*American Journal of Law & Medicine* (2023), 49: 1, 1–23
doi:10.1017/amj.2023.13

American Society of Law, Medicine & Ethics
Where Multidisciplinary Education Improves Practice

ARTICLE

# The Case Against Race-Based Quotas in Pharmaceutical Trials

Michael Conklin

Angelo State University, San Angelo, TX, USA
Email: michael.conklin@angelo.edu

**Abstract**

This Article is the first to offer a comprehensive case against using racial quotas in pharmaceutical studies by providing a detailed examination of the arguments for and against the practice. It begins by discussing the current racial classification system, calls for racial quotas in pharmaceutical trials, and the troubling history of combining race and scientific investigation. It next examines the cautionary tale of BiDil, the first drug authorized by the U.S. Food and Drug Administration (FDA) for use in only Black people. The third part of the Article sets forth the arguments against racial quotas. The fourth part provides legal analysis of these arguments, concluding that racial quotas in pharmaceutical trials likely would not satisfy the strict scrutiny standard for two independent reasons. The fifth part evaluates the alleged benefits of racial quotas and demonstrates that when properly understood they are insignificant in comparison to the disadvantages. The final part weighs the evidence to arrive at a conclusion and considers future implications.

Ultimately, this Article provides a valuable framework for assessing the legal and pragmatic implications not just for pharmaceutical trial quotas but also for other racial-classification issues in health care. For example, while it presents a cumulative case against the proposed practice of racial quotas in pharmaceutical trials, many of the same arguments presented are also applicable to the currently mandated practice of acquiring and reporting racial data of pharmaceutical trial participants. It will serve as a valuable resource not only for opponents of racial quotas but also for advocates. For example, this Article provides numerous race-neutral alternatives for consideration. And the strong case against racial quotas helps facilitate a refocus of efforts away from merely ameliorating the end results of health care disparities and instead targeting the root causes. Evidence suggests that this redirected focus on root causes is more effective at producing positive change. In this way, rejecting these quotas is not in conflict with addressing health disparities; rather, it is beneficial to it. This Article will hopefully serve as a catalyst for future research regarding best practices on how pragmatic; legal; and diversity, equity, and inclusion considerations can synergistically exist.

**Keywords:** Racial Classifications; Directive 15; BiDil; discrimination; quota; pharmaceutical trials

"*Pooling people in race silos is akin to zoologists grouping raccoons, tigers, and okapis on the basis that they are all stripey.*"[1]

## Introduction

In 2020, while over 5,000 people worldwide were dying from COVID-19 every day, Moderna intentionally slowed enrollment in its vaccine clinical trial to increase minority racial representation among

[1] *Illuminating BiDil*, 23 Nature Biotechnology 903, 903 (2005).

study participants.[2] The Moderna CEO even stated that racial diversity among research subjects "matters more to us than speed."[3] This decision was unsupported by any scientific evidence showing that race[4] would affect the safety or efficacy of the vaccine.[5]

Moderna's decision to prioritize scientifically irrelevant racial demographics over that of saving lives was likely the result of pressure from the National Institutes of Health (NIH). Francis Collins, director of the NIH and Anthony Fauci's boss, threatened to withhold approval of the Moderna vaccine if it did not increase minority representation.[6] The relationship between racial demographics and pharmaceutical research is one that evokes misinformation, even among those in the scientific community. As demonstrated by the Moderna example, the consequences can be significant.

This Article is the first to offer a comprehensive case against the use of racial quotas in pharmaceutical studies by providing a detailed examination of the arguments for and against the practice. Part I provides background information, such as the current racial classification system, calls for racial quotas in pharmaceutical trials, and the troubling history of combining race and scientific investigation. Part II examines the cautionary tale of BiDil, the first drug authorized by the U.S. Food and Drug Administration (FDA) for use in only Black people. BiDil demonstrates how unnecessarily racializing pharmaceutical trials results in statistical, legal, scientific, and sociological problems. Part III lays out the arguments against racial quotas. These include discussions of the unscientific nature of the practice; why using DNA to populate trials is a superior practice; how use of racial quotas in clinical trials promotes harmful stereotypes; how it uses race as a proxy for disadvantage; how it is based on a reductionist, monolithic assumption of racial groups; issues of autonomy; the problematic nature of combining race with corporate profiteering; the inefficiencies of the practice; recruitment issues created; and unique problems with international research. Part IV provides the legal analysis, concluding that racial quotas in pharmaceutical trials likely would not satisfy review under the strict scrutiny standard for two independent reasons. Part V evaluates the alleged benefits of racial quotas and demonstrates that when properly understood they are insignificant in comparison to the disadvantages. Finally, Part VI weighs the evidence to arrive at a conclusion and considers future implications. While this Article presents a cumulative case against the proposed practice of racial quotas in pharmaceutical trials, many of the same arguments presented are also applicable to the currently mandated practice of acquiring and reporting racial data of pharmaceutical trial participants.

## *Racial Classifications in the United States*

In 1977, Statistical Directive 15 created the modern U.S. racial classification system.[7] The five racial classifications it created have been largely maintained over the last forty-five years; only the wording has been altered. The five races are currently described as American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.[8]

[2]Meg Tirrell & Leanne Miller, *Moderna Slows Coronavirus Vaccine Trial Enrollment to Ensure Minority Representation, CEO Says*, CNBC (Sept. 4, 2020, 12:47 PM), https://www.cnbc.com/2020/09/04/moderna-slows-coronavirus-vaccine-trial-t-to-ensure-minority-representation-ceo-says.html [https://perma.cc/L7AQ-3G6T].

[3]*Id.*

[4]Under the applicable Directive 15 classifications, "Hispanic/Latino" is defined as the Caucasian race but its own ethnicity. For the purposes of this Article, Hispanics are included in discussions of race, and the term "white" refers only to non-Hispanic whites.

[5]David E. Bernstein, Classified: The Untold Story of Racial Classification in America 152 (2022).

[6]Planet Money, *Moonshot in the Arm*, NPR, at 20:40 (Nov. 5, 2021), https://www.npr.org/2021/11/05/1053003777/moonshot-in-the-arm [https://perma.cc/WC4U-4P45].

[7]Bernstein, *supra* note 5, at xi.

[8]Nat'l Insts. of Health, *Racial and Ethnic Categories and Definitions for NIH Diversity Programs and for other Reporting Purposes*, Nat'l Insts. of Health (Apr. 8, 2015), https://grants.nih.gov/grants/guide/notice-files/not-od-15-089.html [https://perma.cc/4Z6M-MESZ]. Note that under this system, "Hispanic or Latino" is not a racial classification but an ethnic classification within the white racial class.

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

The longevity, in the United States, of these five categories means that the basis for our racial classification system is rarely critically examined. Upon such an examination the lack of any objective scientific basis for the classifications created quickly becomes apparent. The process that resulted in these classifications has been accurately described as "a combination of amateur anthropology and sociology, interest group lobbying, incompetence, inertia, lack of public oversight, and happenstance."[9] The drafters of Directive 15, likely recognizing these shortcomings, explicitly warned that these "classifications should not be interpreted as being scientific or anthropological in nature."[10]

### *Calls for Racial Quotas in Pharmaceutical Trials*

Currently, no statute or regulation explicitly requires pharmaceutical trials to meet any racial quotas among their study participants.[11] The FDA does, however, require the collection of data regarding the racial composition of study participants in pharmaceutical trials.[12] And in 2022, the FDA posted a draft of its diversity plan, which "recommends" the submission of a race and ethnicity diversity plan when seeking approval for medical trials.[13] The FDA and the NIH have made strong public statements about how important they perceive minority representation to be in pharmaceutical trials. The FDA states that "[e]nsuring people from diverse backgrounds join clinical trials is key to advancing health equity."[14] The NIH states that

> clinical trials must be appropriately inclusive of racial and ethnic minority groups. . . . It's essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities benefit from scientific advances.[15]

These strong statements, combined with the fact that the FDA and the NIH have unilateral authority to halt pharmaceutical investigations and promulgate and enforce their own rules, may already have the effect of creating implicit racial quotas.[16]

The ability of the FDA to exert great influence in the racial makeup of pharmaceutical trial participant groups was likely exercised during Moderna's COVID-19 vaccine trial. With over $1 billion in guaranteed contracts on the line,[17] Moderna had a strong incentive to produce the first COVID-19 vaccine during Operation Warp Speed.[18] The highly counterintuitive decision by Moderna

[9]Bernstein, *supra* note 5, at xi.

[10]Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting, 43 Fed. Reg. 19, 269 (1978) (to be codified at 20 C.F.R. 416).

[11]Roxanne Melvin, Comment, *Open Door to Pharmaceutical Shortcuts: How the FDA Can Regulate Race-Based Personalized Medicine*, 6 Health L. & Pol'y Brief 25, 27 (2012).

[12]*Id.*

[13]U.S. Food & Drug Admin., Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry: Draft Guidance (2022), https://www.fda.gov/media/157635/download [https://perma.cc/P5CG-NMS7].

[14]*Clinical Trial Diversity*, U.S. Food & Drug Admin. (May 13, 2022), https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity [https://perma.cc/K8K8-DR4S].

[15]*Diversity & Inclusion in Clinical Trials*, Nat'l Insts. of Health, https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html [https://perma.cc/26GL-5KQN] (last visited Nov. 5, 2022). It is never explained how a pharmaceutical trial that lacks diversity somehow denies all communities the benefits of scientific advances.

[16]Melvin, *supra* note 11, at 27–28.

[17]Leah Rosenbaum, *How the U.S. Government's Billion Dollar Bet on Moderna's Covid-19 Vaccine Paid Off*, Forbes (Dec. 18, 2020, 7:41 PM), https://www.forbes.com/sites/leahrosenbaum/2020/12/18/the-feds-risky-billion-dollar-bet-on-moderna-pays-off-as-fda-authorizes-its-covid-19-vaccine/?sh=65a1d7cc65ad [https://perma.cc/5Y4Z-LD4M].

[18]*Id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

to halt pharmaceutical trials in order to alter the racial demographics of the study's participants—again, a decision which has no scientific basis[19]—only makes sense in context of the pressure NIH director Francis Collins put on Moderna.[20]

Various individuals and organizations have called for racial quotas in pharmaceutical research. In 2021, a Harvard Medical School professor called for racial quotas despite acknowledging that "[r]ace is a social construct, a poorly defined marker of genetic diversity, and an imprecise proxy for the relationship between genetics and ancestry."[21] In 2017, the National Black Church Initiative called for the FDA to mandate racial quotas in all clinical trials.[22] Some are even calling for currently underrepresented minority groups to be overrepresented.[23]

## Troubling History of Race and Scientific Investigation

Advocacy in favor of racial quotas in pharmaceutical trials should be examined in light of the history of the use of race in medicine. Racial salience in medicine has an extraordinarily problematic history in the United States. Many of these problems stemmed from the unscientific notion of significant genetic differences between races, a notion that is advanced with calls for racial quotas.[24]

The inception of racialized medical research was essentially a search for racial inferiority.[25] In 1850, the Louisiana State Legislature requested a medical study and concluded that slavery was the only antidote for the natural lethargy of the Black race.[26] The "father of modern gynecology" experimented on female slaves, including one who was forced to undergo thirty gynecological surgeries without anesthesia.[27] Post-emancipation medical research often concluded that freedom was overwhelming for Black people and that their allegedly inherent incompetence was incompatible with equality in a free society.[28] In 1904, a teenager from the Congo was kidnapped and displayed in the Bronx Zoo alongside monkeys.[29] The exhibit was intended to be educational, promoting the belief among many medical experts at the time that Black people were a separate species, a "degraded and degenerate race."[30]

In the 1927 Supreme Court's *Buck v. Bell* decision, the Court upheld the practice of forcible sterilizations on the ground that the procedure provides a public good by fostering a more intelligent populace.[31]

[19]Bernstein, *supra* note 5, at 152.

[20]Planet Money, *supra* note 6, at 20:40.

[21]Farrah J. Mateen, *Is it Time for Quotas to Achieve Racial and Ethnic Representation in Multiple Sclerosis Trials?*, 12 Frontiers Neurology 1, 3 (2021); *see also id.* ("Enrollment targets have risks but, at least in the short term, are a singularly clear mechanism to remain accountable and attempt to ensure research progress is collective.").

[22]Caroline Chen & Riley Wong, *Black Patients Miss Out on Promising Cancer Drugs*, ProPublica (Sept. 19, 2018, 5:00 AM), https://www.propublica.org/article/black-patients-miss-out-on-promising-cancer-drugs [https://perma.cc/9VXC-Z7QF].

[23]Chelsea Weidman Burke, *The Importance of Diversity in Clinical Trials (Because Right Now, It's Lacking)*, BioSpace (Oct. 10, 2018), https://www.biospace.com/article/the-importance-of-diversity-in-clinical-trials-because-right-now-it-s-lacking-/ [https://perma.cc/V6LB-UD26] ("Simply mimicking the U.S. population percentages in trials may not be enough to draw statistically significant conclusions based on race. For example, including only 6 Asian or 1 Native American participant in a trial of 100 people wouldn't provide enough data to generalize results for the whole race.").

[24]*See* discussion and accompanying footnotes *infra* Part III(B).

[25]Rene Bowser, *Racial Profiling in Health Care: An Institutional Analysis of Medical Treatment Disparities*, 7 Mich. J. Race Law. 79, 104–05 (2001).

[26]Nancy Krieger, *Shades of Difference: Theoretical Underpinnings of the Medical Controversy on Black/White Differences in the United States, 1830-1870*, 17 Int'l J. Health Servs. 259, 268–69 (1987).

[27]Sarah Zhang, *The Surgeon Who Experimented on Slaves*, Atlantic (Apr. 18, 2018), https://www.theatlantic.com/health/archive/2018/04/j-marion-sims/558248/ [https://perma.cc/TBP3-46C7].

[28]John S. Haller, *The Physician Versus the Negro: Medical and Anthropological Concepts of Race in the Late Nineteenth Century*, 44 Bull. Hist. Med. 154, 156 (1970).

[29]Pamela Newkirk, *The Man Who Was Caged in a Zoo*, Guardian (June 3, 2015, 12:59 AM), https://www.theguardian.com/world/2015/jun/03/the-man-who-was-caged-in-a-zoo [https://perma.cc/7L2U-N7T4].

[30]*Id.*

[31]*See* Buck v. Bell, 274 U.S. 200 (1927).

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

The U.S. Surgeon General praised forced sterilization as a "step toward a super-race."[32] Eugenicist and founder of Planned Parenthood Margaret Sanger advocated for the "exterminate[ion of] the Negro population."[33] During World War II, secret experiments used Black patients to test the effects of chemical agents, such as mustard gas.[34] In the Tuskegee syphilis experiments, researchers intentionally withheld information from Black research subjects about a newfound cure for syphilis.[35] In the 1940s, the Red Cross had segregated blood banks and would sometimes ban donations from Black people.[36] The U.S. government funded research from 1960 to 1972 regarding the dangers of nuclear war.[37] This involved subjecting disproportionately Black subjects to deadly levels of radiation without their informed consent.[38] At least eighty-nine of these subjects died as a result of the exposure.[39] In the 1970s, over 3,000 American Indian women were forcibly sterilized.[40] A 1990s study on the now banned drug fenfluramine was made up of entirely Black and Hispanic subjects who were labeled as "at risk" of criminal behavior based only on family history.[41] The controversial study used a misleading consent form.[42] The science of measuring cognitive ability has also been racialized to infer inferiority, popularized in the controversial 1990s book *The Bell Curve*.[43] A 1996 study found significant racial disparities in the provision of Medicare services.[44]

Black patients continue to receive disparate medical treatment in the twenty-first century. Similarly situated Black patients were 22% less likely to be hospitalized for ischemic heart disease, 49% less likely to undergo coronary angioplasty, 57% less likely to have a hip-fracture repair, 57% less likely to have coronary-artery bypass surgery, and 25% less likely to have a mammography.[45] Physicians are significantly less likely to refer Black patients for a state-of-the-art diagnostic measure compared to white patients, controlling for symptoms, occupation, and insurance status.[46] Black patients are significantly less likely to receive pain medication than white patients with comparable complaints of pain.[47]

---

[32]Paul A. Lombardo, Three Generations, No Imbeciles: Eugenics, The Supreme Court, and *Buck v. Bell* 175 (Johns Hopkins University Press ed., 2d ed. 2022).

[33]Kristan Hawkins, *Remove Statues of Margaret Sanger, Planned Parenthood Founder Tied to Eugenics and Racism*, USA Today (July 23, 2020, 4:00 AM), https://www.usatoday.com/story/opinion/2020/07/23/racism-eugenics-margaret-sanger-deserves-no-honors-column/5480192002/ [https://perma.cc/F5UY-URTX].

[34]Caitlin Dickerson, *Secret World War II Chemical Experiments Tested Troops Based on Race*, NPR (June 22, 2015, 4:59 AM), www.npr.org/2015/06/22/415194765/u-s-troops-tested-by-race-in-secret-world-war-ii-chemical-experiments [https://perma.cc/84BL-32K5].

[35]Elizabeth Nix, *Tuskegee Experiment: The Infamous Syphilis Study*, History (Dec. 15, 2020), https://www.history.com/news/the-infamous-40-year-tuskegee-study [https://perma.cc/AWS4-3AVW].

[36]Thomas A. Guglielmo, *Desegregating Blood: A Civil Rights Struggle to Remember*, PBS (Feb. 4, 2018, 11:17 AM), https://www.pbs.org/newshour/science/desegregating-blood-a-civil-rights-struggle-to-remember [https://perma.cc/63NF-RS63].

[37]Ryan Grim, *American Mengele: Human Radiation Experiments*, Brooklyn Rail (Autumn 2002), https://brooklynrail.org/2002/10/express/american-mengele-human-radiation-experim [https://perma.cc/T953-C92A].

[38]*Id.*

[39]*Id.*

[40]*1976: Government Admits Unauthorized Sterilization of Indian Women*, Nat'l Libr. of Med., https://www.nlm.nih.gov/nativevoices/timeline/543.html [https://perma.cc/9EAR-DUWW] (last visited Nov. 5, 2022).

[41]Mark Schoofs, *Half-Truths and Consequences*, Vill. Voice (May 5, 1998), https://www.villagevoice.com/1998/05/05/half-truths-and-consequences/ [https://perma.cc/4T5V-2Q4A].

[42]*Id.*

[43]Michael J. Malinowski, *Dealing with the Realities of Race and Ethnicity: A Bioethics-Centered Argument in Favor of Race-Based Genetics Research*, 45 Hous. L. Rev. 1415, 1427 (2009) (quoting Richard Herrnstein & Charles Murray, The Bell Curve: Intelligence and Class Structure in American Life 269 (1994)) ("'Large human populations differ in many ways, both cultural and biological. It is not surprising that they might differ at least slightly in their cognitive characteristics.'").

[44]Marian E. Gornick et al., *Effects of Race and Income on Mortality and Use of Services Among Medicare Beneficiaries*, 355 New Eng. J. Med. 791, 791 (1996).

[45]*Id.* at 798.

[46]Kevin A. Schulman et al., *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 New Eng. J. Med. 618, 618-23 (1999).

[47]Knox H. Todd et al., *Ethnicity and Analgesic Practice*, 35 Annals Emergency Med. 11, 11-12 (2000).

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

A 2016 study found that 40% of first- and second-year medical students believe that Black people's skin is thicker than white people's.[48] Black women are significantly more likely to die in childbirth than white women.[49] Black patients are less likely than similarly situated white patients to receive organ transplants.[50]

## The cautionary tale of BiDil's racial salience

The issue of racial salience in pharmaceutical drug testing is illustrated by BiDil, the first-ever drug to receive FDA approval to treat only one race.[51] It was authorized in 2005 for the sole treatment of self-identified Black patients with heart disease.[52] After conducting initial trials, the FDA rejected BiDil's application on the ground that it was not an effective treatment of heart disease.[53] Only after this failure to secure FDA approval did BiDil creator Dr. Jay Cohn review the trial's data and notice that when one isolates and considers only Black participants—less than 30% of study participants[54]—the drug appeared to be more effective.[55] Based on this finding, the drug was retested using only Black subjects, and the FDA approved its use exclusively for Black patients.[56] But no explanation was provided for why the results of BiDil would differ based on race, and any biological evidence was lacking.[57] There are numerous problems with BiDil's race-based authorization, which range from statistical, to legal, to scientific, to sociological.

### *Statistical*

The statistical problem that BiDil presents involves the low burden of proof implemented in pharmaceutical trials, which generally require only that the trial drug be better than a placebo.[58] Therefore, some drugs obtain approval despite only demonstrating efficacy in less than one-third of study participants.[59] This low threshold welcomes the practice of "data dredging," whereby study results are selectively analyzed in creative ways in an effort to create an appearance of effectiveness.[60] Allowing pharmaceutical companies to retroactively divide the study subjects by their race gives them additional bites at the apple.

[48]Janice A. Sabin, *How We Fail Black Patients in Pain*, Ass'n of Am. Med. Colls. (Jan. 6, 2020), https://www.aamc.org/news-insights/how-we-fail-black-patients-pain [https://perma.cc/CZS3-6682].

[49]Press Release, Ctrs. for Disease Control, Racial and Ethnic Disparities Continue in Pregnancy-Related Deaths (Sept. 5, 2019, 1:00 PM), https://www.cdc.gov/media/releases/2019/p0905-racial-ethnic-disparities-pregnancy-deaths.html [https://perma.cc/B9FZ-CWNL].

[50]Yue-Harn Ng et al., *Does Racial Disparity in Kidney Transplant Persist After Accounting for Social Determinants of Health?*, 104 Transplantation 1445, 1445 (2020).

[51]Melvin, *supra* note 11, at 26.

[52]*Id.*

[53]*Id.*

[54]*Id.*

[55]*Id.*

[56]*Id.*

[57]*Id.*

[58]Malinowski, *supra* note 43, at 1446.

[59]*Id.*

[60]It is also referred to as "data fishing," "data snooping," and "p-hacking." Ragul Awati, *Data Dredging (Data Fishing)*, TechTarget, https://www.techtarget.com/searchdatamanagement/definition/data-dredging [https://perma.cc/794H-75ZT] (last visited Nov. 5, 2022). An analogy helps illustrate this principle: If each student in a class of 100 is asked to flip a coin ten times, the overall average of the class will likely be close to 50% heads and 50% tails. However, if the results are then selectively analyzed, seemingly unlikely results will emerge. Perhaps people with red shirts are more likely to flip heads, the back row is more likely to flip tails, people born in the summer are more likely to flip heads, etc. Then, in hindsight and reported independently, the result can be made to appear skewed from the overall class average.

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

### Legal

The FDA's race-based approval of BiDil may violate the Fifth Amendment. Insurance companies are unlikely to reimburse patients for experimental or investigatory use.[61] This results in non-Black patients whose genetic profile nevertheless make them ideal candidates for BiDil to be denied insurance coverage for the treatment based solely on their race. Therefore, action by the FDA has directly caused people to either be denied medical treatment or forced them to pay a premium for a medical treatment based solely on their race. This government-sanctioned racial discrimination would likely not satisfy the strict scrutiny test, because there is a non-discriminatory alternative available, namely, the use of genetic markers.[62] Not only is this a non-discriminatory alternative; it is a more precise way to measure drug efficacy, and avoids the substantial negative consequences of using race.

In 1987, the Human Genome Project was characterized as the "biggest, costliest, most provocative biomedical research project in history."[63] Upon the project's completion in 2003, radical improvements in DNA-sequencing techniques began to allow for genomic advances to be implemented into routine medical care.[64] This includes the systematic genetic mapping of small populations which allow scientists to target the genetic variations that contribute to diseases.[65] Recently, genomics research advanced beyond analyzing DNA variation to that of gene expression in individual cells.[66] The dramatic efficiency gains in genetic mapping—from $3 billion in the 1990s to only $600 in 2021—are expected to continue producing such advancements.[67]

### Scientific

FDA approval of a drug for only one race implies that race is a genetic category, which even BiDil researchers admit is false.[68] Thus, racializing pharmaceutical trials ultimately risks promoting race-based scientific misinformation, especially when combined with a strong corporate profit motive. For example, the creators of BiDil claimed that Black people in the United States are twice as likely to die from heart failure than white people.[69] This false claim[70] contributes to the belief that Black people are genetically different—perhaps even inferior—to other races.[71] Additionally, some Black consumers believe that a drug approved exclusively for Black people has in some way been customized for that use, and is therefore more effective for treating Black people than other drugs for use by any race. This incorrect belief could lead to the unintended consequence of Black people preferring BiDil over other, more effective drugs and treatments.

Many people, perhaps even general practitioners, will likely conclude based on the media coverage of BiDil and its FDA approval only for Black people, that it only works on Black people.[72] But this conclusion is inaccurate—even BiDil's trial investigators have acknowledged that BiDil will work on patients regardless of their race.[73] And since BiDil's second trial was conducted using only Black

[61] *Experimental Treatments and Clinical Trials*, Fair Health Consumer, https://www.fairhealthconsumer.org/insurance-basics/your-health-plan/experimental-treatments [https://perma.cc/48MV-5T4M] (last visited Feb. 4, 2023).

[62] Taunya Lovell Banks, *Funding Race as Biology: The Relevance of "Race" in Medical Research*, 12 Minn. J.L. Sci. & Tech. 571, 600 (2011).

[63] Francis S. Collins, et. al, *Human Molecular Genetics and Genomics—Important Advances and Exciting Possibilities*, New Eng. J. Med (Jan. 7, 2021), https://www.nejm.org/doi/full/10.1056/NEJMp2030694 [https://perma.cc/CZ4T-MMNE].

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] Jonathan Kahn, *From Disparity to Difference: How Race-Specific Medicines May Undermine Policies to Address Inequalities in Health Care*, 15 S. Cal. Interdisc. L.J. 105, 107 (2005).

[69] *Id.* at 116.

[70] *Id.* at 116–17.

[71] *Id.*

[72] *Id.* at 106.

[73] *Id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

participants, it cannot even be claimed that BiDil works differently for Black patients, despite it only being authorized to treat Black patients.[74]

### *Sociological*

Promoting race-specific drugs may function to reduce the salience of environmental factors that are largely causing disparate health outcomes in minorities.[75] Race-specific drugs, such as BiDil, may cause people to incorrectly conclude that, since interracial health disparities are genetic, the solution lies with genetic-based answers. This mindset will ignore the true causes of these health disparities, such as unequal access to health care,[76] food deserts,[77] lower referral rate to specialists,[78] heightened medical skepticism,[79] and pollution exposure.[80]

Also implicit in the BiDil authorization is the problematic notion that whiteness is the standard and that Black people are to be set apart as the exceptions to mainstream health care. A drug trial with almost exclusively white participants is acceptable for authorizing a treatment for any race. However, the BiDil trial with only Black participants was only acceptable for authorizing treatment on Black people.[81] This behavior from the makers of BiDil and the FDA essentially promotes the notion that white people are an excellent representation of all humanity while Black people are not.[82] The harms of such an implicit message likely extend far beyond medicine.

## Harms of race-based quotas in pharmaceutical trials

### *Unscientific Nature of Directive 15 Racial Classifications*

Current racial classifications are not based on scientific principles and are more the result of political gamesmanship and happenstance.[83] Therefore, using these unscientific classifications in scientific research makes little sense. As one expert explains, medical decisions based on this classification system "should be dismissed out of hand if for no other reason than the government has no scientific or other reasonable basis for determining who qualifies as African American or Hispanic/Latino."[84]

The use of race in pharmaceutical trials is further unscientific in that trial quotas are based on self-reporting, which is highly unreliable. There is great inconsistency in how individuals arrive at their stated

[74]*Id.*

[75]*Id.* at 107.

[76]Latoya Hill, Samantha Artiga & Sweta Haldar, *Key Facts on Health and Health Care by Race and Ethnicity*, Kaiser Family Found. (Jan. 26, 2022), https://www.kff.org/racial-equity-and-health-policy/report/key-facts-on-health-and-health-care-by-race-and-ethnicity/ [https://perma.cc/UJZ2-P6DV].

[77]*Too Many Black Americans Live in Food Deserts*, McKinsey & Co. (Sept. 9, 2021), https://www.mckinsey.com/featured-insights/coronavirus-leading-through-the-crisis/charting-the-path-to-the-next-normal/too-many-black-americans-live-in-food-deserts [https://perma.cc/JU66-9ZEG].

[78]*See supra* notes 45–46 and accompanying text.

[79]Michael Conklin, *Racial Preferences in COVID-19 Vaccination: Legal and Practical Implications*, 5 How. Hum. & C.R.L. Rev. 141, 147–48 (2021).

[80]*Racial, Ethnic Minorities and Low-Income Groups in U.S. Exposed to Higher Levels of Air Pollution*, Harv. Sch. of Pub. Health (Jan. 12, 2022), https://www.hsph.harvard.edu/news/press-releases/racial-ethnic-minorities-low-income-groups-u-s-air-pollution/ [https://perma.cc/4L4U-RKJ8].

[81]Dorothy E. Roberts, *What's Wrong with Race-Based Medicine?: Genes, Drugs, and Health Disparities*, 12 Minn. J.L. Sci. & Tech. 1, 3 (2011).

[82]*Id.*

[83]*See supra* notes 7–10 and accompanying text.

[84]David E. Bernstein, *Two Decades Ago, the FDA and NIH Mandated the Use of Race to Categorize Subjects and Report Results in Medical and Scientific Research They Oversee. It was a Huge Mistake*, Yale J. on Reg. (Jan. 12, 2022), https://www.yalejreg.com/nc/two-decades-ago-the-fda-and-nih-mandated-the-use-of-race-to-categorize-subjects-and-report-results-in-medical-and-scientific-research-they-oversee-it-was-a-huge-mistake-by-david-e-bernstein/ [https://perma.cc/8LLB-3YNH].

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

racial identity. Some maintain a Native American identity with only 1/4,096 ancestry.[85] Black freedmen may be classified as Native Americans despite not having any Native American ancestry.[86] The troubling history in the United States around multiracial people being defaulted into the Black category makes self-reporting even more unreliable.[87] In the past, people who were only one-eighth Back ("octoroons") were counted as Black.[88] And under the "one drop" rule, any Black ancestry meant that one was considered Black.[89]

In the twenty-first century, the practice of identifying as a race in the complete absence of any evidence further complicates self-reporting.[90] There is also confusion surrounding what the proper classification is for certain populations.[91] Some protocols allow researchers to classify study participants based on their guess from the participant's surname and address.[92] Classifying study participants based on their appearance may be even worse. One study found that one-third of Asians and seventy percent of Native Americans were labeled by census workers as either Black or white.[93] There is even great inconsistency in race self-reporting at the individual level. A 1989 study found that a third of people report a different race after a year from the initial reporting.

Even turning to case law and government agency policies may provide little guidance on how racial classifications should be constructed. Some government agencies have no documented procedure for how racial classifications are to be arrived at.[94] And agencies that do have stated policies for racial classifications are often in conflict with each other.[95] The same person may be classified as one race at the first agency and then another at the second agency.[96] Sometimes an individual government agency will even change its mind regarding its previous racial determination of an individual ex post facto.[97] And racial classifications vary from state to state.[98]

The substantial ambiguity regarding racial classification and the nature of how it is self-reported becomes even more problematic when considering racial quotas in pharmaceutical trials because people who are desperate to gain access to a trial could simply claim to be an underrepresented race. This would risk skewing the trial's data. And there is likely little that could be done to avoid this behavior. Those who

[85]Bernstein, *supra* note 5, at 130.

[86]"Freedmen" are the descendants of Black slaves owned by Native Americans. Harmeet Kaur, *The Cherokee Nation Acknowledges That Descendants of People Once Enslaved by the Tribe Should Also Qualify as Cherokee*, CNN (Feb. 25, 2021, 8:53 PM), https://www.cnn.com/2021/02/25/us/cherokee-nation-ruling-freedmen-citizenship-trnd/index.html [https://perma.cc/TUJ4-9J54].

[87]Rene Bowser, *Race as a Proxy for Drug Response: The Dangers and Challenges of Ethnic Drugs*, DePaul L. Rev. 1111, 1113 (2004).

[88]F. James Davis, *Who Is Black? One Nation's Definition*, PBS: Frontline, https://www.pbs.org/wgbh/pages/frontline/shows/jefferson/mixed/onedrop.html (last visited Nov. 5, 2022).

[89]*Id.*

[90]*See, e.g.*, Kirk Johnson et al., *Rachel Dolezal, in Center of Storm, Is Defiant: 'I Identify as Black,'* N.Y. Times (June 16, 2015), https://www.nytimes.com/2015/06/17/us/rachel-dolezal-nbc-today-show.html [https://perma.cc/G5RA-T9YL].

[91]For example, should a blond-haired, blue-eyed person from Spain be classified as Caucasian or Hispanic? Should a dark-skinned Muslim from Yemen be classified as Caucasian? Are native people from India and Afghanistan Asian or Caucasian?

[92]Janet K. Shim et al., *Race and Ancestry in the Age of Inclusion: Technique and Meaning in Post-Genomic Science*, 54 J. Health & Soc. Behav. 504, 511 (2014).

[93]Bernstein, *supra* note 5, at 151.

[94]David Bernstein, *May an Individual Claim Minority Status Based on a DNA Test Showing a Small Amount of African Heritage?*, Reason: The Volokh Conspiracy (Jan. 8, 2020, 12:14 PM), https://reason.com/volokh/2020/01/08/may-an-individual-claim-minority-status-based-on-a-dna-test-showing-a-small-amount-of-african-heritage/ [https://perma.cc/M8M9-LSBL].

[95]David E. Bernstein, *The Modern American Law of Race*, 94 S. Cal. L. Rev.171, 173–74 (2021) (providing the example of mixed-race George Zimmerman, who would be classified as different races depending on which entity is doing the classifying). For a detailed explanation of the differences between states and governmental agencies in how race is determined, see *id.* at 209–14.

[96]*Id.*

[97]*Id.* at 219 (citing a case of erroneous racial classification in *Jana-Rock Construction, Inc. v. New York State Department of Economic Development*, 438 F.3d 195 (2d Cir. 2006)).

[98]Bernstein, *supra* note 5, at 25.

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

administer the trials are unlikely to question the stated racial classification of participants, and even if they did, on what grounds would they be able to prove the participant wrong? Likewise, law enforcement is unlikely to invest resources prosecuting sick people who were desperate to take a potentially life-saving drug. And again, given the highly ambiguous standards of how race is to be determined, it would be difficult for the government to prove, beyond a reasonable doubt, that someone does not possess "one drop" of African ancestry.

### *DNA versus Race*

Fortunately, there is a superior alternative to race for measuring genetic variation in pharmaceutical trial participants: instead of using race as a proxy for genetics, the actual genetics of participants can be used.[99] Governmental departments, such as the Department of Health and Human Services, have called for the FDA to use gene-based studies over race-based studies.[100] There has never been a genetic variation found exclusively in one racial group.[101] The vast majority of genetic variation occurs *within* continental populations, not between continental populations,[102] meaning there is greater genetic variation within racial groups than between them.[103] In this context, race emerges not only as a poor substitute for genetics in pharmaceutical trials; it is actually a counterproductive one.

The use of genetic classifications, rather than racial classifications, in pharmaceutical trials offers an additional benefit beyond scientific precision. The practice could also provide positive societal benefits regarding race relations. For example, a white person discovering that he or she shares the same rare, genetic condition as someone who is Black may lead to more racial harmony and less racial division. Use of genetic classifications rather than racial ones in pharmaceutical trials could also serve to dispel the incorrect notion that racial differences imply significant genetic differences. The false belief that race is a biological category was abandoned by the genetics community in the 1900s but still persists in the twenty-first century.[104] A 2020 study found that over 25% of Black people believe that their worse health outcomes are due to genetic differences.[105] And even some in the medical community still promote the notion. U.S. Senator Tom Coburn—a medical doctor—provided an example of this when criticizing the Social Security system.[106] He was commenting on how Social Security is unfair to Black males because they are disproportionately more likely to die before collecting Social Security.[107] Coburn posited, "What kind of plan is that, that we are going to take from those who have a *genetic predisposition* of less life expectancy, that we are going to steal from those and give it to somebody else."[108]

The controversial 1994 book, *The Bell Curve*, is also premised upon the notion of genetic differences between races. The authors comment on the racial differences on intelligence tests by stating, "It is not surprising that they might differ at least slightly in their cognitive characteristics. That they do is confirmed by the data on ethnic differences in cognitive ability from around the world."[109]

[99]Banks, *supra* note 62, at 600.

[100]Turna Ray, *HHS Draft Report Suggests Genetic Test for BiDil; NitroMed Does Not Rule Out Dx*, GenomeWeb (Sept. 2, 2011, 5:30 PM), http://www.genomeweb.com/dxpgx/hhs-draft-report-suggests-genetic-test-bidil-nitromed-does-not-rule-out-dx [https://perma.cc/TUL7-9ZKX].

[101]For example, some mistakenly believe that sickle cell anemia is limited to the Black community. *See* Elizabeth Landau, *How Medicine is Advancing Beyond Race*, CNN: Defining Am. (July 8, 2011, 7:41 AM), http://www.cnn.com/2011/HEALTH/07/08/race.personalized.medicine/index.html.

[102]Bowser, *supra* note 87, at 1115.

[103]Malinowski, *supra* note 43, at 1427.

[104]*Id.* at 1426–1427.

[105]Liz Hamel et al., *KFF/The Undefeated Survey on Race and Health*, Kaiser Family Found. (Oct. 13, 2020), https://www.kff.org/report-section/kff-the-undefeated-survey-on-race-and-health-main-findings/ [https://perma.cc/LYS7-ZGKD].

[106]Kahn, *supra* note 68, at 127.

[107]*Id.*

[108]*Id.*

[109]Malinowski, *supra* note 43, at 1427 (quoting Richard Herrnstein & Charles Murray, The Bell Curve: Intelligence and Class Structure in American Life 269 (1994).

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

Rejecting policies such as racial quotas in pharmaceutical research that imply a strong link between race is not guaranteed to eradicate the harmful effects imposed by comments like those of Senator Coburn and by books like *The Bell Curve*. However, it would likely reduce popular acceptance of such positions.

Dispelling the incorrect association between race and genetics is further beneficial in that it avoids the defeatist and reductionist implication that there is little Black people can do to improve their negative health outcomes. After all, there is little one can do to alter his or her genetic destiny. However, when these negative health outcomes are correctly attributed to environmental factors rather than genetic ones, a more encouraging message emerges, as some of these factors are able to be altered.

The focus on genetics rather than race is also consistent with scientific advancement.[110] Substantial progress has been made in the area of pharmacogenomics, or personalized medicine.[111] Instead of doctors prescribing medicine based on rough approximations based on a patient's age, weight, gender, symptoms, and medical history, drugs could potentially be prescribed based on one's genetic profile in the future.[112] This area of research offers much promise as technological abilities that make the process feasible continue to advance.[113]

### *Promotion of Harmful Stereotypes*

The harms of using race as a proxy for genetic differences are discussed in the preceding two sections. Unfortunately, this is not the only stereotype implicated in race-based pharmaceutical trials. Just the practice of differentiating groups of people based on their race in a medical setting likely reinforces harmful stereotypes. These stereotypes can result in adverse outcomes for minority groups both inside and outside the medical context. For example, studies have found that medical professionals, subconsciously or otherwise, provide inferior care to Black patients in numerous ways.[114] Increasing the emphasis on patients' race will likely only exacerbate this treatment.[115]

Racialized pharmaceutical trials could also contribute to the harmful profiling of Black people as an "unhealthy" burden on society,.[116] The increased salience of such a policy may cause some to inadvertently associate Blackness with the presence of medical defects. Consequently, the dangerous conclusion that some may arrive at is that if Black people are destined to have poor health outcomes, then less resources should be invested in their medical treatment.[117] In 2020, U.S. health care spending grew nearly 10% to over $4 trillion.[118] With a national debt over $30 trillion and a stagnant economy,[119] people may look to health care spending cuts as a solution. If this occurs, the increased focus on racial differences in health outcomes could become detrimental to the most vulnerable populations. Similarly, increasing race-based salience in medicine could have the unintended consequence of promoting the

[110] *See e.g.,* Malinowski, *supra* note 43, at 1426-27.

[111] Rustin Crutchley, *Personalized Medicine and the Future of Pharmacogenomics*, Wash. State Univ. (Feb. 11, 2022), https://pharmacy.wsu.edu/2022/02/11/personalized-medicine-and-the-future-of-pharmacogenomics/ [https://perma.cc/4DC5-86MD].

[112] *Id.*

[113] *Id.*

[114] *See e.g.,* Gornick et al., *supra* note 44; Schulman et al., *supra* note 46; Todd et al., *supra* note 47; Sabin, *supra* note 48; Ctrs. For Disease Control, *supra* note 49; Khuali, *supra* note 50.

[115] *See generally* Bernstein, *supra* note 5, at 146.

[116] Bowser, *supra* note 25, at 115.

[117] *Id.*

[118] *National Health Spending in 2020 Increases due to Impact oof COVID-19 Pandemic,* Ctrs. for Medicare & Medicaid Servs. (Dec. 15, 2021), https://www.cms.gov/newsroom/press-releases/national-health-spending-2020-increases-due-impact-covid-19-pandemic [https://perma.cc/RUW2-DFZA].

[119] *Financial Audit: Bureau of Fiscal Service's FY 2022 and FY 2021 Schedules of Federal Debt*, U.S. Gov't Accountability Off. (Nov. 9, 2022), https://www.gao.gov/products/gao-23-105586 [https://perma.cc/4GDS-YSLA].

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

misconception that there are "Black" diseases and "white" diseases.[120] For example, some mistakenly believe that sickle cell anemia is exclusive to the Black community.[121]

Another problem is how promoting the belief that race should play a significant role in medicine is likely a welcome misconception among racial hate groups.[122] Such groups could use this concept to promote unscientific notions of racial inferiority.[123] Perhaps worse, racial hate groups could also use this misconception to boost their perceived victimhood status, which is an effective recruitment tool.[124] It is not difficult to imagine the persuasive rhetoric such hate groups could use to, for example, recruit someone whose sick mother recently died because she was denied access to a life-saving pharmaceutical trial due to her race.[125]

One may be tempted to posit that the continuation of medical trials with predominantly white subjects promotes harmful notions of whiteness as the default standard. However, a better understanding of the issue shows that in fact, an increased emphasis on race in medical trials generates this effect. In almost all racialized medical research in the United States, the group to which all others are compared is the majority white group.[126] Put simply, "[t]he norm in racialized research is and has always been an unspoken but taken-for-granted White norm."[127] This notion of white people as the "gold standard" to which all other races are to be compared likely does not foster a healthy mindset toward race in either white people or other races. Therefore, it is the racially neutral approach to medical trials, properly understood, that avoids the perpetuation of harmful race-based stereotypes in medicine.

### *Race as a Proxy for Disadvantage*

Another way that racial quotas in pharmaceutical research can promote harmful stereotypes is how they are sometimes used as a proxy for disadvantage.[128] This reinforces harmful notions of inferiority and the belief that races are to be treated as different. For example, the government interpretation of regulatory language uses race as a proxy for disadvantage.[129] To recognize past instances of research abuse, the federal government created regulations to provide additional safeguards to protect "vulnerable populations" in clinical research, including pregnant women, prisoners, physically and mentally disabled people, children, and educationally and economically disadvantaged people.[130] These regulations have been interpreted by the implementing agencies as including racial minorities by linking them to the "educationally and economically disadvantaged" category.[131] Presumptively including all Black people

[120]Troy Duster, *Race and Reification in Science*, 307 Science 1050 (2005).

[121]Cindy George, *Families Find Sickle Cell Anemia Not Limited to Blacks*, Hous. Chron. (Dec. 1, 2010), https://www.chron.com/news/houston-texas/article/Families-find-sickle-cell-anemia-not-limited-to-1702983.php.

[122]Conklin, *supra* note 79, at 168.

[123]*Id.*

[124]Olga Khazan, *How White Supremacists Use Victimhood to Recruit*, Atlantic (Aug. 15, 2017), https://www.theatlantic.com/science/archive/2017/08/the-worlds-worst-support-group/536850/ [https://perma.cc/965L-5L4U].

[125]This would be similar to the link between affirmative action in college admissions and white resentment, except the severity of losing a loved one would likely enhance the potential for resentment. *See, e.g.*, Vann R. Newkirk II, *The Myth of Reverse Racism: The Idea of White Victimhood is Increasingly Central to the Debate over Affirmative Action*, Atlantic (Aug. 5, 2017), https://www.theatlantic.com/education/archive/2017/08/myth-of-reverse-racism/535689/ [https://perma.cc/9WBE-NCH2] (discussing "white resentment that's surrounded the use of race in job and university application processes since the 1960s").

[126]Bowser, *supra* note 25, at 111.

[127]*Id.*

[128]*See e.g.,* Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824 (proposed Aug. 4, 2022) (to be codified at 42 C.F.R. pt. 438).

[129]*Id.*

[130]CFR § 46.111(b) (2023).

[131]Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 Am. J.L. & Med. 221, 239 (2003).

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

in the category of "educationally and economically disadvantaged" is not only inaccurate but also highly reductionist and insulting.

Unfortunately, this problematic governmental practice of attributing disadvantage to an entire racial classification is not limited to the health care sector. The Small Business Administration (SBA) refers to minorities as "presumptively disadvantaged."[132] And in a 1992 case, the SBA denied a Hispanic loan applicant because she was unable to present evidence of discrimination for being Hispanic.[133]

One researcher's description of how he classifies biracial study participants demonstrates how race is used as a proxy for disadvantage. "We say African-American trumps everything else. Then Hispanic then trumps everything else that's remaining. And then the Asian trumps everything else that's remaining. That's kind of what I think the standard thing that people do."[134] Here, it is likely no coincidence that this researcher has created an informal sorting mechanism that corresponds to perceived disadvantage, with Black people on top, followed by Hispanic people, and lastly Asian people. While perceived disadvantage is inherently subjective, this is the corresponding ranking based on metrics such as life expectancy,[135] incarceration rate,[136] unemployment rate,[137] homicide victimization rate,[138] single parent rate,[139] and high school graduation rate.[140] Surveys of perceived discrimination by race also support this hierarchy, with 46% of respondents saying Black people face "a lot" of discrimination, 30% for Hispanic people, and 27% for Asian people.[141] It is also interesting to note the unscientific, informal nature of this researcher's racial classification procedure and, therefore, the lack of meaningful data that would be derived from such a haphazard methodology.

### *Monolithic Assumption*

Another harmful implication of prioritizing race in pharmaceutical trials is that it promotes the stereotype that those within a racial group are all similar. In reality, there is substantial medical diversity within racial groups. For example, while 55% of Asian children in California had been immunized by kindergarten, only 21% of Southeast Asian children were.[142] And while 6% of Native Americans in New Mexico had a low birth rate, only 1.8% of Santa Clara Pueblo Indians did, compared to 10.4% of Mescalero Apache.[143]

---

[132] 13 C.F.R. § 124.103(b)(1) (2022).

[133] DCS Elec., Inc., SBA No. 399 MSBE-91-10-4-26 (May 8, 1992).

[134] Bernstein, *supra* note 5, at 146.

[135] *Life Expectancy: Your Race Should Not Determine Your Ability to Live a Long and Healthy Life*, Nat'l Equity Atlas, https://nationalequityatlas.org/indicators/Life_expectancy#/ [https://perma.cc/V3YF-SXXQ] (last visited Feb. 5, 2023) (showing the average life expectancy for Black people, Hispanic people, and Asian people as 75, 81, and 84, respectively).

[136] *Jail Incarceration Rate of Confined Inmates in the United States in 2020, by Race/Hispanic Origin*, Statista, https://www.statista.com/statistics/816699/local-jail-inmates-in-the-united-states-by-race/ [https://perma.cc/UD2W-6SNX] (last visited Feb. 5, 2023) (showing the rate of incarceration per 100,000 individuals for Black people, Hispanic people, and Asian people is 465, 134, and 19, respectively).

[137] *Labor Force Statistics from the Current Population Survey*, U.S. Bureau of Lab. Stat., https://www.bls.gov/web/empsit/cpsee_e16.htm [https://perma.cc/J4VU-BAJL] (last visited Feb. 5, 2023) (showing that the 2022 third quarter unemployment rate for Black people, Hispanic people, and Asian people is 5.5%, 3.9%, and 2.6%, respectively).

[138] *2018 Crime in the United States*, U.S. Dep't of Just., https://ucr.fbi.gov/crime-in-the-u.s/2018/crime-in-the-u.s.-2018/tables/expanded-homicide-data-table-6.xls [https://perma.cc/CDH7-HQND] (last visited Feb. 5, 2023) (showing that Black people have a higher homicide victimization rate than Hispanic people, who have a higher rate than Asian people).

[139] Gretchen Livingston, *The Changing Profile of Unmarried Parents*, Pew Rsch. Ctr. (Apr. 25, 2018), https://www.pewresearch.org/social-trends/2018/04/25/the-changing-profile-of-unmarried-parents/ [https://perma.cc/6CPB-GPTV] (showing that Black people have a higher rate of single parent homes than Hispanic people, who have a higher rate than Asian people).

[140] *Public High School Graduation Rates*, Inst. for Educ. Scis., Nat'l Ctr. for Educ. Stat., https://nces.ed.gov/programs/coe/indicator/coi/high-school-graduation-rates [https://perma.cc/24UC-4R6X] (May 2021) (showing that Black students have a lower high school graduation rate than Hispanic students, who have a lower rate than Asian students).

[141] Andrew Daniller, *Majorities of Americans See at Least Some Discrimination Against Black, Hispanic and Asian People in the U.S.*, Pew Rsch. Ctr. (Mar. 18, 2021), https://www.pewresearch.org/fact-tank/2021/03/18/majorities-of-americans-see-at-least-some-discrimination-against-black-hispanic-and-asian-people-in-the-u-s/ [https://perma.cc/BN3H-CAAR].

[142] Bernstein, *supra* note 5, at 148.

[143] *Id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

The act of making assumptions about people based solely on their racial classifications is not only problematic from both a scientific and social standpoint but also in how it likely reinforces stereotypes. For example, the negative portrayal of Black people in the news may cause viewers to incorrectly conclude that, since Black people are similar, the Black people they encounter are likely criminals as well.[144] The more society normalizes the practice of treating racial groups as monolithic, the more we should expect to see generalizations like this become. And when it is the government that is mandating the practice, it acquires an implicit stamp of credibility. The notion that there are inherent, significant differences between the races, and that assumptions about people are justified due solely because of their racial identity, is antithetical to social progress.

### *Autonomy*

Requiring quotas for underrepresented racial minorities could produce unintended consequences regarding the autonomy of these same individuals. The decision to participate in pharmaceutical trials is a highly personal one. It is the result of weighing numerous financial, temporal, and psychic costs.[145] Different people place different significance on variables like the discomfort they receive from complying with trial requirements such as biopsies, blood draws, and physical examinations.[146] Also, potential participants would consider various probabilities, like the risk of being put in the placebo group and the risk of acquiring harmful side effects from an untested drug.[147] Black people are consistently underrepresented in pharmaceutical trials.[148] While some of this might be the result of doctors being less likely to suggest these trials to their Black patients, the main driver is likely a conscious decision from Black people that the benefits do not outweigh the costs. This ultimate decision may in part be the result of misinformation, but regardless, participation in medical trials remains a personal decision.

Attempts to overcome this decision that individuals in the Black community make risks violating their autonomy. Imagine a drug trial that requires one additional Black participant to satisfy a racial quota. The trial is for a drug that treats a rare disease. The recruiters are in contact with a Black person with the rare disease. In such a scenario, there would be a tremendous incentive to pressure this individual to participate, as the costs and time delays involved in finding a replacement could be prohibitive. This pressure could come in the form of emotional pleas for the good of society; downplaying the risks, discomfort, and travel involved in the study; or offering a financial incentive. Any one of these would function to reduce the autonomy involved in deciding to participate in the study. This issue of autonomy is particularly problematic when dealing with racial minorities, given the history of governmental actions denying autonomy in these groups.[149]

### *Race and Corporate Profiteering*

The combination of pharmaceuticals, race, and the corporate profit motive is a problematic mixture. Research into pharmaceutical trials shows that when a trial is sponsored by the pharmaceutical company, the study is much more likely to find the drug effective compared to studies not supported by the

[144]Travis L. Dixon & Daniel Linz, *Overrepresentation and Underrepresentation of Agrican Americans and Latinos as Lawbreakers on Television News*, 50 J. Commc'n 131, 131 (2000).

[145]*See* Luther T. Clark et al., *Increasing Diversity in Clinical Trials: Overcoming Critical Barriers,* 44 Current Probs. In Cardiology, no. 5, 2019, at 152-53.

[146]*See generally id.*

[147]*See generally id.*

[148]"Black patients account for just 5% of clinical trial participants." Patrick Boyle, *Clinical Trials Seek to Fix Their Lack of Racial Mix*, Ass'n of Am. Med. Colls. (Aug. 20, 2021), https://www.aamc.org/news-insights/clinical-trials-seek-fix-their-lack-racial-mix [https://perma.cc/JP98-5HAG].

[149]*See e.g.,* Bernice Roberts Kennedy, et al., *African Americans and Their Distrust of the Health Care System: Healthcare for Diverse Populations*, 14 J. Cultural Diversity 56 (2007).

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

company.[150] Adding race as an additional metric that these corporations can exploit for profits is unwise, especially when these corporations have a history of selectively using data in a deceptive manner.[151]

A non-racial example of this comes from Eli Lilly's drug Xigris. After millions were spent on the drug, the study revealed it was not effective at treating sepsis.[152] Undeterred, Eli Lilly dredged through the data and found that when it excluded certain categories of people the drug appeared to be effective.[153] When it published the results of the study, its deceptive tactic was not mentioned.[154] In statistical analysis, this practice is generally referred to as "data dredging."[155] By data dredging, if there are enough variables to play with, one is almost certain to find some combination that will reach statistical significance.[156] The propensity for pharmaceutical companies to engage in such a practice is highly relevant to the discussion of race and pharmaceutical trials because race provides another category that can be used to engage in data dredging.

### *Inefficiencies*

The imposition of racial quotas in medical research would produce numerous inefficiencies, increasing the cost and the time needed to complete important trials. Suggested methods for increasing representation in medical trials include creating community advisory boards and implementing them into the study design, training staff to assist with Social Security numbers and W-9 forms that minority groups disproportionately are unable to provide, extending research clinic hours, creating and staffing mobile units, training employees on effective communication and cultural humility, creating and implementing educational sessions for employees regarding the history of racism, creating and implementing implicit bias training for employees, hiring multilingual staff, engaging in demographic research and then hiring new staff to ensure that they are representative of the communities being served, and creating and training staff to use multilingual informed consent forms.[157]

These efforts risk diversion from the important work of conducting a safe, accurate, timely, and cost-effective trial. This inherent tradeoff involved is explained by the former principal deputy commissioner of the FDA with the following analogy:

> When it comes to clinical research in this country, there's a credit card, and there's a limit on the credit card. If we spend on one thing, it won't get spent on another. We have to be judicious in what we require and what we demand and what we encourage.[158]

With the reality of this tradeoff in mind, it is likely more prudent to use the proverbial credit card toward accuracy of results, safety among participants, and speed in developing life-saving pharmaceuticals, as opposed to using the credit card on the items listed in the preceding paragraph.

The criteria for being admitted to a clinical trial is often stringent.[159] Admitting patients with conditions—such as stroke, hypertension, and diabetes—that are unrelated to the study can complicate the study results.[160] Since Black people are disproportionately likely to suffer from these medical

[150]Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications,* 75 Chi.-Kent L. Rev. 15, 34 (1999).
[151]*See e.g.,* Bowser, *supra* note 87.
[152]*Id.* at 1126.
[153]*Id.*
[154]*Id.*
[155]Awati, *supra* note 60.
[156]Adrian Erasmus, Bennett Holman, & John P A Ioannidis, *Data-dredging bias*, 27 BMJ Evidence-Based Med. 209, 209.
[157]*See* Lana Khalil et al., *Racial and Ethnic Diversity in SARS-CoV-2 Vaccine Clinical Trials Conducted in the United States*, 10 Vaccines 290 (2022).
[158]Lindsey Wahlstrom-Edwards, *Delivering on Diversity: How Do We Move the Needle?*, Antidote, https://www.antidote.me/blog/delivering-on-diversity-how-do-we-move-the-needle (last visited Nov. 5, 2022).
[159]Chen & Wong, *supra* note 22.
[160]*Id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

conditions,[161] racial quotas would either result in great difficulty finding enough Black recruits who meet these stringent requirements or produce less accurate results.

Another potential inefficiency that quotas would incur is addressing the issue of medical professionals who view the quotas as an ethical violation. Potential issues with informed consent due to quota pressures—as discussed in the next section—could result in ethical problems. Even trials that are able to avoid issues of informed consent may elicit other ethical issues. For example, the American Medical Association's Code of Medical Ethics requires physicians to "respect the law."[162] As Part IV illustrates, these racial quotas are likely unconstitutional, thus creating a potential ethical violation for the medical professionals asked to work on a trial with quotas.[163] Firing such a person would likely lead to costly and time-consuming litigation. And reassigning such a person to a different position would risk lowering morale.

Another inefficiency stems from the inconsistency in using minority status as a proxy for poor health outcomes. While it is true that Black people have lower life expectancies than non-Hispanic whites in America, Hispanics have higher life expectancies than non-Hispanic whites.[164] And Asians have significantly higher life expectancies than non-Hispanic whites.[165] Therefore, medical policies that view minorities as somehow "other" from the white norm are not only inconsistent with health outcomes, but also likely harmful in the broader since that minority groups have distinct experiences in America and should not be viewed monolithically.

Finally, the inevitable litigation that would follow would produce inefficiencies that may include the imposition of a stay from the courts. The eventual case law on the issue could result in the pharmaceutical trial recruitment process changing from the way it is now, to a quota system, to a third legally imposed standard.

### *Recruitment Issues*

Quotas could incentivize researchers to pressure minority subjects to participate in a study, thus violating principles of informed consent.[166] And quotas could result in researchers developing unhealthy frustration toward those groups whose unwillingness to participate results in delays in life-saving research. Such a development of negative opinions in the medical community toward minorities might further exacerbate existing health disparities. The potential solution of offering financial incentives to those in underrepresented minority groups might do more harm than good. For example, the act of paying Black people to participate in a study while not paying white participants could have the adverse effect of creating even more skepticism in the Black community. This is similar to how Black people voiced skepticism about potentially receiving preferable treatment for the newly approved COVID-19 vaccines.[167] Those in the Black community may have become increasingly skeptical about what they might have perceived as being used as "guinea pigs."[168]

[161] *Id.*

[162] *AMA Code of Medical Ethics*, Am. Med. Ass'n, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf (last visited Nov. 5, 2022).

[163] *See infra* footnotes Part IV.

[164] *See supra* note 136 (showing the Hispanic life expectancy to be 81 years and the non-Hispanic white life expectancy to be 79 years).

[165] *Id.* (showing the Asian life expectancy to be 84 and the non-Hispanic white life expectancy to be 79).

[166] Sandra Crouse Quinn et al., *Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys*, 7 J. Empirical Rsch. Hum. Rsch. Ethics 44, 45 (2012).

[167] Sigal Samuel, *Should People of Color Get Access to the COVID-19 Vaccine Before Others?*, Vox (Oct. 28, 2020, 10:55 AM), https://www.vox.com/future-perfect/2020/10/2/21493933/covid-19-vaccine-black-latino-priority-access [https://perma.cc/8L7P-7P2A] (explaining that, when asked about receiving priority for the COVID-19 vaccine, some Black people respond, "In other words, we're the guinea pigs," and, "We are not crash test dummies, we'll go after you.").

[168] *Id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

Unnecessarily interjecting race into pharmaceutical trials also runs the risk of igniting misinformation regarding race and the medical community. Panic and distrust could develop following news coverage of a pharmaceutical company that engaged in targeted recruitment in Black communities for a trial in which some Black study participants had extreme adverse effects—potentially even death—during the trial. Even just one event like this ignites imaginative conspiracy theories in the Black community, which would in turn amplify Black hesitancy toward the medical community. On the subject of vaccine rates, such hesitancy not only risks negative health outcomes in the Black community but also for everyone nationwide. For example, it was estimated that COVID-19 herd immunity required around 80% vaccination rates.[169] Therefore, high vaccine hesitancy from a group that makes up over 13% of the U.S. population is problematic for all.

Even absent media coverage of a sensational event, quotas could result in increased skepticism in the very minority communities they were designed to benefit. Experts argue that the same unintended consequence could result if Black and Hispanic people received preferential access to COVID-19 vaccines. Co-chairperson of the National Academies of Science, Engineering, and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus Helene Gayle explained:

> It's not hard to imagine that if you put Black and brown people first in the line, there's going to be some real mistrust about whether or not people are being used as guinea pigs, because in the past they have been . . . [s]o I think it would probably be counterproductive.[170]

It is interesting to note the counterintuitive demographics regarding medical skepticism in the Black community. One would expect that this skepticism would follow a downward trend as health disparities decrease[171] and as events such as the Tuskegee experiments, slavery, and Jim Crow grow more distant in time.[172] But the data reveals that the opposite is occurring: the percentage of Black people who believe race-based discrimination in health care happens very or somewhat often has been increasing. In 1999, it was 56%, and in 2020, it was 70%.[173] While this statistic cannot dispositively answer the question, the correlation between the government's increased focus on race in health care and the increased skepticism of race-based discrimination in health care suggests the need for a different course of action.

### *International Research Issue*

A significant number of U.S. pharmaceutical trials are conducted in other countries.[174] Mandating that companies use Directive 15 categories in these trials is problematic because these categories are often incompatible with how other countries classify race. For example, "African American" and "Hispanic/Latino" are largely not used outside the United States.[175] Therefore, their use in international trials could result in incorrect classifications and disgruntled participants. Substantial differences exist between racial groups in different geographic regions. For example, Black people in sub-Saharan Africa have nearly 100% African alleles, while Black people in the United States have around a 26% Caucasian

[169]Dezimey Kum, *Fueled by a History of Mistreatment, Black Americans Distrust the New COVID-19 Vaccines*, Time (Dec. 28, 2020, 8:30 AM), https://time.com/5925074/black-americans-covid-19-vaccine-distrust/ [https://perma.cc/H7U2-NB5W] ("Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases, predicted at a recent Harvard event that the number will need to be somewhere between 75 to 85%.").

[170]Samuel, *supra* note 168.

[171]*See, e.g.*, Maria Marabito, *Life Expectancy Gap Between Black and White Americans Diminishes by 48.9%*, Healio (Oct. 11, 2021), https://www.healio.com/news/primary-care/20211011/life-expectancy-gap-between-black-and-white-americans-diminishes-by-489 [perma.cc/98T5-ELH4].

[172]This in no way implies that modern-day issues that the Black community face are insignificant, only that they are less severe than past treatment such as slavery and Jim Crow.

[173]Hamel et al., *supra* note 106.

[174]*See* Bernstein, *supra* note 5, at 162–63.

[175]*See id.*

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

admixture.[176] And the socioeconomic hierarchy of different races in the United States may not be the same as that in other countries, which means that using race as a proxy for environment could produce inconsistencies in international research. Finally, difficulties may emerge in conducting medical trials when potential research subjects are confused or offended by their American-centric racial classification. For example, Muslims in the Middle East may not understand or appreciate being classified in the same race as Jewish people, and Japanese individuals might not understand or appreciate being classified in the same race as Filipinos, Chinese, and people from India.

## Legal analysis

Racial quotas in pharmaceutical trials appear to violate numerous antidiscrimination standards. When the government implements a policy that explicitly singles out racial groups for disparate treatment, such a policy is "inherently suspect"[177] and faces the demanding legal standard of "strict scrutiny."[178] This stringent standard requires that the policy be "narrowly tailored to further compelling governmental interests."[179] Even when race is just one of many factors considered, the strict scrutiny standard still applies.[180] Not even emergency situations allow for the strict scrutiny standard to be bypassed.[181]

Strict scrutiny is applied regardless of the good intentions of those who implemented the discrimination.[182] The benign nature of the racial classification being analyzed does not alleviate the strict scrutiny standard.[183] And the Supreme Court has held that there is no relevant distinction for which direction the discrimination is applied.[184] As the Court explained, "the level of scrutiny does not change merely because the challenged classification operates against a group that historically has not been subject to governmental discrimination."[185]

### *Narrowly Tailored to Further a Compelling Governmental Interest*

Under the strict scrutiny standard, the government policy at issue must be "narrowly tailored to further compelling governmental interests."[186] This requirement imposes a high burden on the state. The racial quotas discussed in this Article cannot be upheld under the strict scrutiny standard unless there is "no workable race-neutral alternative" that could attain the compelling interest at hand.[187]

The quotas in pharmaceutical trials are generally advocated for in an attempt to improve the health outcomes of racial minorities.[188] While improving the health outcomes of racial minorities

[176]Abdallah S. Daar & Peter A. Singer, *Pharmacogenetics and Geographical Ancestry: Implications for Drug Development and Global Health*, 6 Nature Revs. Genetics 241, 242 (2005).

[177]Fisher v. Univ. of Tex. (*Fisher*), 570 U.S. 297, 310 (2013) (quoting Fullilove v. Klutznick, 448 U.S. 448, 523 (1980) ("'[A]ny official action that treats a person differently on account of his race or ethnic origin is inherently suspect.'").

[178]Johnson v. California, 543 U.S. 499, 505 (2005).

[179]*Fisher*, 570 U.S. at 310 (quoting Grutter v. Bollinger, 539 U.S. 306, 326 (2003)).

[180]*Id.* at 310–11.

[181]*Johnson*, 543 U.S. at 512-13 (applying strict scrutiny to assess a prison policy that placed inmates with cellmates of the same race in order to minimize gang-related violence).

[182]Mitchell v. Washington, 818 F.3d 436, 444 (9th Cir. 2016).

[183]*Johnson*, 543 U.S. at 505 ("We have insisted on strict scrutiny in every context, even for so-called 'benign' racial classifications, such as race-conscious university admissions policies, race-based preferences in government contracts, and race-based districting intended to improve minority representation." (citations omitted)).

[184]Wygant v. Jackson Bd. of Educ., 476 U.S. 267, 271 (1986).

[185]*Id.*

[186]Fisher v. Univ. of Tex., 570 U.S. 297, 310 (2013) (quoting Grutter v. Bollinger, 539 U.S. 306, 326 (2003)).

[187]*Id.* at 312.

[188]While some advocates may indicate that the goal is to decrease health disparities between different racial groups, the goal here is defined as improving health outcomes of racial minorities. This is because the latter is a far better goal than the former, as health disparities could be reduced by simply decreasing the health outcomes of white people while leaving the poor health outcomes of racial minorities the same, thus benefitting nobody.

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

is a compelling governmental interest, these quotas are not narrowly tailored, as there are numerous alternatives available that could be used in efforts to improve health outcomes of minority populations that *do not* require racial classifications. Examples include programs to reduce food deserts in minority communities, programs targeting minority communities to increase physical activity, educational programs in minority schools that emphasize the benefits of a healthy lifestyle, or programs using Black churches and Black community leaders to dispel misinformation regarding vaccines.[189] Furthermore, genetic markers could be used to ensure a diverse genetic makeup of those participating in the trials. Finally, if it is deemed important to represent diverse socioeconomic backgrounds in pharmaceutical trials, racially neutral means testing could be utilized.

One might attempt to argue that these race-neutral alternatives are not true alternatives because they too target the same minority groups that are targeted in the quotas. After all, governmental resources are finite, and money spent on educational programs targeting minority communities cannot simultaneously be spent elsewhere. However, case law helps to provide a clear distinction between these alternatives and explicitly race-focused approaches. Money invested in public health education in minority communities does not exclude other racial groups from receiving the same education.[190] In this context, these targeted advertising campaigns are more accurately viewed as a preference for certain geographic areas, not preferences for certain racial groups.

An advocate for quotas may attempt to satisfy the narrowly tailored standard by stating the governmental interest more specifically. For example, one could claim that the governmental interest is simply to increase access to medical trials for racial minorities. But even this more specific attempt at defining the governmental interest would likewise fail judicial scrutiny because quotas are still not narrowly tailored to accomplish this compelling governmental interest as there are also race-neutral alternatives here. Options include offering low-income tax incentives, targeted educational campaigns, and logistical support for low-income participants.

The existence of racially neutral alternatives to serve the compelling governmental interest at play renders the quotas unconstitutional. Notably, these alternatives are likely far better options than the quotas themselves, since the quotas would likely result in *reduced* health outcomes in racial minorities, not improvements. As explained in this Article, quotas could function to increase the skepticism among racial minorities toward the medical community.[191] This would likely produce lower vaccination rates, fewer medical checkups, and a reduced willingness to take prescribed medicine, all outcomes that would result in worse health outcomes.

### *Remedying Past Discrimination*

There is another distinctive way in which racial quotas fail strict scrutiny analysis. Racial quotas are generally only allowed when they are implemented by the public entity that is responsible for the initial discrimination that is being remedied.[192] Additionally, a direct and timely nexus is required; does one exist here? Courts have held that when fourteen years have passed since the initial discrimination, this is

[189]This is similar to what was done to increase the willingness of those in the Black community to get the COVID-19 vaccine. *See* Conklin, *supra* note 79, at 157.

[190]For a detailed discussion of race-based outreach in the medical context, see Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 Harv. C.R.-C.L.L. Rev. 391, 456 (2004) ("In general, . . . courts have classified efforts to increase minority participation in employment and housing as race-neutral, and therefore constitutionally permissible.").

[191]*See supra* notes 155–56 and accompanying text. The medical skepticism that the quotas threaten to ignite could produce lower vaccination rates, fewer medical checkups, and a reduced willingness to take prescribed medicine, all outcomes that would result in worse health outcomes.

[192]*See* People Who Care v. Rockford Bd. of Educ., School Dist. No. 205, 111 F.3d 528, 535 (7th Cir. 1997) ("It is true that 'reverse discrimination'… is not unlawful per se, at least when it is intended to remedy past misconduct by the reverse discriminator."); Builders Ass'n of Greater Chi. v. Cnty. of Cook, 256 F.3d 642, 643–44 (7th Cir. 2001) ("A law that grants

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

too remote to qualify for a program to reverse such discrimination.[193] The 1989 Supreme Court case of *City of Richmond v. J.A. Croson Co.* also demonstrates the difficulty of implementing a program that discriminates based on race in an effort to remedy the effects of past discrimination. The Court explained:

> The city's argument that it is attempting to remedy various forms of past societal discrimination that are alleged to be responsible for the small number of minority entrepreneurs in the local contracting industry fails, since the city also lists a host of nonracial factors which would seem to face a member of any racial group seeking to establish a new business enterprise … .[194]

Similarly, there are a number of nonracial factors that affect the health outcomes of those in racial minorities.

Additionally, in order for a governmental policy to use racial quotas in a constitutional manner, "the policy must target a specific episode of past discrimination."[195] And this past discrimination must have been intentional.[196] "Statistical disparities don't cut it, although they may be used as evidence to establish intentional discrimination."[197] The burden for these issues would not be on the plaintiff to prove these elements are not met; rather, the burden would fall on the government to prove the elements are satisfied.[198] And this burden on the government is high, requiring more than just isolated examples of past discrimination.[199] At best, the FDA could allege that its prior efforts to eliminate racial disparities in pharmaceutical trials were unsuccessful. But case law addresses the inability of this argument to support the legality of racial quotas: "[a]n observation that prior, race-neutral relief efforts failed to reach minorities is no evidence at all that the government enacted or administered those policies in a discriminatory way."[200]

Advocates may attempt to use *Regents of University of California v. Bakke* to support the use of quotas in pharmaceutical trials.[201] In that case, Justice Powell explained how "[i]t may be assumed that in some situations a State's interest in facilitating the health care of its citizens is sufficiently compelling to support the use of a suspect classification."[202] This quote, read in isolation, may appear to create an exception that pharmaceutical trial quotas could potentially satisfy. But properly understood in context, this excerpt does little to support pharmaceutical trial quotas. Powell is only referencing the *possibility* of satisfying strict scrutiny, which supports the notion that racial classifications generally do not.[203] Furthermore, *Bakke* would be a peculiar case to present as evidence here. While the case did allow for

---

preferential treatment on the basis of race or ethnicity does not deny the equal protection of the laws if it is … committed by the public entity that is according the preferential treatment.").

[193]*See, e.g.*, Brunet v. City of Columbus, 1 F.3d 390, 408–09 (6th Cir. 1993) (citing examples of racial preferences that were allowed to remedy discrimination that occurred eight years before the preferences were instituted but not after fourteen years had passed); Hammon v. Barry, 826 F.2d 73, 76–77 (D.C. Cir. 1987) (holding that a time period of eighteen years between the discriminatory conduct and the institution of the preferences was too remote).

[194]City of Richmond v. J.A. Croson Co., 488 U.S. 469, 470 (1989).

[195]Vitolo v. Guzman, 999 F.3d 353, 361 (6th Cir. 2021).

[196]*Id.*

[197]*Id.*; *see also Richmond*, 488 U.S. at 503.

[198]*See Guzman*, 999 F.3d at 360-61

[199]"For example, in a 1993 case involving an affirmative action plan in hiring female firefighters, a finding that the city did not intentionally discriminate against women in the past was upheld despite the facts that prior to 1975 women were barred from the position, that only five in 832 firefighters were women, that the director of the training academy was biased against women, and that the city had previously refused to adopt testing methods less discriminatory against women." Michael Conklin, *Legality of Explicit Racial Discrimination in the Distribution of Lifesaving COVID-19 Treatments*, 19 Ind. Health L. Rev. 315, 320–21 (2022) (referencing Brunet v. City of Columbus, 1 F.3d 390, 405–06 (6th Cir. 1993)).

[200]*Vitolo*, 999 F.3d at 362.

[201]Regents of the Univ. of Cal. v. Bakke, 438 U.S. 265 (1978).

[202]*Id.* at 310.

[203]Lillquist & Sullivan, *supra* note 191, at 444 ("[V]ery few governmental interests have been found by the Supreme Court to be compelling enough to validate a racial classification.").

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

racial preferences, it explicitly barred racial quotas.[204] Finally, college education is largely an exception to antidiscrimination principles[205] and is therefore not a strong place to look for supporting racial quotas in other contexts.[206]

Existing case law presents numerous stringent standards that are not met when considering racial quotas in pharmaceutical trials. No matter how one defines the compelling governmental interest, there are a number of alternatives available, thus rendering the quotas not narrowly tailored. These quotas also fail to satisfy the standards required for remedying past discrimination. Additionally, some legal scholars have even questioned whether certain race-based scientific research also violates discrimination protections found in Section 1981, Title VI, and Title II of the Civil Rights Act of 1964.[207]

The likelihood of such quotas being struck down by the courts is perhaps even greater than the existing case law portrays. The current makeup of the Supreme Court might not even uphold existing racial classifications such as those in college admissions.[208] The famous quote from Chief Justice John Roberts in *Parents Involved* may be an indication of such a decision: "the way to stop discrimination on the basis of race is to stop discriminating on the basis of race."[209] It is not difficult to imagine the Court adopting a similar position regarding the role of participants' race in medical trials: "The way to stop treating people differently in health care based on race is to stop treating people differently in health care based on race."

## Alleged Benefits

Setting aside the unconstitutionality of the practice the negative consequences of racial quotas in pharmaceutical research discussed in this Article do not per se mean that the practice should be eradicated. These are simply costs that must be weighed against any benefits. As with any policy proposal, if the total costs—financial and societal—are outweighed by the total benefits, then the policy should be implemented.

Here, however, this calculus indicates that the alleged benefits of race quotas in pharmaceutical trials, properly understood, are far outweighed by the significant costs. Most of the alleged benefits from racial quotas in pharmaceutical research are the result of using race as a proxy for environmental disadvantages. Even advocates for quotas acknowledge that the resulting racial differences are a function of environmental factors, not genetic ones.[210] Therefore, instead of using race as a proxy for disadvantage, the environmental factors themselves could simply be used. This would not only avoid the negative

[204] *You Can Quote SCOTUS on Quotas (Regents of the University of California v. Bakke)*, Am. Bar Ass'n for Law Students: Student Law. (June 8, 2018), https://abaforlawstudents.com/2018/06/08/quimbee-regents-of-the-university-of-california-v-bakke/ [perma.cc/HBM7-BF6Y].

[205] Title VI allows colleges to voluntarily implement an affirmative action plan, even when there is no past discrimination being remedied.

[206] Additionally, on October 31, 2022, the Supreme Court heard two cases challenging the constitutionality of affirmative action in college admissions. Given the oral arguments and the current makeup of the Court, many are predicting that the Court will overrule *Grutter* and ban racial preferences in college admissions. See, e.g., Ann E. Marimow et. al., *Supreme Court's Conservative Majority Questions Race-Conscious Admissions*, Wash. Post (Oct. 31, 2022, 4:08 PM), https://www.washingtonpost.com/nation/2022/10/31/supreme-court-affirmative-action-case-harvard-unc/ [perma.cc/A2NN-2FV4].

[207] Malinowski, *supra* note 43, at 1438–39.

[208] *See* Vinay Harpalani, *The Supreme Court and the Future of Affirmative Action*, Am. Const. Soc'y: Expert F. (Oct. 28, 2019), https://www.acslaw.org/expertforum/the-supreme-court-and-the-future-of-affirmative-action/ [perma.cc/8ECU-3EZA] (explaining that, even before Amy Coney Barrett replaced Ruth Bader Ginsburg, Justices John Roberts, Samuel Alito, Clarence Thomas, Neil Gorsuch, and Brett Kavanaugh would likely vote to strike down affirmative action in college admissions as currently implemented).

[209] Parents Involved in Cmty. Schs. v. Seattle Sch. Dist. No. 1, 551 U.S. 701, 748 (2007).

[210] Malinowski, *supra* note 43, at 1444–45 ("[R]ace and ethnicity should be accepted as possible research variables, especially in light of how environmental factors interact with and influence genetics, the influence of race and ethnicity on how we group ourselves socially, the impact of these groupings on environmental exposures, and the fact that race and ethnicity have influenced social groupings for centuries.").

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

outcomes and legal implications discussed in this Article but also provide the benefit of more accurate data. For example, if one wanted to research health outcomes based on income, education, living in a multi-generational home, etc., far more accurate data for those factors would be obtained by direct measures rather than relying on race as a presuppositional proxy for these factors. Some advocates mistakenly point to examples of medical research that focused on differences in subgroups such as the Amish and Ashkenazi Jews.[211] The need to resort to such nuanced groups demonstrates the dearth of evidence in favor of racial quotas, because racial quotas use the far broader Directive 15 classifications.[212]

Some advocates point to the benefits received from participating in pharmaceutical trials.[213] And there are certainly benefits to participating in clinical trials, such as increased medical monitoring from healthcare professionals and access to the latest drug treatments. However, these benefits must be weighed against the downsides of participating in pharmaceutical trials. Examples include numerous potential harmful side effects; the risk of being placed in the placebo group; discomfort from complying with required biopsies, blood draws, and examinations; and how participation in a trial may forbid receiving other treatments.[214]

## Conclusion

This first-of-its-kind Article provides a valuable framework for assessing the strengths and weaknesses of racial quotas in pharmaceutical trials. While advocates for quotas may be well-intentioned, this Article demonstrates that the practice would do far more harm than good. Directive 15 racial classifications were created devoid of any scientific standards and therefore have no basis in scientific investigation. Their use will likely lead to numerous harmful effects, such as the conflation of race with genetics, the implication of racial inferiority, the perception of everyone within a racial category as monolithic, and increased skepticism among people of color. Hate groups would likely be able to exploit the practice to further promote harmful racial stereotypes, support their perceived martyrdom status, and enhance recruitment efforts. Additionally, these racial quotas would likely negatively affect the progress of science by injecting numerous inefficiencies into the already complex and timely process of pharmaceutical trials. Finally, linking race with pharmaceuticals and the corporate profit motive is a dangerous mixture.

Racial quotas in pharmaceutical trials should not only be rejected because of the numerous negative consequences they would elicit but also because they violate anti-discrimination jurisprudence. The legal burden for government-imposed racial discrimination is intentionally onerous. These racial quotas are not narrowly tailored since there are multiple, race-neutral alternatives. Also, the practice would not be allowed under the theory of remedying past discrimination, because the nexus between the two is neither direct nor timely.

The strength of the case against quotas is likely even stronger than presented in this Article because here, quotas were considered in a general sense, largely ignoring the intricacies that would inevitably be involved in a real-world application. When these are considered, further problems emerge. For example, would the quotas be set based on the racial breakdown of the overall U.S. population? Percent of the population in the city the research is conducted? Percent of the U.S. population with the ailment in question?[215] Percent of the U.S. population at a heightened risk of acquiring the medical ailment? Assuming that these trials would not have to perfectly match the target racial percentages set, how much flexibility would be allowed? On what standard would the racial determinations be made? Would the one-drop rule be followed? What is the proper classification for someone with equal parts Hispanic and

[211] *Id.* at 1444–45.

[212] Under this classification system, the five races are American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Nat'l Insts. Of Health, *supra* note 8.

[213] Chen & Wong, *supra* note 22.

[214] For example, the *ProPublica* piece emphasizes the potential benefits of participating in a pharmaceutical trial but does not mention any of these potential downsides. *Id.*

[215] Given the disproportionately low average life expectancy of Black people, these two standards could be very different.

https://doi.org/10.1017/amj.2023.13 Published online by Cambridge University Press

Asian ancestry? Why are Hispanics treated as a racial group when they are an ethnicity, not a separate racial group? Would exceptions be made for international research? If a researcher doubts the self-reported race of a participant, is he or she obligated to report this potential fraud to the authorities? If so, what standards and mens rea requirements would be implemented to punish those who do not? If reported to law enforcement, what policies and mens rea elements would be implemented to punish wrongdoers? Further problematic is that some of these questions may provoke heated debates that risk conflict among racial groups.

This Article provides a valuable framework for assessing the legal and pragmatic implications not just for pharmaceutical trial quotas but also for other racial-classification issues in health care. This is a valuable resource not only for opponents of racial quotas but also for advocates. For example, this Article provides numerous race-neutral alternatives for consideration. And the strong case against racial quotas helps facilitate a refocus of efforts away from merely ameliorating the end results of health care disparities and instead targeting the root causes. Evidence suggests that this redirected focus on root causes is more effective at producing positive change.[216] In this way, rejecting these quotas is not in conflict with addressing health disparities; it is consistent with the effort to address those disparities. This Article will hopefully serve as a catalyst for future research regarding best practices on how pragmatic; legal; and diversity, equity, and inclusion considerations can synergistically exist.

**Michael Conklin** is the Powell Endowed Professor of Business Law at Angelo State University. He has published in over 100 academic journals. His research focus is expansive, but often centers on bridging the gap between theory and practice. He is an avid mountaineer having summitted the 100 highest peaks in Colorado and the world's highest volcano in South America.

[216] *Root Cause Analysis Principles*, Tonex, https://www.tonex.com/root-cause-analysis-principles/ [perma.cc/ZD2D-VCC7] (last visited Nov. 5, 2022) ("The logic behind [root cause analysis] is [that] correcting or completely removing root causes, rather than addressing the surface symptom is the best way to solve problems.").

**Cite this article: Conklin, M.** (2023), 'The Case Against Race-Based Quotas in Pharmaceutical Trials', *American Journal of Law & Medicine*, **49**, pp. 1–23. https://doi.org/10.1017/amj.2023.13