr. 17, 2021), <https://twitter.com/PharmaScrip/status/1383329928867762180> [<https://perma.cc/TA9V-MFK3>].
165. U.S. FOOD & DRUG ADMIN., VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING, PFIZER-BIONTECH COVID-19 VACCINE BRIEFING DOCUMENT (2020) [hereinafter PFIZER-BIONTECH BRIEFING DOCUMENT], <https://www.fda.gov/media/144245/download> [<https://perma.cc/32EP-JVTS>].
166. U.S. FOOD & DRUG ADMIN., VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING, MODERNATX, INC., PRESENTATION FOR EMERGENCY USE AUTHORIZATION (EUA) APPLICATION FOR MRNA-127 (2020), <https://www.fda.gov/>

comments to the FDA on the proposed vaccines also raised concerns about clinical trial diversity. For example, the American Academy of Pediatrics cautioned that “the population studied *must reflect the racial and ethnic diversity* of the US population[.]”¹⁶⁷ the Associate Director of Health Policy for the National Consumers League requested “that the FDA continue to prioritize vaccine clinical trial data that reflects diversity[.]”¹⁶⁸ and the Executive Director of the National Women’s Health Network flatly asserted that “there were not enough Black and Indigenous people included in the Moderna phase 3 trial.”¹⁶⁹ In response, Dr. William Gruber, Senior Vice President of Pfizer Vaccine Clinical Research and Development, assured the FDA review committee that “[w]e also recognized the importance of conducting the study in people of color; so we have adopted an approach that assures a diverse racial and ethnicity profile.”¹⁷⁰

Such calls to diversify clinical trials for COVID-19 vaccines at times came to take on the character of a sort of diversity panic. Horrible things, it seemed, would happen if clinical trials did not sufficiently represent diverse populations. The vaccine would not work; it would not be safe; it would not be trusted. Only through diversity could such catastrophes be avoided. Upon close inspection, however, such claims were often based on questionable assumptions, incomplete data, and problematic definitions of such basic concepts as “diversity” and “representation.”

Calls to diversify the clinical trials for COVID-19 vaccines were repeated, widespread, and persistent. Rationales for diversifying clinical trials, and more specifically diversifying them by *race*, can be organized into three basic (and sometimes overlapping) categories: biological, social, and political. Biological rationales generally had to do with concerns for safety, efficacy, and generalizability of trial results. Social rationales revolved around addressing issues of trust and vaccine hesitancy. Lastly, political rationales involved commitments to address equity in access to care and therapeutics.

media/144583/download [https://perma.cc/BR76-PD97] (presented by Tal Zaks, Chief Medical Officer).

167. Letter from Mark Del Monte, Chief Exec. Officer, Am. Acad. of Pediatrics, to Hana El Sahly, Chair, U.S. Food & Drug Admin.: Vaccines & Biological Products Advisory Comm. & Prabhakara Atreya, Director, U.S. Food & Drug Admin: Div. of Sci. Advisors & Consultants (Oct. 15, 2020) (on file with the Am. Acad. of Pediatrics).

168. 162ND MEETING OF VACCINES, *supra* note 161 (available at 172).

169. Letter from Cynthia A. Pearson, Executive Director, National Women’s Health Network, to U.S. Food & Drug Admin. Vaccines and Related Biological Products Advisory Committee (Dec. 17, 2020), <https://www.regulations.gov/comment/FDA-2020-N-2242-0379> [https://perma.cc/5A4X-7P3].

170. 162ND MEETING OF VACCINES, *supra* note 161, at 211.

III. UNPACKING THE BIOLOGICAL RATIONALES FOR DIVERSE VACCINE CLINICAL TRIALS

Biological, social, and political rationales for diversifying clinical trials may be reasonable, but only if clearly articulated and justified. Too often when race is introduced into the field of biomedicine these rationales become intertwined, confused, and conflated in a manner that threatens to reify race as genetic and divert attention away from the social and political bases of health inequities.

A. Empirical Bases for Concerns about Diversity

Calls to diversify vaccine clinical trials focused on the importance of obtaining data that showed the vaccines were safe and effective in *all* relevant racial and ethnic groups. The Democratic Senators' April 20, 2020 letter to leading pharmaceutical CEOs was very clear about this, ominously quoting from a statement issued by the Johns Hopkins University Science Policy Group in 2017. The quote read:

Inequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.¹⁷¹

Months later, in answering “Key Questions” on “Racial Diversity within COVID-19 Vaccine Clinical Trials[.]” researchers from the Kaiser Family Foundation asserted that “[d]iversity within clinical trials for a COVID-19 vaccine helps ensure safety and effectiveness[.]”¹⁷² Significantly, this report also noted that “[d]iverse racial/ethnic representation in COVID-19 vaccine trials is important because drugs and vaccines can differentially affect groups reflecting variation in underlying experiences and environmental exposure.”¹⁷³

Such sensitivity to the complex relationship between race and non-genetic factors in immune response stands in marked contrast to many media reports, such as one by NBC News from June 2020, which quoted a retired pulmonologist who asserted that “[g]enetics related to racial differences make it essential that we be involved in broad-based and diverse clinical trials of medications and vaccines.”¹⁷⁴ The NBC report

171. Menendez et al., *supra* note 141 (citing Leah Cairns, *Diversity in Clinical Trials*, JOHNS HOPKINS SCI. POL. GROUP (Sept. 6, 2017), <https://www.jhscipolgroup.org/blog-1/2017/9/6/diversity-in-clinical-trials> [<https://perma.cc/U3LP-LV6K>]).

172. Artiga et al., *supra* note 148.

173. *Id.*

174. Bunn, *supra* note 154.

then flatly stated this meant that “[a] vaccine might not work in African Americans if African Americans do not participate in the clinical trials to create the drug.”¹⁷⁵

Not all media reports quite so baldly geneticized race. A quote from a story in *StatNews* by UC San Francisco oncologist Hala Borno is more typical of media reporting; Borno stated: “I think that if we do not ensure diversity in these Covid-19 clinical research studies, we may ultimately render interventions, whether it be drug or vaccines, that do not uniformly demonstrate efficacy across populations, or have side effects that we only capture later on.”¹⁷⁶ A more recent study of inclusion in vaccine trials published in *JAMA Network Open* asserted: “Historically, clinical trials have lacked equitable inclusion of people identifying as members of racial/ethnic minority groups and female and older individuals. When people with diverse backgrounds are not adequately represented, treatments shown to be effective in trials may not be generalizable to or effective for all populations.”¹⁷⁷ Similarly, Paulette Chandler, a primary care physician and lead of community engagement and education for COVID-19 vaccine trials at Boston’s Brigham and Women’s Hospital stated in September 2020 that “unless we have a diverse group of people involved in the trial, we will not be able to generalize our findings to every group.”¹⁷⁸

The theme is clear and consistent. There is an assumption that essential biological racial difference is somehow directly related to how a vaccine works – either in terms of its efficacy or its side effects. References to “generalizability” are particularly concerning because, without explicitly invoking the idea of racial differences, they imply that results from trials conducted in people of one race simply cannot be extrapolated to people of another race. The problem is that there was little or no evidence to support these race-specific concerns about safety, efficacy, or generalizability, and certainly not sufficient evidence to warrant major efforts to reconfigure (and perhaps delay) clinical trials in a time of pandemic emergency.

While diversifying clinical trials has long been a concern of both the federal government and an array of biomedical institutions, prior to 2020 there had been relatively little discussion of the need or importance of diversity in vaccine trials specifically. Just over two years before the COVID-19 outbreak, the World Health Organization issued a report

175. *Id.*

176. Feuerstein, Garde, & Robbins, *supra* note 153.

177. Laura E. Flores et al., *Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials*, 4 JAMA NETW. OPEN, at 3 (2021).

178. Kristin Toussaint, *COVID-19 Vaccine Trials Are Being Undermined By a Lack of Diversity*, FAST CO. (Sept. 28, 2020), <https://www.fastcompany.com/90555722/why-covid-19-vaccine-trials-still-need-more-diversity> [<https://perma.cc/5DQE-4YBY>].

titled “Design of vaccine efficacy trials to be used during public health emergencies—points of considerations and key principles”¹⁷⁹ that made no reference to race at all, and only one reference to ethnicity in the context of considering vulnerable groups in potential need of protection from exploitation by researchers.¹⁸⁰ An article titled “Design of vaccine efficacy trials during public health emergencies,” published in *Science Translational Medicine* in July 2019 on the eve of the COVID-19 outbreak, similarly had no mention of race or ethnicity in relation to issues of safety, efficacy, of generalizability of trial results.¹⁸¹ Another lengthy review article published in 2019 examining “factors that influence the immune response to vaccination” does mention studies of ethnic variability in response to vaccines in one sentence out of 30 pages of text.¹⁸² However, the studies it references tend to involve not large racial groups, but localized ethnic populations, such as different ethnic groups within Guatemala or a particular region of China.¹⁸³ None of the cited studies found any difference in safety or efficacy based on race or ethnicity.¹⁸⁴ To the contrary, instead of focusing on race, the bulk of the Zimmerman and Curtis article is devoted to examining factors such

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179. *Design of Vaccine Efficacy Trials to Be Used During Public Health Emergencies – Points of Considerations and Key Principles*, WORLD HEALTH ORG., [https://www.who.int/docs/default-source/blue-print/working-group-for-vaccine-evaluation-\(4th-consultation\)/ap1-guidelines-online-consultation.pdf](https://www.who.int/docs/default-source/blue-print/working-group-for-vaccine-evaluation-(4th-consultation)/ap1-guidelines-online-consultation.pdf) [<https://perma.cc/2SYQ-RUX5>] (last visited Feb. 20, 2022).
180. *Id.*
181. Natalie E. Dean et al., *Design of Vaccine Efficacy Trials During Public Health Emergencies*, 11 SCI. TRANSL. MED. 499, 499 (2019).
182. Petra Zimmermann & Nigel Curtis, *Factors That Influence the Immune Response to Vaccination*, 32 CLIN. MICROBIOL. REV., at 1, 5 (2019).
183. *Id.* at 37. It also cites three studies by one researcher who uses broader racial groups to identify variable immune response to certain vaccines but without identifying any underlying genetic mechanism to explain the difference or finding any difference in safety or efficacy. *Id.*
184. Three of the articles cited by the study, all with the same lead author, do purport to find racial difference in immune response to certain vaccines, but these findings are both limited and equivocal. As one of these studies states: “Ethnicity and race-specific data on infectious disease susceptibility and clinical course, and/or differences in immune responses to pathogens and vaccines is limited in the literature, and the underlying mechanisms for the reported observations are still unknown,” and goes on to note that “the observed statistically significant effects (cytokine response differences) in our study are relatively small and there is no known correlate of protection for vaccinia-specific cell-mediated immunity.” Iana H. Haralambieva et al., *Race and Sex-Based Differences in Cytokine Immune Response to Smallpox Vaccine in Healthy Individuals*, HUMAN IMMUNOL., 2013, at 1, 4.

as co-morbidities, behavior, nutrition, environmental exposures and the nature of the vaccine itself and its administration.¹⁸⁵

As for the three COVID-19 vaccines that were ultimately developed in the United States during 2020 and approved by the FDA—all found to have a similar safety and efficacy profile across all racial subgroups. This can largely be explained by the simple fact that race is not genetic. The FDA reported that the first approved vaccine, developed by Pfizer, showed efficacy to be “consistent across various subgroups, including racial and ethnic minorities,”¹⁸⁶ and its “safety profile” to be “generally similar across age groups, genders, ethnic and racial groups.”¹⁸⁷ The FDA came to similar conclusions regarding the Moderna vaccine, finding vaccine efficacy among racial and ethnic “subgroups” to be similar to that “seen in the overall study population”¹⁸⁸ and identifying “no specific safety concerns . . . in subgroup analyses by age, race, [or] ethnicity.”¹⁸⁹ Finally, for the Johnson & Johnson vaccine, the FDA concluded that efficacy “among the subgroups (age, comorbidity, race, ethnicity) appears to be similar to the [vaccine efficacy] in the overall study population,”¹⁹⁰ and “there were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.”¹⁹¹

Given the consistency of these results (not to mention their concordance with experience from previous vaccines) it is, perhaps, worth revisiting some of the early, urgent calls to diversify the COVID-19 vaccine trials. What were their rationales and what sort of evidence did they present to support their concerns? Noteworthy in this regard is the April 20, 2020 letter from the sixteen Democratic U.S. Senators to leading pharmaceutical CEOs calling for diversity in vaccine clinical trials. Coming from such prominent and powerful politicians, relatively early in the pandemic, it set a powerful frame for conceptualizing the clinical trial process. Of particular force was the quotation, referenced

185. Zimmermann & Curtis, *supra* note 182, at 3.

186. PFIZER-BIONTECH BRIEFING DOCUMENT, *supra* note 165.

187. *Id.*

188. U.S. FOOD & DRUG ADMIN., VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING, MODERNA COVID-19 VACCINE BRIEFING DOCUMENT (2020), <https://www.fda.gov/media/144434/download> [<https://perma.cc/A249-CXLK>].

189. *Id.*

190. U.S. FOOD & DRUG ADMIN., VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING, JANSSEN AD26.COV2.S VACCINE FOR THE PREVENTION OF COVID-19 BRIEFING DOCUMENT (2021) [hereinafter JANSSEN BRIEFING DOCUMENT], <https://www.fda.gov/media/146217/download> [<https://perma.cc/MVT9-6XYQ>].

191. *Id.*

above, to a statement issued by the Johns Hopkins University Science Policy Group in 2017. The full paragraph in the letter states:

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population. “As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”¹⁹²

Let us unpack this reference and the work it did in the Senators’ letter. First, even on its face, the quoted passage refers to drugs, not vaccines. More specifically, it refers to drug metabolism and toxicity. The biological mechanisms underlying drug metabolism and immune response, while often related, are distinct.¹⁹³ Variance in drug metabolism is common and is affected by many things, including diet, other medications, comorbidities, and genetics. For any given drug there will be a standard or normal rate of metabolization, and there will also be a certain range of individuals who metabolize the drug more quickly or more slowly than the norm. This can be particularly important for determining proper dosage. Rapid metabolizers might require a higher dose for the drug to be effective, while slower metabolizers might need a lower dose because the drug stays in their system longer. When slow metabolizers receive normal or high doses, this can cause toxic reactions. Several drugs’ labels mention race or ethnicity as a factor in determining whether someone is likely a rapid or slow metabolizer, but this is a crude proxy for prediction of the rate of metabolization.¹⁹⁴ It is important to note that there is no clear concordance of race and drug metabolization. Instead, in some cases, there is merely an observation that for some drugs certain racial groups may have, on average, a higher frequency of rapid or slow metabolizers than others. In any event, drug metabolization is not directly related to the immune response provoked by a vaccine.¹⁹⁵

192. Menendez et al., *supra* note 141 (citing Cairns, *supra* note 171).

193. See, e.g., Gökhan S. Hotamisligil, *Inflammation, Metaflammation and Immunometabolic Disorders*, 542 NATURE 177, 177 (2017).

194. S. U. Yasuda, L. Zhang, & S-M. Huang, *The Role of Ethnicity in Variability in Response to Drugs: Focus on Clinical Pharmacology Studies*, CLIN. PHARMACOL. THER., 2008, at 1, 2-3.

195. A classic example of this is the widely prescribed anti-coagulant drug warfarin, which is commonly prescribed to patients who are at risk of developing blood clots, such as persons with atrial fibrillation, recurrent strokes, deep venous thrombosis, pulmonary embolism, or those who have

Second, the Johns Hopkins statement cited by the Senators is itself only a blog post that, in turn, cites a study from the Journal of Women's Health to support its statement.¹⁹⁶ This study¹⁹⁷ does *not* support the Johns Hopkins assertion that many drugs “have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.” Rather, it states that “several drugs have been withdrawn from the market over the last two decades because of **sex-based** adverse events,” and then goes on to merely observe that “with regard to race and ethnicity, a number of studies have found variations in drug metabolism and toxicity” in various drugs. Again, this is without reference to any vaccines.¹⁹⁸ This is not an insignificant difference. It refers only to withdrawing drugs for sex-based differences, not race. For race, it simply restates the widely observed phenomenon that for certain drugs there may be different frequencies of rapid and slow metabolizers in different ethnic groups.

This second study itself references a third study to support its statement about sex-based drug withdrawals.¹⁹⁹ That study, published in the European Journal of Clinical Pharmacology, observed that “[s]everal publications indicate that the female gender experiences a higher incidence of adverse drug reactions (ADRs) than does the male gender. *The reasons, however, remain unclear.* Gender-specific differences in the pharmacokinetic and pharmacodynamic behaviour of

received heart valve replacements. It is difficult to calibrate the right dose for an individual patient because warfarin has a narrow therapeutic window of efficacy and a wide-range of inter-individual variability in response; that is people tend to metabolize the drug at different rates. If you are fast metabolizer and do not get a high enough dose, you risk developing clot clots. If you are a slow metabolizer and get too high a dose, you risk having a dangerous hemorrhage. Many studies over the years have noted correlations between certain broad ethnic or racial groups and likelihood of being a rapid or slow metabolizer. Drug labels have noted this for years. In the past decade specific genetic variations have been identified that greatly affect warfarin metabolization and dosing algorithms have been developed to replace the cruder use of racial categories with genetic testing. Nonetheless, the use of race as a crude proxy in drug dosing for warfarin (and some other drugs) persist. See KAHN, *supra* note 64, at 157-92.

196. Cairns, *supra* note 171.

197. Meghan Coakley et al., *Dialogues on Diversifying Clinical Trials: Successful Strategies for Engaging Women and Minorities in Clinical Trials*, 21 J. WOMENS HEALTH 713, 714 (2012).

198. *Id.* at 714-15 (emphasis added).

199. *Id.* at 714 (citing Y. Zopf, C. Rabe, A. Neubert et al., *Women Encounter ADRs More Often Than Do Men*, 64 EUR. J. CLIN. PHARMACOL. 999 (2008)).

drugs could not be identified as an explanation.”²⁰⁰ The study concluded that while “our data confirm the higher risk of ADRs among female subjects compared with a male cohort . . . [n]o single risk factor could be identified.”²⁰¹ This study, while confirming gender-specific differences in drug response, made no mention of withdrawing drugs from the market.

This is not to say the claim regarding FDA concerns with sex-based differences in drug response is wholly without merit. Indeed, a 2001 General Accounting Office study (not cited by the Johns Hopkins statement) did find that eight of the ten drugs withdrawn from the market between 1997 and 2000 posed higher risks for women.²⁰² Even so, there is a marked difference between finding that the drugs withdrawn *happened* to have a higher risk for women, and determining that the drugs were withdrawn *because* they had a higher risk for women. Still none of this speaks to alleged race-based differences in safety or efficacy as grounds for drug withdrawal, and also does not speak to race-based differences in vaccine response. In short, despite what the letters from the Senators claimed, existing evidence supported the conclusion of bioethicists Angela Ballantyne and Agomoni Ganguli-Mitra that, “on balance there is no biological imperative to achieve representative recruitment of minoritized populations in COVID vaccine trials.”²⁰³

The example of the Senators’ letter illustrates how the casual blurring of boundaries and elision of distinctions can lead to the reification of racial difference as genetic. Moreover, as is made evident by the 2019 review of factors influencing vaccine response referenced above,²⁰⁴ non-genetic behavioral, environmental, and social factors certainly dwarf any possible importance of race for assessing variable vaccine response. A vaccine cannot elicit any response in someone who is either unable to access it or unwilling take it.

The questionable empirical basis for concerns about racial variance in vaccine efficacy or safety is only the first issue that needs to be unpacked in the realm of biological rationales for diversifying clinical

200. Y. Zopf, C. Rabe, A. Neubert et al., *Women Encounter ADRs More Often Than Do Men*, 64 EUR. J. CLIN. PHARMACOL. 999, 999 (2008) (emphasis added).

201. *Id.*

202. Letter from Janet Heinrich, Director Health Care – Public Health Issues, U.S. General Accounting Office, to Senators Tom Harkin, Olympia J. Snowe, and Barbara A. Mikulski and Representative Henry A. Waxman (Jan. 19, 2001), <https://www.gao.gov/assets/gao-01-286r.pdf> [<https://perma.cc/A8AY-JTAK>].

203. Angela Ballantyne & Agomoni Ganguli-Mitra, *To What Extent Are Calls for Greater Minority Representation in COVID Vaccine Research Ethically Justified?*, 21 AM. J. BIOETHICS 99, 99 (2021).

204. Zimmermann & Curtis, *supra* note 182, at 3.

trials. The second issue is what exactly was meant by “diversity” when diversity was called for in clinical trials for COVID-19 vaccines.

B. What Is Meant By “ Diversity” in Vaccine Trials?

Calls to “diversify” the COVID-19 vaccine clinical trials typically invoked, in a commonsense fashion, the basic Census categories of race and ethnicity (*i.e.*, White, Black, Asian/Pacific Islander, American Indian/Alaska Native, Hispanic/Non-Hispanic) that have their foundation in a 1997 Directive from the Office of Management and Budget.²⁰⁵ These categories structured the 1993 NIH Revitalization Act directive to increase diversity in clinical trials, and have since become the default categories for much of biomedical research and regulation.²⁰⁶ They are also generally the same categories that were used to identify and trace racial disparities in the impact of COVID-19.

But why the focus on race in the first place? Often in studies arguing for the relevance of race as a genetic category in biomedical research, the authors argue that race is an apt proxy for continental genetic ancestry.²⁰⁷ This sort of conceptualization of diversity was evident in some of the studies of the possible genetic underpinnings to COVID-19 disparities, particularly those involving the global distribution of HLA haplotypes.²⁰⁸ Yet, such efforts to capture ancestral genetic diversity were not prominent in discussions of COVID-19 vaccine trials. Presentations before the FDA during the review processes for the various vaccines generally did not engage issues of genetic diversity but simply focused on the demographic Census categories.

Apparently, then, when it came to calls to diversify vaccine trials, clinical trial designers simply assumed, without evidence, that demographic categories of race had some biologic relevance to vaccine performance. One might just as easily have called for diversifying vaccine trials to ensure adequate representation of left-handed people. Left-handedness as a phenotype is perhaps more closely related to

205. Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 Fed. Reg. 58,782 (Oct. 30, 1997).

206. *See generally*, KAHN, *supra* note 64, at 25-47; EPSTEIN, *supra* note 133, at 74-93.

207. *See e.g.*, Esteban González Burchard et al., *The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice*, 348 NEW ENG. J. MED. 1170, 1170 (2003); Luisa N. Borrell et al., *Race and Genetic Ancestry in Medicine – A Time for Reckoning with Racism*, 384 NEW ENG. J. MED. 474, 474 (2021).

208. Nguyen et al., *supra* note 46; Debnath et al., *supra* note 46; Langton et al., *supra* note 46.

genetic difference than is race.²⁰⁹ In the United States about 13% of the population is left-handed.²¹⁰ Roughly the same percentage of the population is Black; thus, if researchers are concerned with genetically diverse representation, why was nobody talking about this or any number of other possible population group differences? Perhaps because we do not have a centuries-old biomedical tradition of trying to discern biological differences between “righties” and “lefties” as a means to justify social hierarchy or explain away disparities. Of course, historically, being left-handed has also been stigmatized, but the consequences of such stigmatization have always been understood to be social in character and not due to any underlying genetic difference. Hence, no need to enroll lefties in clinical trials in proportion to their representation in the population. Black people, however, are another story. As the marked disparities in COVID-19’s impact were attributed “in part” to some presumed, if unidentified, genetic differences – that is, as the consequences of the stigmatized characteristic were attributed to biology instead of society – there emerged a purported biological rationale to single out race, among a wide range of possible demographic characteristics, as essential for representation in vaccine trials.

As we look more closely at invocations of the need for diversity, we see further refinements of the basic Census categories that elaborate the biological rationales for the call. For example, in its November 2020 Guidance for Industry on “*Enhancing the Diversity of Clinical Trial Populations*,” the FDA emphasized the importance of enrolling subjects who will better reflect the population most likely to use the drug,²¹¹ i.e., those affected with the condition the drug is meant to treat. However, the same Guidance also makes it clear the “sponsors should enroll participants who reflect the characteristics of clinically relevant populations with regard to age, sex, race, and ethnicity . . . [because] analyzing data on race and ethnicity may assist in identifying population-specific signals.”²¹² This echoes concerns about possible racial differences in response to some drugs; however, as discussed, in the response to COVID-19, we are not dealing with a drug, nor with a

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209. *Genes Associated with Left-Handedness Linked with Shape of the Brain’s Language Regions*, OXFORD U. (Sept. 5, 2019), <https://www.ox.ac.uk/news/2019-09-05-genes-associated-left-handedness-linked-shape-brains-language-regions> [https://perma.cc/7V5T-9CP3].
210. Niall McCarthy, *The Countries with the Most Left-Handed People*, STATISTA (Feb. 4, 2020), <https://www.statista.com/chart/20708/rate-of-left-handedness-in-selected-countries/> [https://perma.cc/8GSS-4FUH].
211. *Enhancing the Diversity of Clinical Trial Populations*, 85 Fed. Reg. 71,654 (Nov. 10, 2020).
212. *Id.*; U.S. FOOD & DRUG ADMIN., *ENHANCING THE DIVERSITY OF CLINICAL TRIAL POPULATIONS — ELIGIBILITY CRITERIA, ENROLLMENT PRACTICES, AND TRIAL DESIGNS GUIDANCE FOR INDUSTRY* (2020), <https://www.fda.gov/media/127712/download> [https://perma.cc/44QY-MCH].

“population most likely to use the drug.” Rather, we are dealing with a vaccine, and the population most likely to use it is – ideally – everyone.

More specific to the COVID-19 vaccine trials was the idea that the trials must be representative of communities bearing the heaviest disease burden or at the highest risk of contracting the disease. These categories certainly have a public health logic to them, but they can also be moving targets during a period of emergent crisis. Certainly, as in the case of COVID-19 with its well-documented disparate impact in the United States, they may loosely map onto racial groupings. Thus, for example, in its June 2020 Guidance to Industry on “*Development and Licensure of Vaccines to Prevent COVID-19*,” the FDA, when urging the “inclusion of diverse populations” in clinical trials, “strongly encourage[d] the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”²¹³ In order to evaluate “vaccine safety and efficacy,” the Guidance encouraged “adequate representation of elderly individuals and individuals with medical comorbidities.”²¹⁴ The distinctions between the two categories of inclusion are significant. This is the only place race is mentioned in the Guidance, and it is *not* directly connected to concerns of safety or efficacy. The rationale for racial inclusion in the Guidance is that it is a marker of populations “most affected” by COVID-19. Similarly, Dr. Ann Falsey of the University of Rochester School of Medicine further contextualized diversity as a function more of *risk* than of race when she told a journalist at *JAMA*: “[w]e are thinking very hard about not only how to get a diverse population that reflects the US population but also people at high risk—postal workers, home health workers, you name it.”²¹⁵

In comments submitted to the FDA regarding its review of the Pfizer vaccine, the Infectious Diseases Society of America emphasized that “COVID-19 vaccines should be adequately studied in populations that have been disproportionately impacted by the pandemic and who face disparities in care, including the elderly; individuals with chronic conditions; and Black/African American, Indigenous, Latinx, and other communities of color.”²¹⁶ Here disparate impact is connected with access to care. There is, in other words, no explicit biological rationale for racial inclusion. Rather, in these examples we see the rationale for using race as being grounded in concepts of risk or concerns for equity. It is

213. GUIDANCE FOR INDUSTRY, *supra* note 145.

214. *Id.*

215. Jaklevic, *supra* note 143.

216. *Comment Letter on Vaccines and Related Biological Products Advisory Committee Notice*, INFECTIOUS DISEASES SOC'Y AM. (Dec. 4, 2020), <https://www.regulations.gov/comment/FDA-2020-N-1898-0105> [<https://perma.cc/R5FQ-M7AU>].

thus possible to make appeals for diversity in ways that do not assert or imply that racial difference is genetic. Nonetheless, given that at this time many studies were being published arguing that genetic susceptibility to COVID-19 varied by race, it is also possible that this framing reflected those biologized understandings of racial disparities in COVID-19.

Other calls for diversity in clinical trials more directly geneticized race. In a blog posting by Henry Ford Health System, Dr. Paul Kilgore, co-principal investigator for its Johnson & Johnson COVID-19 vaccine trial, declared: “When people have different genetic and biologic makeup, their bodies can produce antibodies differently. This means to ensure a vaccine will protect people of all ethnic groups, we need to make sure everyone is fully represented in clinical trials.”²¹⁷ We also see an interest in disparate impact blur into presumptions of essential biological difference in the concerns expressed by Dr. Anna Durbin, principal investigator at the Johns Hopkins Center for Immunization Research, who insisted that racial diversity was necessary to “to make sure it works in the groups most affected by COVID-19.”²¹⁸ The focus on equity is laudable, and concerns for safety and efficacy are reasonable, but it is difficult to keep these issues separate and distinct. In juxtaposing the two in relation to race, the reification of race as genetic becomes almost inevitable, especially in a biomedical culture suffused with understandings of race as an essential biological category.²¹⁹

Calls to diversify COVID-19 vaccine trials also extended to hiring the health workforce responsible for carrying out the trials. The general idea was that upstream representation of racial minorities in the health professions would increase downstream willingness to participate in clinical trials. For example, in discussing COVID-19 vaccine trials on National Public Radio, Renee Mahaffey Harris, president of the Center for Closing the Health Gap, noted that “due to the fact that COVID-19 has had a disproportionate impact to Black and Latino people across this country, it is more paramount than ever that the trials be reflective of a bigger proportion of Black and Latino people.” She then went on to assert the importance of having more Black and Latino doctors and researchers represented at “the early part of creating the trial.”²²⁰ In

217. *Why Is Diversity So Important In Vaccine Trials?*, *supra* note 147.

218. Brennen Jensen, *Boosting Diversity in COVID-19 Vaccine Clinical Trials*, HOPKINS BLOOMBERG PUB. HEALTH MAG. (Nov. 9, 2020), <https://magazine.jhsph.edu/2020/boosting-diversity-covid-19-vaccine-clinical-trials> [<https://perma.cc/J596-ZG38>].

219. *See generally* CATHERINE BLISS, RACE DECODED (2020); ANN MORNING, THE NATURE OF RACE: HOW SCIENTISTS THINK AND TEACH ABOUT HUMAN DIFFERENCE (2011); Vyas, Eisenstein, & Jones, *supra* note 116.

220. *More People Of Color Needed In COVID-19 Vaccine Trials*, NAT'L PUB. RADIO (Aug. 23, 2020), <https://www.npr.org/2020/08/23/905181731/>

October 2020, the Pharmaceutical Research and Manufacturers of America (PhRMA) issued “Principles on Conduct of Clinical Trials Communication of Clinical Trial Results,” in which it declared that “[e]nhancing meaningful representation of diverse participants in clinical trials would help provide information about drug response and measures of safety and efficacy in populations that have been historically under-represented and under-studied, in particular Black and Brown people.”²²¹ PhRMA went on to assert that to achieve this goal it was necessary to “enhance[] diversity among clinical trial investigators.”²²² This shows both the flexibility and ambiguity of the concept of diversity. In relation to clinical trial subjects, diversity was often used in a way that presumed essential biological differences among racial groups. Yet it was often invoked by the same actors to apply in a wholly social sense to the need to diversify the workforce. The issue here is not that such uses of diversity are wrong or incorrect, but that it is a slippery concept that ranges across social and biological domains. The concept of diversity needs to be employed carefully in contexts where the conflation or confusion of social and biological conceptions of racial difference are likely to occur.

IV. HOW MUCH DIVERSITY IS ENOUGH?

Once you determine that you want or need representation from diverse racial groups in clinical trials, the next question becomes just how much diversity is enough? In terms of biomedical concerns, one generally wants to enroll “enough” people to ensure statistically robust results showing safety and efficacy in any given “population.” This is, in theory at least, what has been driving calls for inclusion going back to the 1993 NIH Revitalization Act.²²³ When it comes to racially marked populations, concepts of what constitutes adequate representation vary significantly. Such variance may be due, in part, to the particular rationale for diversity one is seeking to serve. It may also simply be due to a lack of attention as to why racial diversity may or may not matter in a vaccine trial. Clarifying such issues matters because it allows us to differentiate among biological, social, and political rationales for diversity and ensure that socio-political concerns for diversity do not

more-people-of-color-needed-in-covid-19-vaccine-trials [https://perma.cc/4ENB-VLDB].

221. *Principles on Conduct of Clinical Trials Communication of Clinical Trial Results*, PhRMA (Oct. 14, 2020), <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMAPrinciples-of-Clinical-Trials-FINAL.pdf> [https://perma.cc/U9NR-RYBQ].

222. *Id.*

223. Jaklevic, *supra* note 143.

become entangled with or transformed into reified biological understandings of race.

To begin with, the FDA has never specified how much minority representation it wanted to see in COVID-19 vaccine trials, and NIH Director Francis Collins acknowledged in July 2020 that there was no general agreement on the percentage of minorities the trials should include. While some scientists were arguing that percentages should be representative of the distribution of the current burden of disease, others were arguing for more straightforward demographic representation equivalent to each group's percentage of the overall use population – approximately 13% for Blacks and 18% for non-White Hispanics.²²⁴

In August 2020 Director Fauci told CNN that he “wanted to see minorities enrolled in coronavirus vaccine trials at levels at least double their percentages in the population, because Covid-19 has hit those groups especially hard.”²²⁵ That would equate to roughly 26% percent representation for Blacks and 36% for non-White Hispanics, amounting to 62% of the entire trial population just for those two groups. The final numbers reported by Pfizer and Moderna were nowhere near this, but they did approach (though fall short of) proportional demographic representation. In December 2020, shortly after the FDA had approved the Pfizer and Moderna vaccines, the National Medical Association reviewed the trial enrollment data and concluded that the roughly 10% of Blacks enrolled in each trial was “sufficient to have confidence in health outcomes of the clinical trials.”²²⁶

What does this mean in terms of absolute numbers? In any clinical trial, if there is a population of interest, enough of those subjects should be enrolled to provide statistically robust data about that population. A typical Phase 3 drug trial enrolls between 300 and 3,000 subjects.²²⁷ Phase 3 trials demonstrate whether or not a product offers a treatment benefit to a specific population and immediately precede submission for FDA approval.²²⁸ Vaccine trials are often much larger, usually in the tens of thousands, in part because they are typically administered to large numbers of otherwise healthy individuals; and so concerns for

224. *Id.*

225. Cohen, *supra* note 144.

226. *NMA COVID-19 Task Force on Vaccines and Therapeutics, Advisory Statement on Federal Drug Administration's Emergency Use Authorization Approval for Pfizer and Moderna Vaccine*, NAT'L MED. ASS'N (Dec. 21, 2020), <https://www.nmanet.org/news/544970/NMA-COVID-19-Task-Force-on-Vaccines-and-Therapeutics.htm> [<https://perma.cc/FY74-8D54>].

227. *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [<https://perma.cc/KBE4-5TPK>] (last visited Feb. 20, 2022).

228. *Id.*

safety are higher.²²⁹ For example, trials for the recently developed HPV (human papilloma virus) vaccine ranged from 5,500 to 18,500 subjects.²³⁰ One review of trials for thirteen vaccines conducted between 2000 and 2010 found that enrollment in Phase 3 trials ranged from 2,358 to 80,427 with a mean of 29,844 and a median of 22,938.²³¹ As noted above, Pfizer enrolled 40,477 subjects and Moderna 30,351 in their COVID-19 trials, thus falling within a fairly standard range, somewhat above both the mean and the median for recent vaccine trials. While the considerations in designing a vaccine trial differ somewhat from those of designing a drug trial, it is worth considering that between them, in absolute numbers, Pfizer and Moderna enrolled 6,633 Black subjects.²³² Indeed, it is over six times the number enrolled in the Phase 3 trial for the race-specific heart failure Drug, BiDil, which enrolled *only* self-identified African American subjects.²³³ In such cases 6,663 subjects would clearly be deemed “enough” representation to address issues of safety and efficacy.

Vaccine trials typically try to enroll larger numbers. Consider the total of 6,633 as compared with the median and mean numbers from the study mentioned above. The 6,633 would amount to approximately 22% of the mean enrollment of 29,844 and 29% of the median enrollment of 22,938, coming very close to the enriched representation numbers suggested by Dr. Fauci. These are very crude calculations and not directly applicable to the complexities of evaluating the adequacy of a given trial design. Nonetheless, they are instructive for thinking about how “representation” was being conceptualized in relation to COVID-19 vaccine trials and just what sorts of consideration might be used in considering how much “diversity” is enough. These figures also bring into relief the sort of diversity panic that seemed to swirl around the

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229. Paul Griffin, *Explaining Vaccine Clinical Trial Phases*, MED. XPRESS (Aug. 27, 2020), <https://medicalxpress.com/news/2020-08-vaccine-clinical-trial-phases.html> [<https://perma.cc/Z7LE-QXVL>].
230. John T. Schiller, Xavier Castellsagué, & Suzanne M. Garland, *A Review of Clinical Trials of Human Papillomavirus Prophylactic Vaccines*, VACCINE, 2012, at 1, 3.
231. Steven H. Weinberg, Amy T. Butchart, & Matthew M. Davis, *Size of Clinical Trials and Introductory Prices of Prophylactic Vaccine Series*, HUMAN VACCINES & IMMUNOTHER., 2012, at 1, 2.
232. Admittedly, combining numbers from two different vaccine trials is problematic for numerous reasons. Nonetheless, the vaccines were based on similar technologies and had similar safety and efficacy profiles. Combining the numbers here is not meant to make a specific biomedical point but rather as a heuristic device for thinking about how numbers are being conceptualized in relation to “diversity” and “representation” in these trials.
233. See Anne L. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 NEW ENG. J. MED. 2049, 2049-50 (2004).

trial enrollment process -- a panic, it seems, which cannot be wholly explained by biomedical considerations of safety, efficacy, and generalizability. Rather, the widespread calls for diversity in clinical trials gained much of their urgency by combining such biomedical concerns with broader social concerns relating to trust and vaccine hesitancy, and political concerns for equity.

A. Unpacking the Social Rationales for Diverse Vaccine Clinical Trials

Foremost among the social rationales for increasing vaccine trial diversity was a concern to address issues of trust and vaccine hesitancy in minority, particularly Black, communities.²³⁴ In 2015, the SAGE Working Group on Vaccine Hesitancy defined vaccine hesitancy as, “delay in acceptance or refusal of vaccination despite availability of vaccination services.”²³⁵ The report also noted that it is “complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence.”²³⁶ Vaccine hesitancy, in short, is neither a static nor monolithic phenomenon. It can range from unyielding “anti-vaxxers” who will not get any vaccine under any circumstance to those who simply do not wish to be first in line, but rather, want to wait and see how any given vaccine roll-out progresses. It could also include many intermediate attitudes.²³⁷ As one review put it, “not all mistrust is created equal.”²³⁸ Vaccine hesitancy among African Americans is distinctively situated in a history of past and ongoing racist encounters with biomedical institutions, and in many cases is quite different in character and tone from vaccine mistrust expressed by White people.²³⁹ In the context of COVID-19, such differences have become particularly pronounced over time, as Black rates of vaccine hesitancy have steadily declined while rates of

234. See, e.g., Artiga et al., *supra* note 148; Zoe Christen Jones, *Fauci Urges Black Community to Be Confident in COVID-19 Vaccine: “The Time is Now to Put Skepticism Aside,”* CBS NEWS (Dec. 8, 2020), <https://www.cbsnews.com/news/fauci-black-community-covid-19-vaccine/> [<https://perma.cc/L96H-MG96>]; Shadim Hussain, *We Need ‘Horizontal’ Trust to Overcome Vaccine Skepticism,* WIRED (Nov. 21, 2020), <https://www.wired.com/story/we-need-horizontal-trust-to-overcome-vaccine-skepticism> [<https://perma.cc/PCS7-SBK4>].

235. Noni E. MacDonald & SAGE Working Group on Vaccine Hesitancy, *Vaccine Hesitancy: Definition, Scope and Determinants*, 33 VACCINE 4161, 4163 (2015).

236. *Id.*

237. Lauren Bunch, *A Tale of Two Crises: Addressing Covid-19 Vaccine Hesitancy as Promoting Racial Justice*, 33 HEC FORUM 143, 244 (2021).

238. *Id.* at 147.

239. *Id.*

hesitancy among White Republicans (particularly White male Republicans) have remained consistently and stubbornly high.²⁴⁰

Before exploring such differences further, it is useful first to recognize that before COVID-19 there was very little, if any, discussion of the importance of diversifying vaccine trials to address issues of trust among minorities. One 2020 study looking at past vaccination hesitancy experiences in order to develop “a Social and Behavioral Research Agenda to Facilitate COVID-19 Vaccine Uptake in the United States” focused on the importance of improving experiences of health care delivery and listed many strategies for improving “transparency and community engagement,” but nowhere did it consider diversifying vaccine trials as a means to improve trust and increase vaccine acceptance.²⁴¹ A major 2016 review of 43 studies of vaccine hesitancy listed 23 different determinants affecting vaccine uptake; diversifying clinical trials was not among them, nor was it even mentioned in the article.²⁴² Beyond this, the article concluded that “most interventions to increase vaccine acceptance have shown little or no effect.”²⁴³ The SAGE Working Group of Vaccine Hesitancy similarly found “that, despite extensive literature searching, there are (1) few existing strategies that have been explicitly designed to address vaccine hesitancy; and (2) even fewer strategies that have quantified the impact of the intervention.”²⁴⁴

In light of such findings, it is perhaps surprising that so many biomedical professionals, academics, and policymakers assumed without evidence that diversifying clinical trials (a strategy that had not even been the subject of previous studies) would reduce vaccine hesitancy

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240. Perry Bacon Jr., *Why a Big Bloc of Americans is Wary of the COVID-19 Vaccine – Even as Experts Hope to See Widespread Immunization*, FIVETHIRTYEIGHT (Dec. 11, 2020), <https://fivethirtyeight.com/features/manyc-black-americans-republicans-women-arent-sure-about-taking-a-covid-19-vaccine/> [<https://perma.cc/HBQ8-PRW2>]; Cary Funk & Alec Tyson, *Growing Share of Americans Say They Plan to Get a COVID-19 Vaccine – Or Already Have*, PEW RES. CTR. (Mar. 5, 2021), <https://www.pewresearch.org/science/2021/03/05/growing-share-of-americans-say-they-plan-to-get-a-covid-19-vaccine-or-already-have/> [<https://perma.cc/VRR4-NE5E>]; *National: One in Five Still Shun Vaccine*, MONMOUTH UNIV. POLLING INST. (Apr. 14, 2021), https://www.monmouth.edu/polling-institute/reports/monmouthpoll_US_041421/ [<https://perma.cc/CP99-PZUG>].
241. Emily K. Brunson & Monica Schoch-Spana, *A Social and Behavioral Research Agenda to Facilitate COVID-19 Vaccine Uptake in the United States*, 18 HEALTH SECURITY 338, 340-41 (2020).
242. Angus Thomson et al., *The 5As: A Practical Taxonomy for the Determinants of Vaccine Uptake*, 34 VACCINE 1018, 1018 (2016).
243. *Id.*
244. Caitlin Jarrett et al., *Strategies for Addressing Vaccine Hesitancy – A Systematic Review*, 33 VACCINE 4180, 4186 (2015).

among affected minority groups. As an illustrative example, consider a 2021 statement from the Kaiser Family Foundation on “Racial Diversity within COVID-19 Vaccine Clinical Trials: Key Questions and Answers,” which declared without citation that “[d]iversity within clinical trials for a COVID-19 vaccine helps ensure safety and effectiveness across populations and may increase confidence in getting the vaccine among people of color.”²⁴⁵ A 2021 study published in *JAMA Network Open* on diversity in clinical trials similarly asserted that “[i]mproving racial/ethnic diversity in clinical trials is important because enrollment *may* be associated with vaccination rates in minority groups. Efforts to improve inclusion *may* help to address vaccine hesitancy, provide education, and counter safety concerns about vaccines by ensuring equitable representation in definitive clinical trials.”²⁴⁶ Note the equivocal use of the term “may” to qualify these claims. This was perhaps wise because, while the authors here did provide three citations to support this claim, none of the cited studies actually discussed diversifying clinical trials as a means to address vaccine hesitancy; instead, they simply explored the phenomenon generally in certain minority populations.²⁴⁷ As Ballantyne and Ganguli-Mitra note, “[g]reater participation of minoritized groups in trials may lead to greater trust in the vaccine products— but not necessarily.”²⁴⁸

Those wringing their hands about potential vaccine hesitancy among minority populations might have done well to consider such studies as the one conducted in 2014 by the CDC’s Office of Minority Health and Health Equity. The CDC study found that the Congressionally-authorized Vaccines for Children program had effectively reduced racial and ethnic disparities in vaccination coverage for the MMR and Polio vaccines by focusing on providing practical access.²⁴⁹ Addressing structural issues is thus perhaps more relevant to addressing disparities than speculating about changing trust attitudes through diversifying clinical trials. Such a conclusion comports well with the findings of the Tuskegee Legacy Project, which addressed a range of issues related to the recruitment and retention of Blacks and other minorities in biomedical research studies in the early 2000s.²⁵⁰ The

245. Artiga et al., *supra* note 148.

246. Flores et al., *supra* note 177, at 6 (emphasis added).

247. *See id.*

248. Ballantyne & Ganguli-Mitra, *supra* note 203, at 101.

249. Allison T. Walker et al., *Reduction of Racial/Ethnic Disparities in Vaccination Coverage, 1995-2011*, 63 MORBIDITY & MORTALITY WKLY. REP. 7, 7 (2014).

250. Ralph V. Katz et al., *The Tuskegee Legacy Project: Willingness of Minorities to Participate in Biomedical Research*, 17 J. HEALTH CARE POOR UNDERSERVED 698, 698 (2006); Ralph V. Katz et al., *Willingness of Minorities to Participate in Biomedical Studies: Confirmatory Findings*

Tuskegee Project found that “although Blacks self-report having a higher fear of participation, they are just as likely as Whites to self-report willingness to participate in biomedical research.”²⁵¹ In these contexts, wariness or mistrust did not translate directly into a refusal to participate.

There is also an important distinction to be made between vaccine hesitancy and trial hesitancy. At an outreach session to Black Americans conducted at Meharry Medical College in the summer of 2020, one participant declared: “The word ‘vaccination’ don’t scare me . . . the word ‘trial’ do.”²⁵² Similarly, there was pushback when the presidents of the Dillard and Xavier Universities (both HBCUs) urged community members to participate in clinical trials. “Our children are not lab rats for drug companies. I cannot believe that Xavier is participating in this,” wrote one parent on Xavier’s Facebook page.²⁵³

Such sentiments raise the concern that overzealous calls to diversify clinical trials could create a backlash in terms of both trial and vaccine hesitancy. First, as noted by Rachel Hardiman, of the Center for Antiracism Research for Health Equity at the University of Minnesota, over-energetic outreach to Black communities could increase wariness, rather than alleviate it.²⁵⁴ Those targeted may simply, and for good reason, feel they are being exploited – like lab rats – and hence decline to participate. Second, if the trials themselves do not meet those diversity goals they or others have set, then taking the proffered biological rationales for diversity at face value, members of minority groups might reasonably conclude that the vaccines have not been proven safe or effective for their group. In calling for increasing diverse enrollment in trials in a *New York Times* Op-Ed, leaders from several major HBCU medical centers fed into this dynamic, asserting that

from a Follow-up Study Using the Tuskegee Legacy Project Questionnaire, 99 J. NAT’L MED. ASSOC. 1052, 1052-53 (2007).

251. Katz et al., *The Tuskegee Legacy Project*, *supra* note 250, at 703; Katz et al., *Willingness of Minorities to Participate in Biomedical Studies*, *supra* note 250, at 1052-53.
252. Blake Farmer, *As COVID-19 Vaccine Trials Move at Warp Speed, Recruiting Black Volunteers Takes Time*, NPR (Sept. 11, 2020), <https://www.npr.org/sections/health-shots/2020/09/11/911885577/as-covid-19-vaccine-trials-move-at-warp-speed-recruiting-black-volunteers-takes> [https://perma.cc/ZY6P-E4DQ]. See April Dembosky, *No, the Tuskegee Study is Not the Top Reason Some Black Americans Question the COVID-19 Vaccine*, KQED (Feb. 25, 2021), <https://www.kqed.org/news/11861810/no-the-tuskegee-study-is-not-the-top-reason-some-black-americans-question-the-covid-19-vaccine> [https://perma.cc/YYK9-EWVK].
253. Reuben C. Warren et al., *Trustworthiness Before Trust – Covid-19 Vaccine Trials and the Black Community*, NEW ENG. J. MED., Nov. 26, 2020, at e121(1), e121(1)-(2). See Dembosky, *supra* note 252.
254. Farmer, *supra* note 252.

“[w]ithout significant participation in clinical trials, there will be no proof that our patients should trust the vaccine.”²⁵⁵

Specific differences among types of vaccine hesitancy are evident when comparing the attitudes of Black Americans vs White Republicans. Throughout 2020, polls consistently showed Black Americans expressing greater degrees of hesitancy than Whites, but they also showed Republicans expressing more hesitancy than Democrats.²⁵⁶ Polls conducted by the Pew Research Center showed the percentage of Black Americans saying they would “definitely or probably” get a vaccine falling from 54% in May to below 40% in September and then climbing back to 42% in December.²⁵⁷ These numbers were consistently close to 20% below those for Whites. During this same period, the percentages for Republicans began at 65% in May, falling well below 50% in September before climbing back to 50% in December. These numbers were between 15-19% below those for Democrats.²⁵⁸

Given such numbers, the widespread concern about vaccine hesitancy among Blacks during this time is certainly understandable. However, there was no comparable concern being expressed about Republican hesitancy, and no evidence pointing to the need to enroll more Republicans in vaccine trials in order to address concerns about vaccine hesitancy. Why is it then that when it came to getting more subjects for clinical trials, trust only became an issue for enrolling more Black bodies instead of more Republican bodies? Clearly, there is no definitive answer, but one cannot help but be concerned that the difference lies, at least in part, in an implicit understanding or belief – a frame – that Black bodies were biologically different from White bodies while Republican bodies (quite understandably) were never conceived of as being biologically different from Democratic bodies.

Partisan divides in vaccine hesitancy had been well documented for years before the outbreak of COVID-19. Back in 2009, in response to the outbreak of H1N1 (Swine Flu), a poll conducted by the Pew Research Center found only 41% of Republicans said they would get

255. Frederick et al., *supra* note 156.

256. Cary Funk & Alec Tyson, *Intent to Get a COVID-19 Vaccine Rises to 60% as Confidence in Research and Development Process Increases*, PEW RES. CTR. (Dec. 3, 2020), <https://www.pewresearch.org/science/2020/12/03/intent-to-get-a-covid-19-vaccine-rises-to-60-as-confidence-in-research-and-development-process-increases/> [<https://perma.cc/7NUG-DZD9>].

257. *Id.* See also Alec Tyson et. al., *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*, PEW RES. CTR. (Sept. 12, 2020), <https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/> [<https://perma.cc/296N-T9G4>].

258. Tyson et. al., *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*, *supra* note 257.

vaccinated, compared to 60 percent of Democrats.²⁵⁹ As Matt Nisbet noted in a 2016 article on “Partisan Pandemics:” “trust in government was ultimately the key driver of decisions to be vaccinated. In contrast to their Democratic counterparts, Republicans . . . were less likely to say that they were willing to take the vaccine.”²⁶⁰ Similarly, a 2018 study found that Republicans were far more likely than Democrats to have inaccurate beliefs about vaccines and attributed that difference, at least in part, to “Democrats’ greater support for government programs and science;”²⁶¹ a finding echoed in another 2018 study concluding that political ideology had a powerful effect on attitudes toward vaccines “that is mediated by trust in government medical experts.”²⁶²

Awareness of the partisan divide was not confined to the pages of academic journals. In May 2019, Politico published an article titled: “How the anti-vaccine movement crept into the GOP mainstream.” In the story, Stephanie Wasserman, executive director of the Colorado Children’s Immunization Coalition, noted that “the antivax messaging has shifted from a focus on questions of safety to things like parental rights and data privacy, and those messages resonate more with conservative lawmakers and play to the GOP political base.”²⁶³ The shift in focus from safety to freedom is notable both because it presaged much Republican resistance to COVID-19 vaccines and because it contrasts markedly with the type of mistrust expressed by Blacks. This shift has its recent roots in vaccine efforts undertaken by the Obama administration in 2009 in response to the Swine Flu. As conservative commentator Glenn Beck told his roughly 3 million followers in 2009, “if you have some idiot government official demanding, telling me I must take this vaccine, I’ll never take it.”²⁶⁴ There was invariably an

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259. *Growing Interest in Swine Flu, Many See Press Overstating Its Danger*, PEW RES. CTR. (Oct. 15, 2009), <https://www.pewresearch.org/politics/2009/10/15/growing-interest-in-swine-flu-many-see-press-overstating-its-danger/> [<https://perma.cc/WJP5-XC65>].
260. Matt Nisbet, *Partisan Pandemics*, 40 SKEPTICAL INQUIRER, July-Aug. 2016, at 21, 22.
261. Mark R. Joslyn & Steven M. Sylvester, *The Determinants and Consequences of Accurate Beliefs About Childhood Vaccinations*, 47 AM. POL. RES. 628, 633 (2019).
262. Bert Baumgaertner et al., *The Influence of Political Ideology and Trust on Willingness to Vaccinate*, 13 PLOS ONE 1, 8 (2018).
263. Arthur Allen, *How the Anti-Vaccine Movement Crept into the GOP Mainstream*, POLITICO (May 27, 2019), <https://www.politico.com/story/2019/05/27/anti-vaccine-republican-mainstream-1344955> [<https://perma.cc/BA95-A66M>].
264. Matthew A. Baum, *Red State, Blue State, Flu State: Media Self-Selection and Partisan Gaps in Swine Flu Vaccinations*, 36 J. HEALTH POL. POL’Y & L. 1021, 1022 (2011).

aspect of racialization informing the rising perception that a government led by a Black man was incompetent and a threat to freedom.

The racialization of trust runs powerfully through recent responses to vaccines. In January 2021, Lauren Bunch reflected upon current issues in vaccine hesitancy in response to COVID-19 by discussing a 2016 study which found that, while Blacks' mistrust was rooted in concerns over governmental motives, White mistrust tended to focus more on issues of competence.²⁶⁵ One might reframe this as Blacks' concern being rooted in experiences of exploitation and Whites' more in an ideology of individualistic meritocracy. This difference perhaps accounts for the radical divergence between Black and Republican vaccine hesitancy as the vaccines were actually rolled out in 2021. In December 2020, Black hesitancy was still quite high, with only 42% saying they would "definitely or probably" get vaccinated, while the number for Republicans was 50%.²⁶⁶ After this point, the numbers began to change dramatically. By February 2021, Pew was finding that 61% of Blacks were saying they would "definitely or probably" get vaccinated – only 8% below the number for Whites; in contrast, only 56% of Republicans said they would "definitely or probably" get vaccinated. In two months' time the numbers had shifted by 19% for Blacks but only 6% for Republicans.²⁶⁷

In March, a series of polls conducted by Civiqs showed the following trend from November 9, 2020 to March 28, 2021: Blacks went from 41% saying they would not get vaccinated and 23% unsure (for a total of 64% hesitant) to 11% no and 10% unsure (for a total of 21% hesitant); Republicans went from 41% saying they would not get vaccinated and 23% unsure (for a total of 64% hesitant) to 42% no and 11% unsure (for a total of 53% hesitant).²⁶⁸ By April, a poll conducted by Monmouth University found 43% of Republicans declaring they "likely will never get" vaccinated, in contrast to only 20% of Blacks.²⁶⁹ Such trends illustrate how vaccine hesitancy is neither static nor monolithic, and throws into relief differences between vaccine wariness and outright

265. Bunch, *supra* note 237.

266. Funk & Tyson, *supra* note 240.

267. *Id.*

268. *Coronavirus: Vaccination: Registered Voters*, CIVIQS, https://civiqs.com/results/coronavirus_vaccine?annotations=true&uncertainty=true&zoomIn=true&trendline=true&endline=true [https://perma.cc/M3MK-JRQT] (last visited Mar. 28, 2021) (reporting 49,573 responses as of Mar. 28, 2021). A Kaiser Family Foundation Tracking polls sound similar trends. *KFF Health Tracking Poll/KFF COVID-19 Vaccine Monitor*, KAISER FAM. FOUND. (2021), <https://files.kff.org/attachment/Topline-KFF-COVID-19-Vaccine-Monitor-KFF-Health-Tracking-Poll-February-2021.pdf> [https://perma.cc/G7E9-EK79].

269. MONMOUTH UNIV. POLLING INST., *supra* note 240.

refusal. Blacks' concerns over exploitation were apparently susceptible to amelioration through experience. For Republicans, however, anti-government attitudes and suspicion of expertise remained relatively intransigent. The polling trends would seem to indicate that Blacks were taking a wait-and-see attitude toward the vaccine and have steadily moved toward acceptance. Republicans, in contrast, have demonstrated remarkably consistent and stubbornly high levels of outright refusal in their stance toward vaccination.

The shift in Black attitudes could be held up as evidence of the success in diversifying clinical trials in reducing Black hesitancy. There is no evidence to support this conclusion. There is evidence, however, from the studies discussed above first, previous attempts to address vaccine hesitancy generally had little effect; and second, that Blacks, while initially more hesitant than Whites, would get vaccinated in similar numbers if simply given access.

Despite the well-documented partisan differences in vaccine hesitancy going back over a decade, it was not until such trends became evident in early 2021 that biomedical professionals, commentators, and policymakers started wringing their hands over Republican vaccine hesitancy – this despite the fact the overall response to the pandemic had become highly politicized and polarized over the course of 2020.²⁷⁰ While major initiatives were taken to address Black vaccine hesitancy by seeking to enroll more Black bodies in vaccine trials, no one was calling for demographically representative samples of Republicans to be enrolled. Moderna did not pause its trial so that it could enroll more Republicans. From all indications, partisan affiliation of those enrolling in clinical trials was never tracked. It certainly was not presented in the demographic breakdown of trial results to the FDA by vaccine developers.

In other words, as COVID-19 ravaged through the United States during 2020 and vaccine developers were frantically seeking to enroll people in clinical trials, somehow White mistrust, specifically White Republican mistrust, was largely ignored – that is until the clinical trials were completed, the vaccines came online, and it became evident that White Republican vaccine refusal presented a much greater challenge than Black vaccine wariness.

270. See, e.g., Hunt Allcott et al., *Polarization and Public Health: Partisan Differences in Social Distancing During the Coronavirus Pandemic*, 191 J. PUB. ECON. 1, 3 (2020); see also Anton Gollwitzer et al., *Partisan Differences in Physical Distancing Are Linked to Health Outcomes During the COVID-19 Pandemic*, 4 NATURE HUM. BEHAV. 1186, 1186-91 (2020); J. Clinton et al., *Partisan Pandemic: How Partisanship and Public Health Concerns Affect Individuals' Social Mobility During COVID-19*, 7 SCI. ADVANCES, Jan. 6, 2021, at 1, 1-2.

1. The Racialization of Trust

How specifically, then, did trust become racialized during the COVID-19 pandemic and what sort of work did this racialization do? Black mistrust of biomedical institutions is a widely recognized and much-discussed phenomenon. It has been part of the debates around increasing inclusion in clinical trials going back to the NIH Revitalization Act of 1993.²⁷¹ Many calls for inclusion invoked the legacy of the Tuskegee syphilis experiments²⁷² where, for decades, representatives from the U.S. Department of Public Health withheld treatments from Black men in order to study the course of a disease that they thought functioned somehow differently in Black bodies.²⁷³ Typical of such framings is a report from National Public Radio that opened: “A lingering mistrust of the medical system makes some Black Americans more hesitant to sign up for COVID-19 vaccines . . . The mistrust is rooted in history, including the infamous U.S. study of syphilis that left Black men in Tuskegee, Ala., to suffer from the disease.”²⁷⁴ Notably, this report aired in mid-February 2021, well after polls had begun to show a dramatic shift in Black attitudes toward vaccine acceptance, thus testifying to the power of this narrative. One problem with framing the issue in this manner is that there is little evidence, if any, to support it. Back in 2006, the Tuskegee Legacy Project found that there was no association between knowledge of Tuskegee and actual willingness to participate in research.²⁷⁵ Reflecting back on the Project during the height of the COVID-19 pandemic, Dr. Reuben Warren, director of the National Center for Bioethics in Research and Health Care at Tuskegee University in Alabama, declared that the association of Tuskegee with Black vaccine refusal “was a false assumption . . . The hesitancy is there, but the refusal is not. And that’s an important difference.”²⁷⁶

271. EPSTEIN, *supra* note 133, at 42-44, 187-95.

272. *See, e.g.*, Bunn, *supra* note 154; Dembowski, *supra* note 252.

273. Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CTR. REP., 21, 21 (1978).

274. Debbie Elliott, *In Tuskegee, Painful History Shadows Efforts to Vaccinate African Americans*, NAT’L PUB. RADIO (Feb. 16, 2021), <https://www.npr.org/2021/02/16/967011614/in-tuskegee-painful-history-shadows-efforts-to-vaccinate-african-americans> [<https://perma.cc/L8ZD-ZJ36>].

275. Katz et al., *The Tuskegee Legacy Project*, *supra* note 250, at 707.

276. April Dembosky, *Stop Blaming Tuskegee, Critics Say. It’s Not an ‘Excuse’ for Current Medical Racism*, KAISER HEALTH NEWS (Mar. 25, 2021), <https://khn.org/news/article/stop-blaming-tuskegee-critics-say-its-not-an-excuse-for-current-medical-racism> [<https://perma.cc/4F3V-TD88>].

Much more powerful in driving contemporary Black hesitancy has been the Black community's ongoing everyday lived experiences of racism in encounters with the health care system. As Dr. Lauren Nephew wrote in January 2021, "as a Black woman, I have borne witness to the very system that says it is ready to protect me with a vaccine, systematically disempower my community, putting many at risk of comorbidity and death. . . . Unfortunately, this lack of trust is not just the result of residual pain from past atrocities like the Tuskegee experiments . . . Many patients of color, including myself, can describe present-day experiences in the health care system where we have been discounted, ignored, and devalued."²⁷⁷ Dr. Nephew also cited the case of Dr. Susan Moore, a black physician, whose video of experiencing racism while being treated for COVID-19 went viral after she died from the disease.²⁷⁸ "He made me feel like a drug addict," Dr. Susan Moore said, accusing a white doctor of downplaying her complaints of pain and suggesting she should be discharged."²⁷⁹ As the *New York Times* noted, "Dr. Moore's experience highlighted what many Black professionals said they regularly encountered. Education cannot protect them from mistreatment, they say, whether in a hospital or other settings."²⁸⁰

The focus on Black trust did the work of diverting attention away from the structural and institutional underpinnings of COVID-19 racial disparities and allowed society to concentrate instead on the subjective attitudes of Black people. Focusing on the symptom of vaccine hesitancy allowed policymakers and biomedical professionals to avoid addressing the underlying structural causes of the mistrust. "It's a scapegoat," said Karen Lincoln, a professor of Social Work at the University of Southern California. "It's an excuse. If you continue to use it as a way of explaining why many African Americans are hesitant, it almost absolves you of having to learn more, do more, involve other people – admit that racism is actually a thing today."²⁸¹ As historian of Tuskegee, Susan Reverby, put it: "the news media's focus on mistrust or seemingly ridiculous conspiracies . . . ignores the racist structures that shape economic, political, and social realities that lead to health disparities. The alarming statistics on who is getting the vaccines, and who is not, should shift our attention away from mere mistrust in

277. Lauren D. Nephew, *Systemic Racism and Overcoming My COVID-19 Vaccine Hesitancy*, ECLINICAL MED., Feb. 1, 2021, at 100713.

278. *Id.*

279. John Eligon, *Black Doctor Dies of Covid-19 After Complaining of Racist Treatment*, N.Y. TIMES (Dec. 23, 2020), <https://www.nytimes.com/2020/12/23/us/susan-moore-black-doctor-indiana.html> [<https://perma.cc/L59Y-94XC>].

280. *Id.*

281. Dembosky, *supra* note 252.

communities of color and toward the structures of racism that cause that mistrust.”²⁸²

During 2020, a focus on Black mistrust became a cheap and easy way to superficially address concerns about the manifest problem of racial disparities. This focus may explain why White Republican mistrust was of no major concern until 2021. White Republicans were not experiencing a disproportionate burden of COVID-19 morbidity and mortality, so there was no need to divert attention from any deeper structural issues giving rise to the mistrust. White mistrust was not perceived to be a problem until 2021 because it was not related to issues of racial equity but rather to concerns about herd immunity. This problem did not become manifest until 2021, and so it was not until then that White mistrust became a concern among policymakers and the broader public health community.

B. Unpacking the Political Rationales for Diverse Vaccine Clinical Trials

Concerns for racial equity lie at the heart of the political rationales for diversifying COVID-19 vaccine trials. In her August 2020 letter to Director Collins and Director Fauci, Representative Nanette Diaz Barragán (D-Calif) directly connected her call to diversify trials to equitable “access to the full range of treatments” for COVID-19.²⁸³ A similar letter sent by 22 members of Congress to FDA Commissioner Stephen Hahn and Secretary of Health and Human Services Alex Azar in June 2020 emphasized that diverse clinical trials were essential “to ensure that no demographic group is left behind.”²⁸⁴ The working assumption was that diverse representation in trials was a prerequisite to racially equitable access to safe and effective treatments.

1. Bearing the Burdens of Diversity

In this scheme, what are the burdens of diversity and who bears them? The dangers of COVID-19 are linked to concepts of risk – risk of contracting the virus, risk of morbidity and mortality from contracting the virus, and risk of “being left behind” or not having

282. Susan M. Reverby, *Racism, Disease, and Vaccine Refusal: People of Color Are Dying for Access to COVID-19 Vaccines*, 19 PLoS BIOL. e3001167 (2021).

283. Letter from Rep. Nanette Diaz Barragán to Francis Collins, Director, Nat’l Inst. of Health and Anthony S. Fauci, Director, Nat’ Inst. of Allergy and Infectious Disease (Aug. 25, 2020), <https://barragan.house.gov/wp-content/uploads/2020/08/Vaccine-Trial-Locations-Barragan.pdf> [<https://perma.cc/PL8Q-F5VR>].

284. Letter from Rep. Sean Casten et al. to Stephen Hahn, Comm’r, Food & Drug Admin. and Alex M. Azar II, Sec’y, Dep’t of Hum. Health Services (June 16, 2020), https://luria.house.gov/sites/luria.house.gov/files/wysiwyg_uploaded/6.16.20_Letter%20to%20Commissioner%20Hahn%20and%20Secretary%20Azar%20on%20COVID-19%20Vaccine%20Inclusion.pdf [<https://perma.cc/4VKU-A64M>].

access to vaccines and other care. As Paul Slovic has argued, “danger is real, but risk is socially constructed . . . Whoever controls the definition of risk controls the rational solution to the problem at hand.”²⁸⁵ In 2020 there was a recognized and very real danger that COVID-19 was having a disproportionate impact on racial minorities. In addressing this danger, calls to diversity clinical trials defined risk in terms of representation of Black and Brown bodies. If there was not a sufficiently diverse representation of subjects in vaccine trials then we risked the possibility that the vaccines might not be safe and effective for all groups, thereby exacerbating disparities. Thus, researchers had to make concerted efforts to reach out to communities of color and convince them to enroll. Even if a given vaccine were proven safe and effective in all groups, there was the additional risk that communities of color, particularly Black Americans, might be mistrustful and hesitate to get vaccinated. Diversifying clinical trials was also cast as a means to address this risk.

These constructions of risk place the burdens of addressing disparities directly on the minds and bodies of Black people. Instead of focusing on the need to develop a better community health infrastructure to ensure equitable access to vaccines and related health care, the focus on diversifying clinical trials foregrounded access as a function of the willingness of Black people to make their bodies available for medical experimentation – which, after all is what a “trial” is. Highlighting trust as a barrier to vaccine uptake makes the problem of potential disparities in vaccine uptake a function of addressing attitudes in Black minds. In this framing, the problem is not the ongoing practices and structures of racism; rather, it is the attitudes of Black people. What needs to be changed here is Black minds, not White institutions. Moreover, emphasizing the legacy of Tuskegee makes it seem like the racism responsible for fostering such mistrust is largely a thing of the past, marginalizing the significance of ongoing lived experiences of racism in the health care system.

Similarly, calling for diversity also in the biomedical workforce in order help encourage minority enrollment or mitigate disparities similarly places the burdens on those “diverse” hires.²⁸⁶ The implication of such calls is that the mere act of hiring Black and Brown professionals will address the problem of trust in the community. Beyond perhaps taking a course in “cultural competency,” (which has been happening at medical schools and medical centers for years), White professionals do not have to confront their own racist behavior, change their practices, or redistribute resources. All they have to do is diversify the workforce a bit and the rest will take care of itself. Or

285. Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 19 RISK ANALYSIS 689, 689 (1999).

286. See, e.g., Saini et al., *supra* note 72; Frederick et al., *supra* note 151.

rather, the newly hired “diverse” professionals will take care of diversifying enrollment for them.

Given that the studies finding that most interventions to address vaccine hesitancy had little or no effect, why did so many policymakers and biomedical professionals think that increasing diversity of enrollment was necessary?²⁸⁷ The answer may be that it was easier to focus on changing Black minds than to improve the infrastructure of vaccine delivery. If diverting attention from larger, more difficult structural reforms involved getting more bodies enrolled in clinical trials – so much the better.

I do not mean to assert that there was some sort of nefarious conspiracy to exploit Black bodies and divert attention from deeper structural issues. I do not think calls to diversify clinical trials necessarily involved the sort of “predatory inclusion” identified by Keeanga-Yamahtta Taylor in her study of real estate practices and mortgage pricing in the African American community.²⁸⁸ Nonetheless, the fact remains that the rationales for including more Black bodies in the COVID-19 vaccine trials were tenuous; further, they dangerously threatened to reify race as genetic, thereby potentially inadvertently worsening problems of racial disparities they were trying to address. Calls for inclusion are appealing because they are comparatively easy. Such calls do not involve conflict or competition for limited resources. They merely expand the pie –and in this case, the pie is simply the number of available test subjects.

In this framing, inclusion becomes a substitute for substantive equity. Without evidence, this frame assumes that downstream inclusion will reduce vaccine hesitancy and improve disparities. Increasing enrollment, in whatever form, serves the interests of those conducting the research – *i.e.*, pharmaceutical corporations. Focusing on equity in trial enrollment diverts attention not only from structural conditions causing disparities, it also diverts attention away from economic issues specific to vaccine equity, such as intellectual property protection.²⁸⁹

The intellectual property issue had been raised as early as April 2020, when a group of intellectual property scholars came together to propose an “Open COVID Pledge” in response to President Trump’s

287. Thomson et al., *supra* note 242.

288. KEEANGA-YAMAHTTA TAYLOR, RACE FOR PROFIT: HOW BANKS AND THE REAL ESTATE INDUSTRY UNDERMINED BLACK HOMEOWNERSHIP 5 (2019).

289. *See, e.g.*, Sheryl Gay Stolberg et al., *Pressure Mounts to Lift Patent Protections on Coronavirus Vaccines*, N.Y. TIMES (May 3, 2021), <https://www.nytimes.com/2021/05/03/us/politics/biden-coronavirus-vaccine-patents.html> [<https://perma.cc/PW62-LQJK>]; Walden Bello, *The West Has Been Hoarding More Than Vaccines*, N.Y. TIMES (May 3, 2021), <https://www.nytimes.com/2021/05/03/opinion/covid-biden-wto-vaccine.html> [<https://perma.cc/PEV6-9886>].

emergency orders on COVID-19.²⁹⁰ “The Open COVID Pledge call[ed] upon organizations around the world to make their patents and copyrights freely available in the fight against the pandemic.”²⁹¹ In October 2020, India and South Africa petitioned the World Trade Organization to waive temporarily certain intellectual property protections to increase production of and access to vaccines.²⁹² A year after the initial Open COVID Pledge was proposed in April 2021, a group of Democratic Senators sent a letter to pharmaceutical executives calling upon them to consider loosening up access to their vaccine-related intellectual property holdings.²⁹³ By this time, Pfizer was reporting that it had already taken in \$3.5 billion in vaccine revenues just in the first quarter of 2021.²⁹⁴ Shortly after the Pfizer announcement, the Biden administration proclaimed its support for the WTO proposal that had been submitted by India and South Africa to make it easier for countries that permit compulsory licensing to allow a manufacturer to export vaccines.²⁹⁵ While this step was certainly important, the call to waive patents rights, at least in the short term, was likely more symbolic than substantive; it would still likely take months of international negotiation before the proposal would take effect, if at all.²⁹⁶ As journalist Melody Schreiber noted soon after the

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290. *About Us*, OPEN COVID PLEDGE, <https://opencovidpledge.org/about/> [<https://perma.cc/VJ9A-3JAL>] (last visited Feb. 6, 2022).
291. *Id.*
292. Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver From Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020).
293. *Warren, Colleagues Call on Pfizer, Moderna, and Johnson & Johnson to Expand Access to COVID-19 Vaccines Across the Globe*, ELIZABETH WARREN (Apr. 28, 2021), <https://www.warren.senate.gov/oversight/letters/warren-colleagues-call-on-pfizer-moderna-and-johnson-and-johnson-to-expand-access-to-covid-19-vaccines-across-the-globe> [<https://perma.cc/6999-SN99>].
294. Rebecca Robbins & Peter S. Goodman, *Pfizer Reaps Hundreds of Millions in Profits from Covid Vaccine*, N.Y. TIMES (May 4, 2021), <https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html> [<https://perma.cc/EZP5-RK6A>].
295. Ed Silverman, *U.S. Will Back Proposal to Waive Intellectual Property Rights and Boost Covid-19 Vaccine Production*, STAT (May 5, 2021), <https://www.statnews.com/pharmalot/2021/05/05/biden-covid19-vaccine-patent-rights/> [<https://perma.cc/CX24-34JE>]; Thomas Kaplan et al., *Taking ‘Extraordinary Measures,’ Biden Backs Suspending Patents on Vaccines*, N.Y. TIMES (May 5, 2021), <https://www.nytimes.com/2021/05/05/us/politics/covid-vaccine-patent-biden.html> [<https://perma.cc/8U66-ELLK>].
296. Damian Garde et al., *Waiver of Patent Rights on Covid-19 Vaccines, in Near Term, May Be More Symbolic Than Substantive*, STAT (May 6, 2021), <https://www.statnews.com/2021/05/06/waiver-of-patent-rights->

Biden Administration announcement, “freeing vaccine patents is just the first step. Next, companies need to share how to make the vaccines—known as technology transfer—and governments need to provide the resources, from raw materials to production capacity, to ramp up global vaccine production in a matter of weeks instead of years.”²⁹⁷ Time matters in a pandemic; it also matters in market share. Given the choice, what corporation would not rather have had Senators sending them letters about diversifying clinical trials instead of letters calling upon them to vitiate their patent protection?

CONCLUSION

Two years before Derrick Bell wrote his critique of diversity as deployed by the Supreme Court in *Grutter v. Bollinger* in 2003, Charles Lawrence III expressed similar concerns over what he characterized as “the liberal defense of affirmative action.”²⁹⁸ Lawrence declared himself to be an “unambivalent advocate for affirmative action,”²⁹⁹ but he, like Bell, was profoundly uneasy at the ways in which “liberal supporters of affirmative action have used the diversity argument to defend affirmative action at elite universities and law schools without questioning the ways that traditional admissions criteria continue to perpetuate race and class privilege.”³⁰⁰ I share a similar unease with respect to the racialized response to COVID-19. On the one hand, I am an unambivalent advocate of the need to take race-conscious measures to address the deep, persistent, and pervasive health disparities in this country. On the other hand, I am intensely wary of attempts to do so in ways that either biologize race or divert attention from deeper structural issues of racism – or both. The otherwise well-meaning liberal concern to take race seriously in the face of a global pandemic is laudable, but like the liberal approach to affirmative action, it might win certain discrete battles (as it did in *Grutter v. Bollinger*) while losing the larger war of challenging race-based privilege.

In the case of COVID-19, I am concerned that some of the well-meaning short-term *means* chosen to address racial disparities might end up placing the *end* of racial health justice further out of reach. In 2001, Charles Lawrence III argued that “as diversity has emerged as

on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/ [https://perma.cc/5LBB-4NT].

297. Melody Schreiber, *There's Something Missing From Biden's Move to Free the Covid Vaccines*, NEW REPUBLIC (May 6, 2021), <https://newrepublic.com/article/162320/theres-something-missing-bidens-move-free-covid-vaccines> [https://perma.cc/3SCS-QLD9].

298. Charles R. Lawrence III, *Two Views of the River: A Critique of the Liberal Defense of Affirmative Action*, 101 COLUM. L. REV. 928, 931 (2001).

299. *Id.* at 930.

300. *Id.* at 931.

the dominant defense of affirmative action in the university setting, it has pushed other, more radical substantive defenses to the background. These more radical arguments focus on the need to remedy past discrimination, address present discriminatory practices, and reexamine traditional notions of merit and the role of universities in the reproduction of elites.”³⁰¹ In the story of liberal responses to COVID-19, the general desire to address issues of racial justice was certainly justified. But, proximate concerns about the safety, efficacy, and uptake of vaccines across racial groups were largely based on weak empirical data and faulty assumptions about biological difference and the sources of Black mistrust. As a result, the means taken to address those concerns, while functioning to signal a symbolic concern for racial equity, may actually have been reinforcing pernicious ideas about essential biological difference among the race while “push[ing] other, more radical substantive” approaches to addressing the structural bases of health disparities “to the background.”³⁰² This tends to be how the discourse of diversity works, whether in affirmative action or in health disparities. In the case of health disparities, this discourse has the added danger of confusing and conflating socio-political concepts of diversity with genetic concepts of diversity. Even in the face of the victory for affirmative action in *Grutter v. Bollinger*, Bell lamented: “These are difficult times for those working for racial equity, and there seemed reason for declaring victory after a years-long litigation that many, including this writer, predicted would result in the invalidation of any use of race in the admissions process. I fear, though, that further events—even in the short term—will render this latest civil rights victory, like so many before it, hard to distinguish from defeat.”³⁰³

There are no easy solutions to the issues I have identified in this article. Over the years many suggestions have been presented to guide the responsible use of racial categories in biomedicine, yet these problems persist.³⁰⁴ Given the complex and dynamic nature of how race

301. *Id.*

302. *Id.*

303. Bell, *supra* note 16.

304. See, e.g. Jonathan Kahn, *Genes, Race, and Population: Avoiding a Collision of Categories*, 96 AM. J. PUB. HEALTH 1965, 1965 (2006); Timothy Caulfield et al., *Race and Ancestry in Biomedical Research: Exploring the Challenges*, GENOME MEDICINE, Jan. 2009, at 8.1-8.2; Joan H. Fujimura & Ramya Rajagopalan, *Different Differences: The Use of ‘Genetic Ancestry’ Versus Race in Biomedical Human Genetic Research*, 41 SOC. STUDIES SCI. 5, 5-6 (2011); Reanne Frank, *What to Make of It? The (Re)emergence of a Biological Conceptualization of Race in Health Disparities Research*, 64 SOC. SCI. & MED. 1977, 1977 (2007); Osagie K. Obasogie, *The Return of Biological Race: Regulating Innovations in Race and Genetics Through Administrative Agency Race Impact Assessments*, 22 S. CAL. INTERDISC. L. J. 1, 5-6 (2012); Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J. L., MED. & ETHICS 491, 491 (2008); Michael

is understood and deployed in biomedical contexts and the persistent controversies around recognizing and addressing the historical and structural manifestations of racism in health and healthcare, I am hesitant to proffer any definitive actions that must be taken to avoid the dangers of geneticizing both race and racial disparities. The most important thing, perhaps, is simply to remain attentive to the dynamics I have discussed here and demand that those who are using racial categories provide more complete and clearer justifications for how they are choosing to use race in particular situations. This is even more important under emergent exigent circumstances such as a pandemic. Bearing this in mind, I offer the following modest suggestions for researchers, clinicians, and policymakers to consider:

1. Adopt a skeptical attitude toward any hypothesized but not yet proven causal link between genetics and disparities. Note that this is different from looking at genetic contributions to specific conditions, for example, high blood pressure (or COVID-19), that disproportionately impact minoritized communities. Understanding genetic contributions to disease is quite distinct from understanding genetic contributions to disease disparities. Do not confuse or conflate the two.

2. When social, historical, legal, and economic factors are clearly shown to be significant contributors to an observed disparity, adopt a null hypothesis approach assuming that such disparities are NOT driven by genetics until proven otherwise.

3. When seeking to diversify clinical trials, particularly under emergent circumstances, clearly distinguish between social or political reasons for inclusion - such as encouraging trust or increasing equitable access to therapies - versus biological or genetic reasons, such as concerns about generalizability or genetically based differential responses to safety or efficacy.

4. When seeking to diversify trials to address such social concerns as trust or vaccines hesitancy, do not simply assume that diversity in trials will address the problem. Do not use this as a rationale to address issues of trust or hesitancy unless you have evidence to support it.

5. When seeking to diversify trials to address biological concerns, especially with vaccines, again assume a null hypothesis: do not assume racial or ethnic diversity is necessary to ensure cross racial/ethnic safety and efficacy unless you have sound evidence supporting the assumption. The mere fact that some drugs have on average shown differential rates of efficacy across racial groups on their own is not enough, as drug response can be affected by myriad social and environmental factors. With respect to vaccines, the fact that certain alleles appear to occur at different frequencies in different populations is not enough to justify calls for racial diversity unless you can show that those alleles have a

Yudell et al., *NIH Must Confront the Use of Race in Science*, 396 SCIENCE 1313, 1313 (2020).

direct relation to vaccine response *and* that the difference in frequencies is significant enough in absolute terms to merit substantial race-based diversification in the trial population. If you are using racial categories as proxies for certain environmental or social factors that might affect vaccine response, be explicit about this, and maintain clarity about the use of race as a proxy throughout the process.

6. Do not assume that the mere substitution of terms such as “genetic ancestry” for race will solve any of these problems. In practice, genetic ancestry all too readily becomes continental ancestry which, in turn, blurs back into racial classifications. If you use terms such as “genetic ancestry,” be specific about precisely what you mean by this term and how it is being used to construct groupings among present-day populations.

Reflecting back upon the first year of COVID-19, we can see that in the short term, vaccine developers did a decent job of enrolling minorities in their clinical trials. In the short term, all of the vaccines have proven to have the same safety and efficacy across races. And in the short term, Black hesitancy has not proved to be a significant obstacle to vaccination. This is all to the good; but let us be careful as we move forward to ensure that the stories we tell of these short-term successes do not further contribute to the narrative that the best way to promote health equity is to focus on purported genetic differences in Black bodies or allegedly misguided attitudes in Black minds. Let us not reflect back upon these victories and find them hard to distinguish from defeat.