

The Regulation of Race in Science

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ABSTRACT

The overwhelming majority of biological scientists agree that there is no such thing as race among modern humans. Yet, scientists regularly deploy race in their studies, and federal laws and regulations currently mandate the use of racial categories in biomedical research. Legal commentators have tried to make sense of this paradox primarily by looking to equal protection strict scrutiny analysis. However, the colorblind approach that attends this doctrine—which many regard as synonymous with invalidation—does not offer a particularly useful way to think about the use of race in research. It offers no way to address how current uses of race in science serve to reinforce biological notions of race long thought discarded. This Article, therefore, takes a different approach by shifting the debate from how strict scrutiny analysis can bear on race-based research, to asking a much deeper question: What normative aims motivate this jurisprudence and can they be instructive in mapping appropriate and equality-enhancing regulations for the use of race in biomedical research? Despite the Supreme Court’s apparent discomfort with government invocations of race, this Article locates in its equal protection race cases elements of an overlooked line of analysis that this Article terms “racial pragmatism,” according to which certain government race-conscious decision-making will not trigger strict scrutiny review. By parsing through the Court’s recent race cases, this Article identifies the goals and concerns that accompany racial pragmatist reasoning and brings them to bear in the biomedical research context to offer a framework for how regulators can mandate the use of race in research without dangerously “geneticizing” race.

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INTRODUCTION

The unprecedented sequencing of the human genome in 2000 revealed the incredible genetic similarity among humans and prompted President Clinton to announce that “one of the great truths to emerge from this triumphant expedition inside the human genome is that in genetic terms all human beings, regardless of race, are more than 99.9 percent the same.”¹ As a result of this leap in scientific knowledge, today, the overwhelming majority of biological scientists agree that “among modern humans, there’s no such thing as race.”²

¹ *White House Remarks on Decoding of Genome*, N.Y. TIMES, June 27, 2000, at F8.

² See Gail Dutton, *Correlating Genomics, Race, and Medicine*, GENETIC ENGINEERING NEWS, Jan. 1, 2006, at 1 (quoting Joseph L. Graves, Jr., Ph.D., Dean of University Studies and

At the same time that many people are heralding the demise of race as a biological or genetic category, the notion of racial difference has taken on a particular salience in biomedical research. The National Institutes of Health Revitalization Act of 1993 (“NIH Revitalization Act”)³ requires the documentation of research subjects’ race in federally financed clinical studies and the use of racial categories as variables in such research.⁴ The Food and Drug Administration (“FDA”) has issued similar guidelines, which, taken together, form a comprehensive mandate to use racial categories in biomedical research.⁵ As a result, today, biomedical researchers use racial categories in their studies in ways that make race appear biological or genetic, which raises disturbing legal and health policy concerns, jeopardizes individual and public health, harms racial minority populations, and reifies outmoded, pejorative, and stigmatizing notions of racial difference.⁶ For example, when researchers seek to conduct studies or test drugs on a group of people who are similar genetically, they might use race as a rough approximation of geographic ancestry.⁷ Despite the fact that race is an imperfect proxy for geographic origin, the information yielded from this crude estimate is increasingly being used in the formulation of race-specific drugs and therapeutics, which raises profoundly troubling public health issues.⁸ Thus, in ways that

Professor of Biological Sciences, North Carolina Agricultural & Technical State University); *see also infra* note 67; *Lab Suspends DNA Pioneer Watson*, BBC NEWS, <http://news.bbc.co.uk/2/hi/science/nature/7052416.stm> (last updated Oct. 19, 2007) (according to Dr. Craig Venter, among the first to map the human genome, “[s]kin colour as a surrogate for race is a social concept[,] not a scientific one”).

³ National Institutes of Health (NIH) Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122.

⁴ *See* 42 U.S.C. § 289a-2 (2006).

⁵ Investigational New Drug Applications and New Drug Applications, Final Rule, 63 Fed. Reg. 6,854, 6,854–55 (Feb. 11, 1998) (codified at 21 C.F.R. pts. 312, 314) (requiring that analyses of effectiveness and safety data for important demographic subgroups, including race, be included in New Drug Applications and that enrollment of subjects in clinical studies for drug and biological products be documented by demographic subgroups in investigational new drug annual reports).

⁶ *See infra* Part I.B–D.

⁷ As discussed by Professors Erik Lillquist and Charles Sullivan, to the extent that they are representative of geographic origin, racial categories are far too broad to be helpful to medical research. Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391, 425-26 (2004). Rather, more dramatic genetic variations are shown between people who are members of separate, more localized population groups: “most genetic differences are really differences between population groups, rather than between races.” *Id.*

⁸ *See generally* Jonathan Kahn, *How a Drug Becomes “Ethnic”: Law, Commerce, and the Production of Racial Categories in Medicine*, 4 YALE J. HEALTH POL’Y L. & ETHICS 1 (2004) (discussing the development of the drug BiDil).

few have predicted, the passage of federal laws and regulations that require the use of race in biomedical studies has contributed to the reification of race as a biological category in research.

The irony of this reinstatement of biological race at a time when many are celebrating its demise has not been lost on legal scholars. A sustained and heated debate about the ways in which the law can be mobilized to regulate the new uses of race in the biomedical sciences is being waged in the literature.⁹ The primary framework used in these scholarly discussions has been that of strict scrutiny.¹⁰ While reliance on this analytical framework makes sense given the Supreme Court's treatment of race under the Equal Protection Clause, to the extent that strict scrutiny review has become synonymous with invalidation, this scholarship offers little guidance on how to address fully the complex issues raised by new uses of race in biomedical research. Further, by relying on strict scrutiny, this scholarship offers an incomplete answer to the preliminary question of how regulators and jurists should think about race.

This Article, therefore, takes a different approach. It constructs a normative analysis of how race should be employed in the biomedical research context by examining the aims and principles that undergird equal protection strict scrutiny jurisprudence. Rather than apply strict scrutiny analysis in a rote fashion, as is often done in scholarship on the use of race in biomedical research, this Article instead reorients discussion from the formal elements of the Supreme Court's equal protection jurisprudence (e.g., scrutiny, racial classifications, compelling interests, etc.) to ask a much deeper question: What overarching objectives motivate this jurisprudence and the Court's concern about government uses of race? And, can this be instructive in devising ap-

⁹ See, e.g., OSAGIE K. OBASOGIE, *CTR. FOR GENETICS & SOC'Y, PLAYING THE GENE CARD?: A REPORT ON RACE AND HUMAN BIOTECHNOLOGY* (2009); Stacie E. Geller et al., *Adherence to Federal Guidelines for Reporting of Sex and Race/Ethnicity in Clinical Trials*, 15 *J. OF WOMEN'S HEALTH* 1123 (2006); Jonathan Kahn, *Race-ing Patents/Patenting Race: An Emerging Political Geography of Intellectual Property in Biotechnology*, 92 *IOWA L. REV.* 353 (2007); Michael Laufert, *Race and Population-Based Medicine: Drug Development and Distributive Justice*, 21 *GEO. J. LEGAL ETHICS* 859 (2008); Lillquist & Sullivan, *supra* note 7; Winnie W.S. Mak et al., *Gender and Ethnic Diversity in NIMH-Funded Clinical Trials: Review of a Decade of Published Research*, 34 *ADMIN. & POL'Y IN MENTAL HEALTH & MENTAL HEALTH SERVICES RES.* 497 (2007); Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 *J.L. MED. & ETHICS* 491 (2008); Dorothy E. Roberts, *Legal Constraints on the Use of Race in Biomedical Research: Toward a Social Justice Framework*, 34 *J.L. MED. & ETHICS* 526 (2006); Symposium, *Race, Pharmaceuticals, and Medical Technology*, 36 *J.L. MED. & ETHICS* 443 (2008).

¹⁰ See Lillquist & Sullivan, *supra* note 7, at 461–65; Obasogie, *supra* note 9, at 494–96; Roberts, *supra* note 9, at 529–30.

propriate and equality-enhancing regulations for the new uses of race in biomedical research? Thus, this Article shifts the debate in the literature on the use of race in biomedical research from the application of strict scrutiny analysis to a different reading of the doctrine, which this Article terms “racial pragmatism.”

This Article positions racial pragmatism as an unexamined strain of analysis employed by jurists in equal protection race cases that allows for certain race-conscious decisionmaking by state actors.¹¹ Racial pragmatism holds that although race lacks a genetic or biological foundation, it is, nevertheless, “real” to the extent that after centuries of institutionalized, state-approved racial discrimination, race has a palpability and a salience in some contexts that cannot and should not be ignored. As a result, according to racial pragmatist reasoning, certain race-conscious decisionmaking by state actors is necessary to account for the social significance of race and will, therefore, not trigger strict scrutiny review.

Jurists’ reliance upon racial pragmatist reasoning illuminates the normative contours of what many legal scholars have identified as the Supreme Court’s discomfort with invocations of racial categories and the “colorblind” ideology animating its equal protection jurisprudence. Indeed, although there is a strong colorblindness norm embedded in the Court’s modern equal protection doctrine, it is neither as coherent nor unwavering as the Court suggests. This flexibility is captured by racial pragmatism. The racial pragmatist approach employed by some Justices and other jurists has enabled them to carve out of the prevailing colorblindness paradigm a pragmatic understanding of the salience of race. Jurists’ adoption of racial pragmatist reasoning demonstrates that even those who generally embrace a colorblindness norm are occasionally concerned about the potential real-world impact of this approach and recognize that there is harm in taking colorblindness to its logical end or in following the concept down the proverbial rabbit hole. As a result, a number of jurists and a minority of justices who ordinarily accept colorblindness have at times distanced themselves from this approach as a practical matter, favoring instead a more pragmatic understanding of the salience of race.

Although some jurists who engage in racial pragmatist reasoning might find race consciousness normatively objectionable but occasionally necessary to account for the social significance of race, this Article contends, by contrast, that race consciousness is critically important

¹¹ See *infra* Part II.C.

and inescapably necessary because race is socially significant. Thus, this Article asserts that race should be used as a variable in biomedical research to account for its social—not biological—salience and demonstrates how racial pragmatist reasoning regarding the social relevance of race can be used to create guidelines to accomplish this goal. Ultimately, this Article seeks to transform the ways in which the regulation of race in biomedical research is conceptualized so that it is more attentive to equality and racial justice concerns.

By parsing through various Supreme Court race cases examining questions of equal protection, this Article identifies the factors and themes that appear to weigh upon whether a particular invocation of race will be examined by courts under a racial pragmatist perspective and be deemed presumptively appropriate, or will be analyzed through a colorblindness lens and be considered a constitutionally suspect “racial classification” deserving of equal protection strict scrutiny review. This Article then applies the principles that undergird racial pragmatism to the biomedical research context. In so doing, it examines how biomedical researchers employ racial categories in their studies in ways that harm minority populations and reinforce pernicious, antiquated, and stigmatizing conceptions of racial difference. This is precisely the type of harm that most concerns the Court in its equal protection jurisprudence. There are, however, some uses of race in research that hold tremendous promise for alleviating the longstanding health disparities that exist among racial groups. These uses of race must be preserved. This Article, by identifying the goals and concerns that drive the Court’s racial pragmatist approach and bringing them to bear in the biomedical research context, offers a framework for how regulators can mandate the use of race in research without dangerously “biologizing” or “geneticizing” race. This framework would, at the same time, still enable regulators to effectively protect the integrity of scientific research, safeguard minority health, ensure the efficacy of government public health measures, and guarantee the viability of government attempts to address the social and economic inequities that cleave along racial lines.

This Article proceeds in four parts. Part I chronicles the origin of race in research and examines the role that race has played in the modern regulation of human-subjects research. This Part then examines the events and concerns that prompted Congress to enact the NIH Revitalization Act and the FDA to devise its rules on the use of race in clinical trials. Part II sets forth the problematic ways in which racial categories are currently deployed in biomedical studies and

maps the dangers that attend the use of race in research, beginning with an examination of the modern use of race in pharmaceutical drug development.

Part III commences by presenting the ongoing debate among scholars about the appropriate regulation of, and the extent to which equal protection strict scrutiny analysis can inform the use of, race in biomedical research. This Part then offers an alternative perspective: racial pragmatism. With an eye toward expanding our understanding of how courts actually conceive of race across legal regimes, Part III engages in a textual analysis of various race cases to delineate the principles that influence whether a particular state invocation of race will be examined by courts under a racial pragmatist perspective and be deemed constitutionally acceptable, or will be examined according to a colorblind approach that triggers strict scrutiny analysis. In so doing, this Part probes the parameters of the Court's recent turn toward colorblindness and demonstrates the extent to which the Court's modern approach to equal protection doctrine includes racial pragmatism. This Part focuses on the Court's education, voting rights, and criminal suspect identification jurisprudence.

Part IV offers a new way of thinking about the regulation of race in biomedical research by integrating into this context a discrete set of principles and themes culled from courts' racial pragmatist reasoning examined in Part III. Part IV asserts that race should be used as a variable in biomedical research to account for its social, not biological, significance, and, relying upon racial pragmatist reasoning, demonstrates how this can be accomplished in a way that preserves the integrity of scientific research, promotes public health, and allows regulators to achieve racial justice in and through biomedical research.

I. RACE IN BIOMEDICAL RESEARCH

The turn of the millennium has brought with it an unparalleled increase in medical research involving human subjects.¹² The veritable explosion of biomedical innovations, including the sequencing of the human genome and pharmacokinetics, as well as improved understandings of microbiology, biochemistry, molecular biology, and the progression of disease, has led to an unprecedented growth in bi-

¹² See Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221, 221 (2003).

omedical research studies.¹³ It has also raised many questions about how race should be regulated in this context.

Biomedical research includes a number of different methodological approaches, including epidemiology, clinical studies, patient case histories, and DNA database genetic research.¹⁴ Although race is implicated in virtually all biomedical research, the use of racial categories in clinical studies has historically raised unique and difficult concerns.¹⁵

Clinical research applies natural science research principles, particularly biology and chemistry, to medical practice in order to examine the underlying biochemical causes of diseases (“clinical studies”) or to evaluate the efficacy of a medication or treatment, such as a medical device (“clinical trials”).¹⁶ While clinical studies examine disease onset and progression, clinical trials compare a medication or treatment to other medicines or treatments, a placebo, or the standard course of treatment for the patient’s condition or disease.¹⁷ Some clinical studies offer the possibility of therapeutic benefits to research participants, while others are conducted primarily to increase and improve scientific knowledge and are not curative or remedial.¹⁸

Some approaches to medical research, such as epidemiology, use racial categories descriptively in statistical or quantitative analyses to evaluate the causes and prevalence of diseases within and across populations.¹⁹ Clinical research, by contrast, often uses race as a biological or genetic category in evaluating disease onset, progression, and severity, as well as drug or treatment response.²⁰ For this reason, the use of race in clinical research has raised unique concerns and opportunities for abuse that do not arise when race is deployed in other types of biomedical research. This Part examines government efforts to regulate the misuses and abuses of race in clinical research, and begins by chronicling the early uses of race in research that prompted the need for regulatory intervention.

¹³ See *id.*

¹⁴ Erik Lillquist & Charles Sullivan, *Legal Regulation of the Use of Race in Medical Research*, 34 J.L. Med. & Ethics 535, 536 (2006).

¹⁵ See *id.*; Lillquist & Sullivan, *supra* note 7, at 461–65.

¹⁶ 3 NAT’L INST. HEALTH BIENNIAL REP. 109–10 (2008–2009), http://report.nih.gov/biennialreport/pdf/NIH_Biennial_FY0809_Volume_III.pdf

¹⁷ *Id.*

¹⁸ Noah, *supra* note 12, at 222.

¹⁹ See Raj Bhopal, *Race and Ethnicity: Responsible Use from Epidemiological and Public Health Perspectives*, 34 J.L. MED. & ETHICS 500, 501 (2006).

²⁰ See Lillquist & Sullivan, *supra* note 7, at 461–65.

A. *The Origin of Race in Research*

During the seventeenth and eighteenth centuries, Western European researchers in the fields of anatomy, biology, and physiology began employing empirical methods to study and create taxonomies of humanity. In 1735, for example, the Swedish biologist Carolus Linnaeus devised a system of classification that divided humans into four categories defined by skin color, geographic ancestry, and personality traits: Africanus (black skin, lazy, careless, carefree), Americanus (red skin, obstinate, ill-tempered), Asiaticus (yellow skin, greedy, distractible), and Eurpoeaus (white skin, innovative and intelligent).²¹ Similarly, in 1781, the physiologist and founder of modern anthropology, Johann Friedrich Blumenbach, extended Linnaeus's system by using his "scientific" theories to demonstrate "objectively" that Africans were biologically, psychologically, and morally inferior to Europeans.²²

These pseudoscientific theories were readily accepted in the United States. During the 1840s and 1850s, some well-respected U.S. scientists began refining these theories by measuring, tabulating, quantifying, and classifying perceived differences among humans in an effort to prove that people of color constituted biologically distinct and inferior species, as opposed to their previous designation as members of "less developed" cultures.²³ One of the most prominent of these scientists was the internationally renowned Harvard professor Louis Agassiz, who posited that the races emerged from separate origins and were inherently unequal.²⁴ Another scientist widely recognized for applying empirical methods to the study of human difference was the famed phrenologist Dr. Samuel George Morton, who measured the cranial capacity of over eight hundred skulls found throughout the world to produce evidence of the inferiority of nonwhite peoples.²⁵ According to Morton's findings, the most highly ranked peoples were the Caucasians, who had the largest skulls and therefore

²¹ WILLIAM H. TUCKER, *THE SCIENCE AND POLITICS OF RACIAL RESEARCH* 9 (1994); Christian B. Sundquist, *The Meaning of Race in the DNA Era: Science, History, and the Law*, 27 *TEMP. J. SCI. TECH. & ENVTL. L.* 231, 234–35 (2008); see also WILLIAM STANTON, *THE LEOPARD'S SPOTS: SCIENTIFIC ATTITUDES TOWARD RACE IN AMERICA, 1815–59*, at 3 (1960).

²² TUCKER, *supra* note 21, at 9. Blumenbach also coined the term "Caucasian," which he deemed to be the ultimate race. *Id.*

²³ See *id.* at 17–21.

²⁴ See *id.*

²⁵ See *id.*

the “highest intellectual endowments.”²⁶ Much lower down the scale were American Indians, who were “averse to cultivation,” and at the very bottom were “Ethiopians,” as blacks were known at the time, who he deemed “the lowest grade of humanity.”²⁷

Although history has shown that the work of the “race scientists” was shaped by then-popular pejorative perceptions of race and their own prejudices,²⁸ their research was nevertheless widely celebrated for its seeming commitment to objectivity and the presumed unbiased use of scientific methods.²⁹ These scientific findings regarding the “natural” inferiority of blacks were also reflected in the caselaw of the time, including the infamous *Dred Scott v. Sandford*³⁰ decision, in which the Supreme Court declared that African Americans were “considered as a subordinate and inferior class of beings, who . . . had no rights or privileges” and therefore were not entitled to the rights and privileges of citizenship or full protection under the Constitution.³¹

The research of race scientists and its effects continued through the nineteenth and twentieth centuries, as biologists applied Charles

²⁶ See *id.* at 18–19 (citing Samuel George Morton, *CRANIA AMERICANA* 5–7, 54, 65, 93 (1839)).

²⁷ See *id.*

²⁸ The famed scientist Stephen J. Gould attempted to recreate Morton’s research on human skulls and deemed the studies to be “a patchwork of fudging and finagling in the clear interest of controlling a priori convictions.” STEPHEN JAY GOULD, *THE MISMEASURE OF MAN* 65, 54 (1981). Moreover, it has been noted by historians that most of the Caucasian skulls that Morton studied belonged to executed felons, and therefore a large skull could just have easily represented criminality. See THOMAS F. GOSSETT, *RACE: THE HISTORY OF AN IDEA IN AMERICA* 74 (1963). Similarly, although Louis Agassiz claimed that his work on racial difference was disinterested and nonpolitical, in his first major article on race he justified his efforts by proclaiming that the fact that “the submissive, obsequious, imitative negro” exhibited a “peculiar indifference to the advantages afforded by civilized society” forced him to conclude that “human affairs with reference to the colored races would be far more judiciously conducted, if, in our intercourse with them, we were guided by a full consciousness of the real differences existing between us and them, and a desire to foster those dispositions that are eminently marked in them, rather than by treating them on terms of equality.” TUCKER, *supra* note 21, at 17–18.

²⁹ See TUCKER, *supra* note 21, at 17. The work of these scientists was also readily accepted by jurists, including the Justices in *Dred Scott v. Sandford*, 60 U.S. (19 How.) 393 (1856) and *Plessy v. Ferguson*, 163 U.S. 537 (1896), as well as those who sought to maintain the prosperity and political power of Southern states, because this research provided empirical support for their arguments that as a subhuman species, Africans and their descendants were exempt from the Declaration of Independence’s “self-evident” truth “that all men are created equal.” See *Plessy*, 163 U.S. at 551–52; *Dred Scott*, 60 U.S. (19 How.) at 410–11; see generally STANTON, *supra* note 21; TUCKER, *supra* note 21.

³⁰ *Dred Scott v. Sandford*, 60 U.S. (19 How.) 393 (1856).

³¹ See *id.* at 404–05, 454.

Darwin's notion of natural selection to humanity,³² giving rise to what became known as "Social Darwinism."³³ This social theory used Darwin's hypotheses to justify its "survival of the fittest" approach to race and class distinctions, and maintained that social programs aimed at elevating the status of the poor and racial minorities contradicted the natural balance.³⁴ Social Darwinist philosophies would ultimately lead to the advent of the eugenics movement, which was largely responsible for the passage of antimiscegenation laws, Jim Crow segregation policies, immigration restrictions, and the forced sterilization of an estimated forty-five thousand people of "inferior stock" in the United States alone.³⁵

Despite the sordid early history of the use of race in science, throughout the twentieth and into the twenty-first centuries, researchers have continued to misuse and abuse race in research. In response, state and federal governments have enacted laws and policies to police the way researchers deploy racial categories in their studies. Those federal regulatory efforts, including the NIH Revitalization Act and FDA rules, are addressed in the next section.

B. *The Regulation of Race in Research*

During the mid-1980s, medical researchers began conducting clinical trials to determine the efficacy of the drug zidovudine ("AZT") in treating HIV/AIDS, a deadly and virulent disease for which there was no known standard of treatment at the time.³⁶ A controversy subsequently arose over the constitution of the drug trials as

³² See generally CHARLES DARWIN, ON THE ORIGIN OF SPECIES BY MEANS OF NATURAL SELECTION (J. Cartoll ed., Broadview Press 2003) (1859). Darwin maintained that all humans belonged to one species and cautioned that his work should not be used to create hierarchies of human beings. According to Darwin: "Although the existing races of man differ in many respects, as in color, hair, shape of skull, proportions of the body, etc., yet if their whole structure be taken into consideration they are found to resemble each other closely in a multitude of points. Many of these points are of so unimportant or of so singular a nature, that it is extremely improbable that they should have been independently acquired by aboriginally distinct species or races." CHARLES DARWIN, THE DESCENT OF MAN, AND SELECTION IN RELATION TO SEX 203 (reprinted from 2d Eng. ed., rev. and augmented 1874).

³³ See Troy Duster, *Lessons from History: Why Race and Ethnicity Have Played a Major Role in Biomedical Research*, 34 J. L. MED. & ETHICS 487, 490–91 (2006).

³⁴ Sundquist, *supra* note 21, at 243. The term "survival of the fittest" was coined by Social Darwinist Herbert Spencer, who, according to Professor Troy Duster, "dominated the social thought of his age as few have ever done." Duster, *supra* note 33, at 490–91.

³⁵ Sundquist, *supra* note 21, at 242–46.

³⁶ Charles Weijer, *Evolving Ethical Issues in Selection of Subjects for Clinical Research*, 5 CAMBRIDGE Q. OF HEALTHCARE ETHICS 334, 338 (1996).

studies revealed that most of the research subjects were white men.³⁷ Critics charged that the homogeneity of the research population denied members of other demographic groups, such as women and racial minorities, the benefits of this and other types of clinical research.³⁸

This demand for broader involvement in clinical trials as a means of expanding the pool of those who might enjoy the advantages of such research was a stark departure from the previous twenty years, when the focus had not been on the fair distribution of research benefits, but rather on the fair distribution of research risks.³⁹ Indeed, until the late twentieth century, the risks attendant to clinical research had been borne disproportionately by people of color and members of disadvantaged or vulnerable groups.⁴⁰

Attitudes towards clinical research practices first began to change in 1971, when the media exposed a forty-year clinical study sponsored by the U.S. Public Health Service, in which nearly four hundred African American men with syphilis were systematically denied known, effective treatments and were not informed that their treatments were

³⁷ *Id.* at 338–39; *see also* Noah, *supra* note 12, at 226 (“In 1996, only twenty-three percent of participants in HIV medication trials were African-American, a markedly low participation rate relative to the incidence of the disease in this population.”).

³⁸ *See* Leslie A. Meltzer & James F. Childress, *What Is Fair Participant Selection?*, in *THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS* 377, 378–79 (Ezekiel J. Emanuel et al. eds., 2008). In addition, intravenous drug users were categorically excluded from these pharmaceutical trials, and the studies included very low percentages of minorities, women of childbearing age, prostitutes, prisoners, and infants, all of whom could have benefitted from participating in these early studies. *Id.* at 379.

³⁹ *Id.* at 378.

⁴⁰ *See* JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 255 (2d ed. 2001) (stating that pressure to strengthen protections for research subjects in the 1970s arose from revelations about “the use of vulnerable populations: developmentally disabled children, elderly persons, and members of disadvantaged minority groups”); Henry K. Beecher, *Ethics and Clinical Research*, 274 *NEW ENG. J. MED.* 1354, 1355–59 (1966) (chronicling twenty-two clinical trials that involved “unethical or questionably ethical procedures” that had been conducted on institutionalized, mentally disabled children; hospital patients; the elderly; and the terminally ill in either university, or state or federally funded facilities). The resulting research results were published in eminent medical journals. *See* Meltzer & Childress, *supra* note 38, at 377. Other unethical research conducted on racial minorities has included: a study in the 1990s that provided lead-contaminated housing to low-income, minority families with healthy children so that researchers could measure the effect of abatement methods on the levels of lead that accumulated in the children’s blood, *see* *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 812–16 (Md. 2001); studies in the 1960s of the effects of massive doses of radiation, performed on mostly low-income African American cancer patients, *see In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 800–01 (S.D. Ohio 1995); medical studies in the 1950s on the effect of radiation on unprotected Navajo uranium miners, *see* *Begay v. United States*, 768 F.2d 1059, 1060–62 (9th Cir. 1985); and surgery conducted on female slaves in the 1800s without anesthesia, *see* Mabelle Allen, *The Dilemma for Women of Color in Clinical Trials*, 49 *J. AM. MED. WOMEN’S ASS’N* 105, 106 (1994).

not diagnostic, but were instead done for research purposes.⁴¹ Although this study, known as the Tuskegee Syphilis Study, was broadly condemned on many ethical grounds, the predominant critique centered on the race-based selection of research participants, who were chosen based upon the mistaken belief that syphilis was a different disease in white people than in black people.⁴²

Public outrage over this and other exploitative, nonconsensual research prompted Congress to enact the National Research Act of 1974,⁴³ which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (“Commission”).⁴⁴ The Commission took a protectionist stance on the selection of research participants and advised researchers to distinguish between possible research participants “based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.”⁴⁵ In 1981, the Department of Health and Human Services and the FDA issued similar regulations that required institutional review boards to ensure that the “selection of subjects is equitable.”⁴⁶

41 See BERG ET AL., *supra* note 40, at 255. The Tuskegee Syphilis Study began in 1930 and concluded during the 1970s, well after penicillin became available to treat the disease. *Id.* For more information about the study, see FRED D. GRAY, *THE TUSKEGEE SYPHILIS STUDY: THE REAL STORY AND BEYOND* (1998); JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* (1981); William J. Cuitran, *The Tuskegee Syphilis Study*, 289 *NEW ENG. J. MED.* 730 (1973); Larry I. Palmer, *Paying for Suffering: The Problem of Human Experimentation*, 56 *MD. L. REV.* 604 (1997); Robert M. White, *Unraveling the Tuskegee Study of Untreated Syphilis*, 160 *ARCHIVES INTERNAL MED.* 585 (2000).

42 Meltzer & Childress, *supra* note 38, at 377; see also Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 *HASTINGS CENTER REP.* 21, 22 (1978) (discussing the opinions of physicians that “blacks [were] especially prone to venereal diseases”).

43 National Research Act of 1974, Pub. L. No. 93-348, 88 Stat. 342.

44 *Id.* § 201, 88 Stat. at 348.

45 Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 *Fed. Reg.* 23,192, 23,196 (Apr. 18, 1979). According to the report, “[c]ertain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects,” and because of “their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.” *Id.* at 23,197.

46 21 C.F.R. § 56.111(a)(3) (2011); 45 C.F.R. § 46.111(a)(3) (2011). The so-called “Common Rule” mandates that, in evaluating studies “[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence,” an Institutional Review Board must ensure that “additional safeguards have been included in the study to protect the rights and welfare of these subjects.” *Id.* §§ 46.101, 46.111(b); see also *Federal Policy for the Protection of Human Subjects*

During the AIDS crisis of the 1980s, however, the pendulum began to swing in the other direction. The focus shifted from concerns regarding the over-enrollment of racial minorities in clinical research and the inequitable distribution of research risks, to fears regarding the under-enrollment of minority populations and the resulting inequitable distribution of research benefits.⁴⁷ With the cost of health care increasing rapidly, participation in clinical studies granted not only access to basic health care, but also an opportunity to enjoy the advantages of state-of-the-art health technology and treatments, along with better disease monitoring.⁴⁸ In addition, studies demonstrated that participants in clinical trials received better health care and health outcomes than those who received the same care outside of the research setting.⁴⁹ Even those individuals who receive placebos in clinical trials show more improvement than those who receive treatment from a physician outside of a trial.⁵⁰ Yet, members of minority populations were less likely to receive these benefits as they were now severely underrepresented in the overwhelming majority of clinical studies.⁵¹

Another major concern was that virtually no clinical trials focused on treatments for the diseases and health conditions that disproportionately afflicted minority populations.⁵² This led to charges that the failure to include sufficient numbers of racial minorities in clinical studies prohibited researchers from gleaning important information regarding disease progression, appropriate treatment, and drug or therapy responses in minority populations.⁵³ Research data suggested

(*Common Rule*), U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited Nov. 19, 2011).

⁴⁷ Meltzer & Childress, *supra* note 38, at 378.

⁴⁸ *Id.*; see also Gina Kolata & Kurt Eichenwald, *For the Uninsured, Drug Trials Are Health Care*, N.Y. TIMES, June 22, 1999, at A1 (noting that clinical trials had become a primary source of medical care for the uninsured); Noah, *supra* note 12, at 222.

⁴⁹ Meltzer & Childress, *supra* note 38, at 378.; see also John D. Lantos, *The "Inclusion Benefit" in Clinical Trials*, 134 J. PEDIATRICS 130, 130 (1999).

⁵⁰ See Lantos, *supra* note 49 at 130; Shankar Vedantam, *Against Depression, a Sugar Pill Is Hard to Beat*, WASH. POST, May 7, 2002, at A1.

⁵¹ See Meltzer & Childress, *supra* note 38, at 379; see also Giselle Corbie-Smith et al., *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 J. GEN. INTERNAL MED. 537, 540–42 (1999); Allen L. Gifford et al., *Participation in Research and Access to Experimental Treatments by HIV-Infected Patients*, 346 NEW ENG. J. MED. 1373, 1379 (2002); Talmadge E. King, Jr., *Racial Disparities in Clinical Trials*, 346 NEW ENG. J. MED. 1400, 1401 (2002); Noah, *supra* note 12, at 227.

⁵² See Allen, *supra* note 40, at 105; Meltzer & Childress, *supra* note 38, at 379; Syed M. Mohiuddin & Daniel E. Hilleman, Editorial, *Gender and Racial Bias in Clinical Pharmacology Trials*, 27 ANNALS PHARMACOTHERAPY 972, 972 (1993); Weijer, *supra* note 36, at 341–42.

⁵³ Meltzer & Childress, *supra* note 38, at 379; Ruth Macklin & Gerald Friedland, *AIDS*

that racial minority groups responded differently to certain drugs, including antihypertensives.⁵⁴ Other studies appeared to show that some diseases, particularly certain cancers, progressed differently in different racial populations.⁵⁵ As a result, critics argued that scientists might be jeopardizing the health of excluded or understudied racial populations by unnecessarily extrapolating research results from whites to racial minorities, who were then at risk of receiving a marketed drug or therapy that was either ineffective or harmful.⁵⁶

In response, the NIH issued guidelines in 1990 designed to ensure the “broadest possible representation of minority groups” in federally funded medical research.⁵⁷ These guidelines were strengthened in 1994,⁵⁸ after Congress enacted the NIH Revitalization Act, which requires researchers who receive federal funds to use race as a variable in research, particularly as a means of measuring possible variations in treatment responses among different racial populations.⁵⁹ In 1998, the

Research: The Ethics of Clinical Trials, 14 *LAW, MED., & HEALTH CARE* 273, 278–80 (1986); see also Carol Levine et al., *Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS*, 13 *IRB: ETHICS & HUM. RES.* 14 (1991).

⁵⁴ See, e.g., Craig K. Svensson, *Representation of American Blacks in Clinical Trials of New Drugs*, 261 *J. AM. MED. ASS'N* 263, 263–65 (1989).

⁵⁵ See, e.g., James J. Dignam et al., *Prognosis Among African-American Women and White Women with Lymph Node Negative Breast Carcinoma*, 80 *CANCER* 80, 88–89 (1997).

⁵⁶ See Meltzer & Childress, *supra* note 38, at 380.

⁵⁷ *ADAMHA/NIH Policy Concerning Inclusion of Minorities in Study Populations*, 19 *NIH GUIDE FOR GRANTS & CONTRACTS* 1, 1 (1990) (requiring research grant proposals to “give appropriate attention to inclusion of minorities in study populations, unless compelling scientific or other justification for not including minorities is provided”).

⁵⁸ See NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 *Fed. Reg.* 14,508, 14,508 (Mar. 28, 1994) [hereinafter NIH Guidelines] (revising and superseding guidelines issued in 1990). The guidelines require the inclusion of racial and ethnic minorities in all NIH-funded behavioral and biomedical research, unless researchers demonstrate “a clear and compelling rationale” for their exclusion. *Id.* at 14,509.

⁵⁹ See National Institutes of Health (NIH) Revitalization Act of 1993, Pub. L. No. 103-43, § 131, 107 *Stat.* 122, 133 (codified as amended in 42 U.S.C. § 289a-2). The Act mandates the inclusion of women and minorities as subjects of federally financed clinical research and requires such researchers to take account of race by: enrolling individuals of diverse racial backgrounds in clinical trials, identifying research subjects by race and ethnicity, using race as a variable in research, and documenting research results by race. See *id.* Researchers conducting Phase III clinical trials must enroll enough minorities to allow analysis of possible variations in treatment responses among different groups. NIH Guidelines, *supra* note 58, at 14,509; see also U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, POLICY STATEMENT ON INCLUSION OF RACE AND ETHNICITY IN DHHS DATA COLLECTION ACTIVITIES (Oct. 24, 1997), available at <http://aspe.hhs.gov/datacncl/inclusn.htm> (acknowledging the “need for an HHS-wide policy on the inclusion of data on racial and ethnic groups in HHS data collection and reporting activities”). Researchers are precluded from circumventing these rules by using cost or geographic location as a means of excluding racial and ethnic minorities. See Ann A. Hohmann & Delores L. Par-

FDA passed similar regulations mandating that safety and efficacy data for drug and biological products be analyzed by racial groups.⁶⁰

C. *Current Understandings of Race in Research*

Federal efforts to curb misuses of race in the biomedical research context have achieved limited success, which can be attributed, in part, to the fact that these laws and rules were not originally intended to address race in research. In fact, the NIH Revitalization Act and FDA rules were initially conceptualized as means of addressing the dangers attendant to the gender imbalance in clinical trial research.⁶¹ The concern with respect to gender was that the underrepresentation of women—particularly pregnant women and women of childbearing age—in clinical research could harm women’s health, both in terms of their lost opportunity to benefit from participating in trials and the potential dangers they could suffer by taking marketed drugs and therapies that had not been tested on women.⁶² These concerns were subsequently extended to racial minorities, and lawmakers revised the law to include these populations.⁶³ Although there are innate biological differences between men and women that justify scientific concerns about extrapolating data from male research subjects to women, current understandings of biology and genetics make clear that race is a genetically meaningless construct.

ron, *How the New NIH Guidelines on Inclusion of Women and Minorities Apply: Efficacy Trials, Effectiveness Trials, and Validity*, 64 J. CONSULTING & CLINICAL PSYCHOL. 851, 852 (1996).

⁶⁰ See Investigational New Drug Applications and New Drug Applications, *supra* note 5, at 6,854. The rule requires that analyses of “effectiveness and safety data for important demographic subgroups,” including race, be included in new drug applications and that enrollment of subjects in clinical studies for drug and biological products be documented by demographic subgroups in investigational new drug annual reports. *Id.* at 6,854–55. Other laws and policies that require biomedical researchers to catalogue research participants by race include: Food and Drug Administration Modernization Act of 1997 § 115, 21 U.S.C. § 355(b)(1) (2006) (“The Secretary [of Health and Human Services] shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials”); FOOD & DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: POPULATION PHARMACOKINETICS 1 (1999), available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM133184.pdf> (advising on the use of population pharmacokinetics in drug development to evaluate the safety and efficacy of drugs in minority populations).

⁶¹ See Jesse A. Berlin & Susan S. Ellenberg, Commentary, *Inclusion of Women in Clinical Trials*, BMC MED. (Oct. 9, 2009), <http://www.biomedcentral.com/1741-7015/7/56>; Ruth B. Merkatz & Suzanne White Junod, *Historical Background of Changes in FDA Policy on the Study and Evaluation of Drugs in Women*, 69 ACAD. MED. 703, 703–04 (1994).

⁶² Berlin & Ellenberg, *supra* note 61.

⁶³ See NIH Revitalization Act § 131, 107 Stat. at 133.

Scientific understandings of race changed decisively after the mapping of the human genome revealed that all humans are 99.9% identical genetically,⁶⁴ and demonstrated that there is no genetic variation responsible for the combination of characteristics and features typically ascribed to race.⁶⁵ As a result, today, scientists broadly agree that “[o]ne definite and obvious consequence of the complexity of human demographic history is that races in any meaningful sense of the term do not exist in the human species.”⁶⁶ Indeed, the overwhelming consensus among geneticists is that “among modern humans, there’s no such thing as race.”⁶⁷

Mutable, malleable, and constantly shifting in its social meanings, race in the United States has historically been defined by skin color, culture, national origin, language, social or socioeconomic class, or an amalgamation of all of these traits.⁶⁸ Race is a social construct, which means that racial categories, the meaning we attach to these categories, and the way we determine which individuals will be assigned to

⁶⁴ See Dutton, *supra* note 2, at 1.

⁶⁵ See *id.*; see also Editorial, *Genes, Drugs, and Race*, 29 NATURE GENETICS 239, 239 (2001) (“[S]cientists have long been saying that at the genetic level there is more variation between two individuals in the same population than between populations and that there is no biological basis for ‘race.’”); Catarina I. Kiefe, Editorial, *Race/Ethnicity and Cancer Survival: The Elusive Target of Biological Differences*, 287 J. AM. MED. ASS’N 2138, 2138 (2002) ([O]ver the past several decades, race as a biological construct became largely discredited among scientists); Robert S. Schwartz, *Racial Profiling in Medical Research*, 344 NEW ENG. J. MED. 1392, 1392 (2001) (“Race is a social construct, not a scientific classification.”); Ritchie Witzig, *The Medicalization of Race: Scientific Legitimization of a Flawed Social Construct*, 125 ANNALS INTERNAL MED. 675, 676 (1996) (“Race is . . . an unscientific social construct . . .”).

⁶⁶ David B. Goldstein & Lounès Chikhi, *Human Migrations and Population Structure: What We Know and Why It Matters*, 3 ANN. REV. GENOMICS & HUM. GENETICS 129, 137–38 (2002); see also JONATHAN MARKS, HUMAN BIODIVERSITY: GENES, RACE, AND HISTORY 162 (1995); Henry T. Greely, *Human Genome Diversity: What about the Other Human Genome Project?*, 2 NATURE REV. GENETICS 222, 225 (2001); Margaret Lock, *Genetic Diversity and the Politics of Difference*, 75 CHI.-KENT L. REV. 83, 87 (1999); Jonathan M. Marks, *Scientific and Folk Ideas About Heredity*, in THE HUMAN GENOME PROJECT AND MINORITY COMMUNITIES: ETHICAL, SOCIAL, AND POLITICAL DILEMMAS 53, 61 (Raymond A. Zilinskas & Peter J. Balint eds., 2001).

⁶⁷ Dutton, *supra* note 2, at 1 (quoting Joseph L. Graves, Jr., Dean of University Studies and Professor of Biological Sciences, North Carolina Agricultural & Technical State University); see also IAN F. HANEY LÓPEZ, WHITE BY LAW: THE LEGAL CONSTRUCTION OF RACE xiii-xiv (1996); Kiefe, *supra* note 65, at 2138; Witzig, *supra* note 65, at 676.

⁶⁸ Dutton, *supra* note 2, at 1, 41 (“The idea of race persists in cultures, but it’s not a genetic definition and it gets confused with cultural relationships.” (quoting Michael Liebman, Executive Director of the Windber Research Institute)); Laura E. Gómez, *Understanding Law and Race as Mutually Constitutive: An Invitation to Explore an Emerging Field*, 6 ANN. REV. L. SOC. SCI. 487, 490–91 (2010); Jennifer McAndrew, *Deep Roots?: New DNA Tests May Reveal Your Ancestry, but Researchers Urge Caution When Interpreting Results*, U. TEX. AUSTIN, <http://www.utexas.edu/features/2007/ancestry/>.

these categories, are all driven by social, cultural, and historical practices, and are not determined *a priori* by genetics.⁶⁹ We assign certain meanings (e.g., stereotypes and attitudes) to the racial categories we have constructed, which inform the ways individuals and groups are perceived.⁷⁰ Both the categories and the meanings are susceptible to rapid change.⁷¹

II. THE NEW “RACE SCIENTISTS” AND CURRENT MISUSES OF RACE IN RESEARCH

Despite the fact that current understandings of biology and genetics make clear that race is a genetically meaningless construct, and that the history of the misuse of race in science illustrates the hazards of deploying racial categories in biomedical studies, federal laws and regulations continue to mandate the use of race in government-funded research.⁷² Those mandates offer little guidance to researchers on how and when the use of racial categories is appropriate in light of new scientific knowledge.⁷³ This has invited widespread abuse of race in biomedical research.

For example, both the NIH Revitalization Act and the FDA rules use the racial classifications delineated in the U.S. Office of Management and Budget’s (“OMB”) Directive No. 15,⁷⁴ which was devised to

⁶⁹ Jerry Kang, *Implicit Bias and the Pushback from the Left*, 54 ST. LOUIS U. L.J. 1139, 1144 (2010). According to Kang: “First, the racial categories change over time and as a function of politics—just consider how the Census has counted ‘race’ differently over the centuries. Second, the mapping rules are also dynamic—consider how and why, in 1854, the California Supreme Court classified the Chinese as racially Indian or Black in order to prevent them from testifying in court. Third, consider how the racial meanings associated with a particular category can rapidly change—e.g., for Asian Americans, debased laborers working on the railroads (mid-1800s) to yellow peril (1940s) to model minority (late 1960s).” *Id.* (footnotes omitted).

⁷⁰ *Id.* at 1143; see also Jerry Kang & Kristin Lane, *Seeing Through Colorblindness: Implicit Bias and the Law*, 58 UCLA L. REV. 465, 468–69 (2010); Jerry Kang, *Trojan Horses of Race*, 118 HARV. L. REV. 1489, 1499 (2005).

⁷¹ See Kang, *supra* note 69, at 1144. Changes to the U.S. Census over the years illustrate the malleability of racial categories, as in 1997 the federal government increased the number of recognized racial categories from four (American Indian or Alaskan Native, Asian or Pacific Islander, Black, and White) to five (American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White). U.S. Census Bureau, *Racial and Ethnic Classifications Used in Census 2000 and Beyond*, <http://www.pacificweb.org/DOCS/PopRaceAncestry/Race/Racial%20and%20Ethnic%20Classifications%202000.pdf>.

⁷² See NIH Guidelines, *supra* note 58, at 14,508–10.

⁷³ See *id.*

⁷⁴ See generally Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 Fed. Reg. 58,782 (Oct. 30, 1997). Directive No. 15 data is also used for tracking many important civil rights efforts in the areas of school desegregation, electoral districting, and the provision of goods and services to those who belong to particular racial groups. See MELISSA NOBLES, SHADES OF CITIZENSHIP: RACE AND THE CENSUS IN MODERN POLITICS 79–84 (2000);

provide a uniform standard for maintaining, collecting, and presenting data on race and ethnicity for the U.S. Census and all other federal reporting purposes.⁷⁵ These racial categories are: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, and White.⁷⁶ Where some biomedical researchers get into trouble is that they assume that these racial categories can provide a scientifically useful means of capturing geographic ancestry to estimate genetic profiles.⁷⁷ Thus, researchers who wish to conduct studies or test drugs on a genetically similar group of people might use race as a rough approximation of geographic ancestry.⁷⁸ This is so despite the fact that race is an imperfect proxy for geographic origin.

The mandate to use racial categories in biomedical studies allows researchers to work from the assumption that people of the same race are likely to have ancestors who originated in the same geographic locale and thus have a similar genetic constitution. This assumption is being used in the estimation of genetic profiles.⁷⁹ This Part maps how this crude estimate is increasingly being employed in the formulation of race-specific drugs and therapeutics by examining the FDA's approval of the drug BiDil, which was developed to treat heart disease in black people.⁸⁰

Kenneth E. Payson, *Check One Box: Reconsidering Directive No. 15 and the Classification of Mixed-Race People*, 84 CALIF. L. REV. 1233, 1234, 1256 (1996) (noting that the racial classifications the Directive identifies are socially created, not "scientific or anthropological").

⁷⁵ See, e.g., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS 2-3 (2005), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf>.

⁷⁶ Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 Fed. Reg. at 58,782; see also Alice Robbin, *Classifying Racial and Ethnic Group Data in the United States: The Politics of Negotiation and Accommodation*, 27 J. GOV'T INFO. 129, 131-32 (2000).

⁷⁷ See, e.g., Pilar Ossorio & Troy Duster, *Race and Genetics: Controversies in Biomedical, Behavioral, and Forensic Sciences*, 60 AM. PSYCHOLOGIST 115, 115 (2005).

⁷⁸ Lillquist & Sullivan, *supra* note 7, at 425-26.

⁷⁹ See generally Race, Ethnicity, and Genetics Working Grp., *The Use of Racial, Ethnic, and Ancestral Categories in Human Genetics Research*, 77 AM. J. HUM. GENETICS 519 (2005). Generally, humans as a species do not randomly mate with one another, but rather have historically tended to mate with those who live in close geographic proximity to them. This has given rise to various subpopulations among humans that express different variations in allelic frequencies. This can be attributed to either the effects of natural selection or genetic drift, which is the propensity of groups that do not randomly mate with other groups to develop distinct allelic frequencies. See *id.* at 519-32.

⁸⁰ See generally Kahn, *supra* note 8 (discussing the development of BiDil).

A. *Pharmaceutical Drug Development*

Deoxyribonucleic acid (“DNA”) is a molecule that encodes the genetic information or hereditary material in humans and almost all other organisms.⁸¹ The DNA molecule is made up of a string of chemicals called nucleotides that consist of sugar, phosphate, and a base.⁸² The bases are critically important, because their order or sequence in the DNA molecule forms the genetic code of the organism.⁸³ Some DNA sequences act as a sort of “genetic fingerprint,” because two unrelated individuals are unlikely to have the same DNA sequence at the same location on the same chromosome.⁸⁴ This variation in gene sequence that differs from person to person is called an allele.⁸⁵ Although all humans are 99.9% identical genetically and hence most gene sequences are the same from person to person, the remaining 0.1% difference is represented in these alleles, which are responsible for producing genetic diseases and for creating the variations among individuals that allow them to be identified by samples of their DNA.⁸⁶

During the late 1990s, pharmaceutical companies began focusing their energy on the 0.1% difference among humans identified by the Human Genome Project in an attempt to develop drugs for, and to

⁸¹ LORI B. ANDREWS ET AL., *GENETICS: ETHICS, LAW, AND POLICY* 17 (3d ed. 2010).

⁸² *Id.* There are four bases—adenine, guanine, cytosine, and thymine—which are identified by their initials: A, G, C, and T. These bases bond to each other according to strict rules: A and T only bond to each other, and G and C only bond to each other. *Id.* According to Lori Andrews: “In humans and other higher organisms, the DNA molecule actually is two strands of DNA, as if you reunited the two halves of [a] ladder. Each of the sides of the ladder is a strip of sugars and phosphates. The rungs are the bases that stick out and that are connected together in pairs according to the bonding rules: A with T, G with C. This double-stranded DNA molecule is twisted around the mid-point of the rungs to give it its famous ‘double-helix’ appearance.” *Id.*

⁸³ *Id.*

⁸⁴ *Id.* at 22–23, 682–83. Genetic identification relies on short, repeated sequences of DNA, known as tandem repeats, which consist of one half of the bonded base pairs of DNA arranged one behind the other throughout a chromosome. *See id.* at 679–83. Thus, a tandem repeat is akin to a “stutter in the genome, e.g., ACCGACCGACCG.” *Id.* at 682. A tandem repeat acts as a sort of genetic “fingerprint” because two unrelated individuals are unlikely to have the same number of tandem repeats at the same location on the same chromosome. *See id.* at 679–83.

⁸⁵ *Id.* at 23.

⁸⁶ *Id.* For example, most people have 26 or fewer CAG repeats in a gene that codes for production of the protein huntingtin, but people with many more repeats on this gene will develop Huntington’s disease. People without the CTT sequence at position 508 of the CFTR gene will develop cystic fibrosis. These are examples of different alleles of the same gene. *Id.* at 22–23.

market them to, specific groups.⁸⁷ The drugs they were formulating are known as pharmacogenomic drugs, which are medications that are devised specifically to target particular genetic variations.⁸⁸ These drugs allow physicians to select the correct drug and dose for each patient, thereby increasing drug efficacy while preventing adverse reactions.⁸⁹ Thus, pharmacogenomic drugs are seen as the first step towards “personalized medicine,” according to which drugs and other therapies are chosen specifically for each patient’s individual genotype.⁹⁰

In March of 2001, the FDA approved biotech company NitroMed’s proposal to conduct the first clinical trials specifically designed to study the efficacy of a pharmaceutical drug for the treatment of heart failure in one particular racial group: African Americans.⁹¹ The African American Heart Failure Trial enrolled exclusively men and women who “self-identified” as black, which was defined as being of African American descent.⁹² The trial appeared to demonstrate a notable health improvement in trial subjects when the drug, BiDil, was taken along with other medications.⁹³ NitroMed also conducted a racial subgroup analysis of African Americans who had participated in an earlier study.⁹⁴

During the FDA hearings that followed the clinical trial, representatives from many diverse organizations and institutions pushed for the approval of BiDil as a means of addressing a life-threatening health condition in a group historically marginalized by the health care and medical research communities.⁹⁵ The Association of Black

⁸⁷ See Guillaume Sillon et al., *An Ethical and Legal Overview of Pharmacogenomics: Perspectives and Issues*, 27 *MED. & L.* 843, 844–45 (2008).

⁸⁸ *Id.* at 844–47. A mix of pharmacology and genomics, pharmacogenomics examines the influence of genetic variation on drug responses in patients to predict patterns of reactions to drugs and facilitate research and development of new, targeted therapies. *See id.* The promise of pharmacogenomic drugs is that they may increase the effectiveness of medications and better predict and thus prevent the adverse effects of medications and therapies. *See id.*

⁸⁹ *Id.*

⁹⁰ Michelle Meadows, *Genomics and Personalized Medicine*, *FDA CONSUMER*, Nov.-Dec. 2005, at 12, 13; *see also* Francis S. Collins et al., *Implications of the Genome Project for Medical Science*, *NAT’L HUM. GENOME RESEARCH INST.*, <http://www.genome.gov/25019925> (last updated Feb. 24, 2011).

⁹¹ Gregory Michael Dorr & David S. Jones, *Facts and Fictions: BiDil and the Resurgence of Racial Medicine*, 36 *J.L. MED. & ETHICS* 443, 445 (2008).

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *See* Susan M. Reverby, “Special Treatment”: *BiDil, Tuskegee, and the Logic of Race*, 36 *J.L. MED. & ETHICS* 478, 478–79 (2008).

Cardiologists, the National Association for the Advancement of Colored People, and the National Minority Health Month Foundation, for example, supported FDA approval of the drug.⁹⁶ Further, the Congressional Black Caucus gave BiDil its “clear and unequivocal” endorsement, and Delegate Donna Christian-Christensen of the U.S. Virgin Islands opined: “Would you deny a life now to us rather than do what the evidence shows can and should be done?”⁹⁷

When the FDA approved BiDil in June of 2005, the agency had never before sanctioned the release of a drug with a race-specific indication.⁹⁸ Upon entering the market, BiDil was celebrated as the first “ethnic drug” and hailed as a revolutionary pharmaceutical that would treat a deadly health condition that had plagued African Americans, a group long and woefully underserved by the health care system.⁹⁹ NitroMed’s Chief Executive Officer declared: “There is absolutely no question of the value of BiDil in the treatment of congestive heart failure in African Americans.”¹⁰⁰ BiDil did prove quite effective in the treatment of heart failure among African Americans.¹⁰¹ The only problem was that it was equally effective at reducing heart failure in people of other races.¹⁰² As it turned out, the drug did not work better or differently in African Americans than in people of other racial groups.¹⁰³

The BiDil case is illustrative of how race is increasingly being employed in biomedical research and also demonstrates the problems that stem from the current use of race in research. This Article now addresses each of these problems and concerns in turn.

B. *Approximating Geographic Ancestry*

When clinicians seek to conduct studies or test drugs on a group of people who are alike genetically, they may use race to estimate

⁹⁶ DOROTHY ROBERTS, *FATAL INVENTION: HOW SCIENCE, POLITICS, AND BIG BUSINESS RE-CREATE RACE IN THE TWENTY-FIRST CENTURY* 181 (2011).

⁹⁷ Reverby, *supra* note 95, at 479.

⁹⁸ *See id.* at 478.

⁹⁹ *See* Jonathan Kahn, “Ethnic” Drugs, 35 *HASTINGS CENTER REP.* inside back cover (2005); Kahn, *supra* note 9, at 379.

¹⁰⁰ Reverby, *supra* note 95, at 484 n.38; *see also* Ron Winslow, *FDA Is Prepared to Approve Heart Drug Intended for Treating African-Americans*, *WALL ST. J.*, Mar. 9, 2001, at B6.

¹⁰¹ Kahn, *supra* note 99.

¹⁰² *Id.*

¹⁰³ *See id.*; Pamela Sankar & Jonathan Kahn, *Bidil: Race Medicine or Race Marketing?*, *HEALTH AFFAIRS* W5-460-61 (Oct. 11, 2005), available at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.455/dc1>.

geographic ancestry.¹⁰⁴ In other words, clinicians use race as a means of determining where on the planet a particular research subject's ancestors could have come from. The assumption is that people whose ancestors originated in the same geographic locale will have similar allele frequencies due to the tendency of individuals to mate with those who live in close geographic proximity to them.¹⁰⁵ Black research participants are presumed to have a preponderance of African ancestry, while white subjects are assumed to have primarily European ancestors.¹⁰⁶ This common practice of using the five racial groups identified by Directive No. 15 as a convenient means of representing common ancestry to predict the presence of certain allele frequencies is problematic for a number of reasons.

First, racial information for clinical trials often is produced through self-identification by research participants.¹⁰⁷ Studies have shown that individuals are typically unable to identify their complete geographic or ethnic ancestry,¹⁰⁸ and a person whose skin color is perceived as white can have eighty percent recent West African ancestry, while a person whose skin color is perceived as black can have a predominance of alleles that indicate European ancestry.¹⁰⁹ In addition, understandings of racial identity differ both within the United States and all over the world.¹¹⁰ Plus, many people do not identify themselves as belonging to any one particular racial group.¹¹¹ Thus, the

¹⁰⁴ See Ossorio & Duster, *supra* note 77, at 116; Anne L. Taylor & Jackson T. Wright, *Should Ethnicity Serve as a Basis for Clinical Trial Design?*, 112 CIRCULATION 3654, 3658 (2005).

¹⁰⁵ See generally Race, Ethnicity and Genetics Working Grp., *supra* note 79.

¹⁰⁶ See Mark D. Shriver et al., *Skin Pigmentation, Biogeographical Ancestry and Admixture Mapping*, 112 HUM. GENETICS 387, 387 (2003).

¹⁰⁷ See Jonathan Kahn, *Genes, Race, and Population: Avoiding a Collision of Categories*, 96 AM. J. PUB. HEALTH 1965, 1965 (2006).

¹⁰⁸ See Celeste Condit et al., *Attitudinal Barriers to Delivery of Race-Targeted Pharmacogenomics Among Informed Lay Persons*, 5 GENETICS IN MED. 385, 388 (2003).

¹⁰⁹ Ossorio & Duster, *supra* note 77, at 118; see also Flavia C. Parra et al., *Color and Genomic Ancestry in Brazilians*, 100 PROC. NAT'L ACAD. SCI. 177, 177 (2003); Shriver, *supra* note 106, at 387-99.

¹¹⁰ Sundquist, *supra* note 21, at 263. Globally, the concept of race is very fluid because ideas regarding racial identification differ sharply among various countries. *Id.* For example, an aboriginal Australian might be considered black (typically understood as Sub-Saharan African ancestry) in the United States. See Race, Ethnicity and Genetics Working Grp., *supra* note 79, at 522. Similarly, an individual who might be considered Hispanic or Chicano in some parts of the United States would be considered white in others. See Ossorio & Duster, *supra* note 77, at 119.

¹¹¹ See Schwartz, *supra* note 65, at 1392 ("Following the decision by the Office of Management and Budget to allow multiple responses to a question on racial identification in the 2000 Census, almost 7 million people identified themselves as members of more than one race; about 800,000 respondents said they were both white and black."); see also Eric Schmitt, *For 7 Million People in Census, One Race Category Isn't Enough*, N.Y. TIMES, Mar. 13, 2001, at A1.

clinicians who rely upon these varying notions of race are accepting others' potentially dissonant decisions about race, and, in so doing, these clinicians produce data that lacks meaningful uniformity. When clinicians impute these sampling biases and discordant understandings of race into their studies, they not only forsake their own professional training, but they generate flawed results.

Second, the notion that the millions of people within each of the Directive No. 15 categories share a common geographic heritage, and are therefore likely to be more "related" genetically in some appreciable way, is scientifically unfounded.¹¹² This notion has long been refuted, as genetic variations based upon ancestral geographic origins do not map seamlessly onto racial categories.¹¹³ This is because any two unrelated individuals selected randomly from anywhere on the planet will be 99.9% the same genetically.¹¹⁴ The overwhelming majority of human genetic variation—roughly 85% of the 0.1% difference—can be found between any two individuals from within the *same* racial or ethnic group.¹¹⁵ Indeed, there is more variation between two individu-

¹¹² See Ossorio & Duster, *supra* note 77, at 116–17. Scientists have long known that human skin color and physical traits tend to be similar among groups that are geographically close and then vary gradually as groups become more distant geographically. This phenomenon, known as clinal variation, also occurs with alleles that differ among human groups. In addition, these varying traits and alleles tend to vary at differing rates. This phenomenon, known as "nonconcordant variation," is the reason why anthropologists of the nineteenth and early twentieth centuries, who attempted to classify human races based on observable physical traits, identified over fifty "races" and finally concluded that there are no discrete, nonoverlapping races. The same has been true of modern scientists studying differences among humans based on allele frequencies. See *id.*

¹¹³ See Dutton, *supra* note 2, at 43; Sundquist, *supra* note 21, at 261–63. As explained by Dr. Ritchie Witzig:

[H]uman complexions do not fit a primary color scheme. No person is absolutely white or black or any other color Rather, complexion hues can be characterized as ranging from very light to very dark, and complexions vary widely within each racial group. For these reasons, grouping by skin color has no scientific meaning when the result of the grouping is construed as either a race or ethnicity.

Witzig, *supra* note 65, at 676; see also Goldstein & Chikhi, *supra* note 66, at 137–38 ("One definite and obvious consequence of the complexity of human demographic history is that races in any meaningful sense of the term do not exist in the human species.").

¹¹⁴ See Ossorio & Duster, *supra* note 77, at 117 (explaining that humans demonstrate strikingly little genetic variation when compared to other species). Indeed, chimpanzees, which are primates that are closely related to humans, have roughly four times as much within-species genetic variation as humans. See *id.* The homogeneity among humans is due to the fact that humans are a relatively young species in evolutionary terms. See *id.*

¹¹⁵ See *id.* For example, when a group of white people from Italy is compared with a group of white people from Norway, about 10% of the time a researcher will find a genetic variant that is relatively frequent in one group and infrequent in the other. The maximum genetic variation between any two groups (ethnic, racial, or religious) is 15% of the 0.1% difference. Of this 15%, the maximum observed genetic variation among different groups from the same continent (e.g.,

als within a racial group than there is between racial groups,¹¹⁶ and black people the world over exhibit more internal genetic diversity than any other racialized group, despite the fact that they are often understood and treated as though they are alike genetically.¹¹⁷ Thus, unrelated people in the same racial population do not necessarily have much shared or common ancestry and cannot be understood to be genetically similar in ways that make a difference for between-group comparisons.¹¹⁸

It is important to note that there are a small number of genetic variants that can affect predispositions to illness, longevity, and other aspects of health status, which manifest among people who share the same ancestral geographic origin. For instance, cystic fibrosis is significantly more likely to afflict individuals of European descent than those of Asian ancestry.¹¹⁹ These gene mutations typically developed in response to particular environmental conditions, and often provide certain advantages. Thus, the so-called “Black Death” gene mutation, which originated in Europe during the fourteenth century during the Black Plague, allowed those with this allele variation to survive the plague and remains an identifiable genetic variation.¹²⁰ Similarly, independent mutations in the β -globin gene, which originated in central and western Africa, cause the sickle cell trait and protect against malaria.¹²¹ While both of these variant genes may indicate geographic ancestry, they do not adhere to a distinct phenotype or express race in a biologically legitimate way.¹²² The most common of these allele fre-

white Swedes and white Croatians) is 10%. And among different groups from different continents (e.g., white Swedes and black Kenyans), there is a mere 5% observed difference. Therefore, because the majority of genetic difference is found within any group, people of the same race are not genetically similar in ways that make a difference for between-group comparisons. *See id.*

¹¹⁶ See Editorial, *Genes, Drugs and Race*, *supra* note 65, at 239; R.C. Lewontin, *The Apportionment of Human Diversity*, in 6 *EVOLUTIONARY BIOLOGY* 381, 397 (Theodosius Dobzhansky et al. eds., 1972); R.C. Lewontin & Daniel L. Hartl, *Population Genetics in Forensic DNA Typing*, 254 *SCIENCE* 1745, 1747 (1991).

¹¹⁷ See Ossorio & Duster, *supra* note 77, at 118.

¹¹⁸ *See id.* at 117.

¹¹⁹ Horacio Cardoso et al., *A Low Prevalence of Cystic Fibrosis in Uruguayans of Mainly European Descent*, 3 *GENETICS & MOLECULAR RES.* 258, 259 (2004).

¹²⁰ See S.R. Duncan et al., *Reappraisal of the Historical Selective Pressures for the CCR5- Δ 32 Mutation*, 42 *J. MED. GENETICS* 205 (2005).

¹²¹ See LUIGI LUCA CAVALLI-SFORZA, *GENES, PEOPLES, AND LANGUAGES* 48 (Mark Seielstad trans., 2000); *see also* Schwartz, *supra* note 65, at 1393.

¹²² Tay-Sachs disease, which is found primarily among Ashkenazi Jews, is another gene mutation that can be linked to a very small population that practices endogamy and who may have derived from a particular geographic region. *See* Lillquist & Sullivan, *supra* note 7, at 425; Nicholas Wade, *Diseases Common in Ashkenazim May Be Random*, *N.Y. TIMES*, Mar. 4, 2003, at

quencies can be found anywhere in the world; thus, having the genetic variant will not necessarily correspond to one's geographic origin, skin color, or "race."¹²³ Indeed, for decades, physicians believed that sickle cell disease was exclusively African,¹²⁴ but it can also be found in other areas where malaria is endemic, such as Greece, Saudi Arabia, Turkey, and Iran.¹²⁵ Notably, although sickle cell is commonly associated with black people, the highest incidence of the gene mutation—a rate double that for African Americans—can be found in a population in Greece.¹²⁶ Meanwhile, Kenyans have a low frequency of sickle cell due to the fact that they live at altitudes where the threat of malaria is significantly reduced.¹²⁷

Thus, while one's allele frequency can tell us something about where some of one's ancestors came from, or something about one's predisposition to certain health conditions, it will not necessarily correspond to a particular racial categorization. Nor does perceived race or an individual's racial self-identification reliably indicate anything meaningful about her or his genes.¹²⁸

C. Commercial Incentives

Today, there are powerful economic and regulatory incentives that encourage researchers to use racial data as the basis for develop-

F2. Like the other variant genes, it does not indicate skin color. See Schwartz, *supra* note 65, at 1393.

¹²³ See Ossorio & Duster, *supra* note 77, at 116. Ossorio and Duster explain that definitions of race as based in geographic ancestry

imply a simplistic model of human migration and expansion throughout the world, a model in which small groups of humans traveled to each continent at about the same time, became reproductively isolated and then expanded rapidly to fill the continent in the absence of subsequent events that would create significant within-race patterns of human genetic variation—a nice 'just so story' that is largely consistent with folk beliefs about race, but a story that is contradicted by data from anthropology and human genetics[.]

Id.

¹²⁴ Elizabeth Landau, *How Medicine Is Advancing Beyond Race*, CNN.COM (July 8, 2011, 7:41 AM), http://www.cnn.com/2011/HEALTH/07/08/race.personalized.medicine/index.html?hpt=hp_bn6.

¹²⁵ See Schwartz, *supra* note 65, at 1393; see also CAVALLI-SFORZA, *supra* note 121, at 48.

¹²⁶ JAMIE D. BROOKS & MEREDITH L. KING, CTR. FOR AM. PROGRESS, GENETICIZING DISEASE: IMPLICATIONS FOR RACIAL HEALTH DISPARITIES 11 (2008).

¹²⁷ *Id.*

¹²⁸ See Dutton, *supra* note 2, at 41 ("The correlation between ancestral origins and self-identified race and ethnicity is often imprecise . . . 'because of other non-genetic connotations of race, the lack of defined boundaries between populations, and the fact that many people have ancestors from multiple regions of the world.'" (quoting Dr. Francis Collins, Director of the National Human Genome Research Institute)).

ing new drugs and therapeutics. Federal patent laws, for example, offer lucrative economic incentives to biotech and pharmaceutical companies that devise drugs for particular groups.¹²⁹ These companies are constantly competing to develop patentable drugs and technologies. If they formulate a new drug or discover a new indication for an existing drug, they could possibly obtain or extend a patent on that drug to enjoy market exclusivity.¹³⁰ Thus, these companies have been scouring the 0.1% difference in the human genome to find allele frequencies that might be responsible for certain conditions or diseases, notwithstanding that this tiny percentage of the genome includes everything from genetic illnesses to blood type.¹³¹

BiDil was a combination of two generic drugs with expiring patents.¹³² If BiDil had been approved for the general population, then NitroMed's patent protection for the drug would have expired in 2007.¹³³ However, by using race as a proxy for geographic ancestry, retrospectively examining race-coded data from old studies, and restricting subsequent clinical trials to only black participants, the company was able to find a race-based difference in drug response.¹³⁴ In so doing, the company persuaded the FDA to approve BiDil's race-specific indication, thereby giving NitroMed an additional thirteen years to sell the drug without competition.¹³⁵ Once on the market, BiDil cost four to seven times more than the equivalent generic drugs.¹³⁶

Not surprisingly, in recent years, many more biotech and pharmaceutical companies have attempted to develop race-specific drugs in an effort to exploit this potential gold mine. The biopharmaceutical company VaxGen, for example, in 2003 conducted a retrospective analysis of racial subpopulations to obtain approval for its proposed AIDS vaccine, AIDSVAX.¹³⁷ In its clinical trials, AIDSVAX did not reduce infection rates in the study population as a whole; neverthe-

¹²⁹ See Kahn, *supra* note 8, at 31–33.

¹³⁰ See *id.* at 32.

¹³¹ See generally Kahn, *supra* note 107; Schwartz, *supra* note 65. Examples of allelic variations include hemoglobin susceptibility to breast cancer and blood type. *Id.*

¹³² Kahn, *supra* note 8, at 30.

¹³³ *Id.* at 32.

¹³⁴ Dorr & Jones, *supra* note 91, at 445.

¹³⁵ See U.S. Patent No. 6,465,463 (filed Sept. 8, 2000) (issued Oct. 15, 2002).

¹³⁶ See ROBERTS, *supra* note 96, at 185; BROOKS & KING, *supra* note 126, at 10. BiDil costs insurers approximately \$1,400 to \$2,800 per year per patient; neither Medicaid nor Medicare will cover the cost of the drug because they cover the two less expensive generic drugs that BiDil combines. *Id.*

¹³⁷ Jonathan Kahn, *Race in a Bottle*, *SCI. AM.*, Aug. 2007, at 40, 45.

less, VaxGen maintained that the black and Asian study participants experienced a significant reduction in infections.¹³⁸ Yet, as Professor Jonathan Kahn has noted, because only a few hundred blacks and Asians participated in the trial, a small number of infections easily could have distorted the results.¹³⁹ In the end, VaxGen's assertion that its drug performed better in particular racial populations was undermined by another clinical trial in Thailand that showed AIDS-VAX was ineffective.¹⁴⁰

Similarly, the British pharmaceutical giant, AstraZeneca, claimed that its lung cancer drug, Iressa, performed better in the Asian subjects enrolled in a 2004 clinical trial, even though survival rates did not improve overall for participants in the trial.¹⁴¹ The FDA, unswayed by the company's claims, ultimately prohibited use of the drug by new patients.¹⁴² Undeterred by the FDA's actions with respect to Iressa, AstraZeneca has more recently conducted trials of its blockbuster cholesterol-reducing drug, Crestor, in African Americans, South Asians, and Hispanics.¹⁴³ The patent for the drug, which has earned the company billions of dollars, is set to expire in 2016.¹⁴⁴ Regardless of whether AstraZeneca succeeds with a race-based indication for Crestor, there are likely many more race-specific drugs in the pipeline.¹⁴⁵

III. RACE-BASED BIOMEDICAL RESEARCH AND CONSTITUTIONAL NORMS

Federal laws and regulations that mandate the grouping of individuals into racial categories in government-funded research, yet provide no meaningful guidance, oversight, or effective curbs for inappropriate uses, not only lead to bad science but also harm minority populations. Some commentators have argued that racial catego-

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *See id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *See* Ben Hirschler, *AstraZeneca Back in Court to Defend Crestor Patent*, REUTERS (Oct. 5, 2011, 8:49 AM), <http://www.reuters.com/article/2011/10/05/astrazeneca-crestor-idUSL5E7L51DQ20111005>. "Consumer groups have claimed that Crestor is less safe than other cholesterol-lowering drugs, but AstraZeneca says the race-specific studies demonstrate the safety and efficacy of the medicine." *See* Kahn, *supra* note 137, at 45.

¹⁴⁵ *See generally* Sarah K. Tate & David B. Goldstein, *Will Tomorrow's Medicines Work for Everyone?*, 36 NATURE GENETICS SUPPLEMENT S34, S36 tbl.1 (2004). At least 29 drugs in development are claimed to be more effective in certain racial groups than others. *Id.* at S34.

ries should never be used as variables in biomedical research, while others contend that the mandate to include racial categories in government-funded studies violates the equal protection doctrine.¹⁴⁶ This Article argues, by contrast, that although there are many important reasons for the state to continue requiring the use of race as a variable in biomedical research, in doing so, the government must proceed with care to avoid enabling the abuses of race that are now rampant in this context.

Determining how to accomplish this goal raises an obvious question: What are the appropriate boundaries for the use of race by the government in this context? The demands of science and law inform this question, and this Article addresses the latter with an eye toward developing a workable model for regulating race in biomedical research, which is advanced in Part IV. The question of how the state may regulate uses of race in research has been debated by scholars from a variety of perspectives. On the one hand, health law scholars who have engaged this question have done so too narrowly, while on the other hand, constitutional law and race scholars have done so too broadly. Health law scholars' focus on the doctrinal contours of equal protection jurisprudence (e.g., strict scrutiny, racial classifications, compelling interests, etc.) constrains their ability to fully appreciate the aspect of the Court's jurisprudence that tolerates some degree of race consciousness without imposing strict scrutiny. Constitutional law and race scholars' argument that the Court's race jurisprudence is predominantly characterized by a norm of colorblindness sweeps too broadly as a comprehensive understanding of that jurisprudence. Although they are correct to recognize that the norm of colorblindness seriously constrains state uses of race, there still are instances in this same body of cases where government invocations of race that reflect its social significance are acceptable.

This Part culls from the Court's race cases across a number of legal regimes a discrete set of principles that reveal the extent to which courts have allowed state actors to engage in race-conscious decisionmaking. This Article terms this strain of reasoning "racial pragmatism." This Part demonstrates how the adoption of racial pragmatist reasoning in the biomedical research context can not only improve the way race is deployed in research, but also increase the likelihood of achieving racial justice in and through biomedical research. Indeed, a reading of the Court's equal protection jurispru-

¹⁴⁶ See *infra* Part III.A.

dence as embracing a form of racial pragmatism has important implications for the use of race in government-sponsored scientific research as well as public health policy.

This Part begins by examining the ongoing debate among legal scholars on the appropriate uses of race in biomedical research and the extent to which equal protection strict scrutiny analysis can inform regulatory decisionmaking. This Part then moves beyond strict scrutiny analysis by examining the racial pragmatist perspective. To reveal the analytical nuances of racial pragmatism, this Part maps the Supreme Court's turn toward colorblindness in its antidiscrimination jurisprudence and demonstrates how, notwithstanding its seeming allegiance to colorblindness, the Court also engages in racial pragmatist reasoning when examining the use of racial categories by state actors. In so doing, the Court allows race-conscious decisionmaking by government under certain circumstances.

This Part concludes by textually examining the Court's equal protection caselaw, across contexts and legal regimes, to identify the factors that appear to determine whether a particular state invocation of race will be examined under a racial pragmatist perspective and be deemed constitutionally unproblematic, or will be considered a constitutionally suspect "racial classification" that triggers equal protection strict scrutiny analysis and requires the state to offer a compelling interest. In so doing, this Part focuses on the Court's education, voting rights, and criminal suspect identification jurisprudence.

A. *Debating the Regulation of Race in Biomedical Research*

Over the past few years, legal scholars have debated and discussed the ways in which the law may regulate the use of race in the biomedical sciences, and most scholars have drawn upon strict scrutiny analysis under the Constitution's Equal Protection Clause.¹⁴⁷ Application of equal protection doctrine¹⁴⁸ involves two analytically distinct steps: the reviewing court must first determine whether the government's action implicates a constitutionally suspect classification (e.g., race or gender), and then it must apply the appropriate level of

¹⁴⁷ See Kahn, *supra* note 107, at 1967; Kahn, *supra* note 8, at 44; Lillquist & Sullivan, *supra* note 7, at 461–65; Obasogie, *supra* note 9, at 496; Roberts, *supra* note 9, at 529–30.

¹⁴⁸ U.S. CONST. amend. XIV, § 1 (no state shall "deny to any person within its jurisdiction the equal protection of the laws"). The Equal Protection Clause "is essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 439 (1985). The Supreme Court has held that this Fourteenth Amendment guarantee applies to the federal government as an aspect of Fifth Amendment due process. *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954).

judicial scrutiny.¹⁴⁹ If the government's action involves a racial classification, the court will apply strict scrutiny, the highest level of judicial review. Under strict scrutiny, the government must prove that its action or law serves a compelling governmental interest and is essential to achieving that interest (i.e., the least restrictive means of realizing that interest).¹⁵⁰

1. *Race Through the Lens of Strict Scrutiny*

Many legal scholars apply equal protection strict scrutiny analysis in the biomedical research context to evaluate the laws and regulations that mandate the introduction of racial categories into biomedical research.¹⁵¹ Some of these scholars focus on the vulnerability of these laws and policies to heightened constitutional scrutiny. They argue that the NIH Revitalization Act “clearly involves a racial classification” that would trigger strict scrutiny review, while the FDA rules allow the agency to “knowingly fund[] discriminatory trials” and therefore require the agency to demonstrate that its actions are narrowly tailored.¹⁵² These legal commentators propose prohibiting “both government authorization of race-based clinical trials and government funding of studies in which race is the variable of interest,

¹⁴⁹ See *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 216 (1995) (quoting *McLaughlin v. Florida*, 379 U.S. 184, 191–92 (1964)). Although the Equal Protection Clause originated from a concern about race-based discrimination, the court has interpreted the clause to apply to such classifications as gender, alienage, and illegitimacy, as well as to government actions that burden a “fundamental interest,” including voting and access to courts. See *Pers. Admin'r of Mass. v. Feeney*, 442 U.S. 256, 273 (1979) (gender); *Sugarman v. Dougall*, 413 U.S. 634, 641 (1973) (alienage); *Levy v. Louisiana*, 391 U.S. 68, 70 (1968) (illegitimacy); *Reynolds v. Sims*, 377 U.S. 533, 561 (1964) (voting); *Griffin v. Illinois*, 351 U.S. 12, 18 (1956) (access to courts).

¹⁵⁰ *Adarand*, 515 U.S. at 235. Depending on the type of classification or whether a fundamental right is involved, the court will apply one of three levels of equal protection scrutiny, listed here in descending order of stringency: Racial classifications receive strict scrutiny, gender classifications receive intermediate scrutiny, and all other classifications, including those that implicate age, socioeconomic status, disability, or sexual orientation, receive rational basis review. See *id.* (applying strict scrutiny to racial classifications); *Feeney*, 442 U.S. at 273 (applying intermediate scrutiny to gender classifications); *Cleburne*, 473 U.S. at 446 (applying rational basis review).

¹⁵¹ See, e.g., Lillquist & Sullivan, *supra* note 7, at 464; Roberts, *supra* note 9, at 532.

¹⁵² Lillquist & Sullivan, *supra* note 7, at 463–65. According to Lillquist and Sullivan: To the extent that racial qualifications are revealed in HHS grant applications, the federal government would be knowingly funding discriminatory trials. To the extent that the FDA is approving [new drug applications] using race as a qualification, the agency is legalizing the use of drugs that would otherwise be illegal in order to authorize discrimination. This would seem to constitute a racial classification that could be justified only by the agency in question demonstrating a compelling interest for the discrimination and that the restriction was narrowly tailored.

Id. at 463; see also Lillquist & Sullivan, *supra* note 14, at 540.

except when a compelling interest can be identified . . . and researchers can show why they need to use race instead of using genetic markers.”¹⁵³

Other scholars employ strict scrutiny analysis as a normative framework through which to evaluate laws that regulate the use of race in research.¹⁵⁴ Professor Dorothy Roberts, for example, proposes using race as a sociopolitical category in biomedical research rather than a genetic category, and grounds her important and innovative “social justice” framework in equal protection strict scrutiny analysis because, according to Roberts:

[T]he strict scrutiny test asks the same fundamental question as a social justice approach: when does attention to race legitimately further the state’s interest in racial equality? While racial categories may further compelling interests in improving health care and promoting racial equality, are they “benign” and narrowly tailored to further these interests, or are they insufficiently tied to these aims?¹⁵⁵

2. *Beyond Strict Scrutiny*

Scholars who rely upon strict scrutiny analysis are constrained by the Supreme Court’s equal protection jurisprudence because the Court’s acceptance of colorblindness as the primary animating principle in the doctrine has, in many ways, rendered application of strict scrutiny “strict in theory, but fatal in fact.”¹⁵⁶ Once courts apply strict scrutiny, the law or government action almost inevitably fails. As a result, examining the regulation of race in biomedical research by applying equal protection strict scrutiny analysis is likely to constitute an exercise in futility.

Even scholars who employ strict scrutiny analysis as a normative lens through which to determine appropriate and inappropriate uses of race in biomedical research will find their theories difficult to put into practice, as the identification of a state interest that courts will

¹⁵³ Lillquist & Sullivan, *supra* note 14 at 547–48.

¹⁵⁴ Kahn, *supra* note 107, at 1967 (suggesting that the government require a “tight fit” when researchers attempt to conflate the social categories of race and ethnicity with genetic categories of populations in biomedical and clinical research); Kahn, *supra* note 8, at 44 (arguing that the FDA should reject an application to use race as a biological or genetic category unless the applicant can satisfy the equal protection strict scrutiny test); Obasogie, *supra* note 9, at 496 (proposing adopting equal protection strict scrutiny analysis as a “regulatory guidepost” for devising an oversight mechanism to govern the development of race-specific drugs).

¹⁵⁵ Roberts, *supra* note 9, at 532.

¹⁵⁶ Fullilove v. Klutznick, 448 U.S. 448, 507 (1980).

find sufficiently “compelling” and “narrowly tailored” to survive strict scrutiny presents a formidable challenge. Hence, legal scholars who seek to preserve the use of race as a variable in biomedical research will likely find reliance upon strict scrutiny analysis to be an insufficient effort.

If, however, we allow ourselves to look beneath strict scrutiny analysis to the normative objectives and concerns that motivate it, we will see that, although the Court’s race jurisprudence is heavily influenced by a colorblind norm, it is neither as coherent nor unyielding as its recent antidiscrimination caselaw suggests.¹⁵⁷ The Court has, in fact, at times permitted certain invocations of race by government actors. The Court has held that such race-conscious decisionmaking is not only presumptively acceptable but normatively desirable and, as such, does not constitute a “racial classification” deserving of strict scrutiny.¹⁵⁸ This line of reasoning by the Court is “racial pragmatism.”

Racial pragmatism represents a strain of judicial reasoning, operating within the existing colorblind analytical paradigm, that allows for real-world understandings of race. Although racial pragmatism does not mitigate the way colorblindness hinders efforts to remedy past and ongoing race discrimination, jurists’ reliance upon racial pragmatist reasoning does demonstrate that even those jurists who generally embrace a colorblindness norm have on occasion been uneasy about the implications of taking colorblindness to its logical conclusion.¹⁵⁹ As a result, some jurists and a minority of Justices whose ordinary orientation is towards colorblindness have at times distanced themselves from it as a normative and practical matter, favoring instead a more pragmatic understanding of the salience of race.¹⁶⁰

The following Sections posit that the principles and themes that undergird racial pragmatist reasoning can provide useful guidelines for thinking about race generally and for conceptualizing appropriate uses of race in science. Indeed, this Part demonstrates that although racial pragmatist reasoning can be problematically applied, the reasoning itself represents a useful approach to considering appropriate regulation in this context. Therefore, because I share the social justice aspirations of Professor Roberts and others with respect to the regulation of race in research, the following Sections demonstrate how these

¹⁵⁷ See *infra* Part III.B.

¹⁵⁸ See, e.g., *Grutter v. Bollinger*, 539 U.S. 306 (2003).

¹⁵⁹ See *id.*

¹⁶⁰ See *infra* Part III.C.

aspirations can be achieved without automatically defaulting to the increasingly circumscribed equal protection strict scrutiny analysis.

B. Colorblind Norms and Limits in Equal Protection

Since the 1960s, culminating in the 2008 presidential campaign and the historic election of the nation's first African American president, commentators, jurists, and academics have increasingly debated, embraced, and bemoaned what is popularly known as "colorblindness." As an ideology, discursive practice, and the Supreme Court's primary analytical approach to antidiscrimination caselaw, colorblindness stands for the proposition that state actions that invoke racial categories are uniformly harmful and normatively ill-advised, regardless of whether they are done to remedy past structural race-based discrimination or to address social inequality.¹⁶¹ As a result, race should be presumptively irrelevant to government decisionmaking. To the most fervent proponents of colorblindness on the Court, the concept encompasses both a practical and moral dimension. According to Justice Clarence Thomas: "The Constitution abhors classifications based on race, not only because those classifications can harm favored races or are based on illegitimate motives, but also because every time the government places citizens on racial registers and makes race relevant to the provision of burdens or benefits, it demeans us all."¹⁶²

The U.S. Supreme Court has struggled over the past forty years to determine the role race should play in government decisionmaking, yet it has incrementally adopted colorblindness as its primary normative framework. Initially, the Court held that race could be considered to remedy past racial discrimination and applied this notion in a few discrete areas: voting, employment, and education.¹⁶³ However,

¹⁶¹ Helen Norton, *The Supreme Court's Post-Racial Turn Towards a Zero-Sum Understanding of Equality*, 52 WM. & MARY L. REV. 197, 208 (2010).

¹⁶² *Grutter*, 539 U.S. at 353 (Thomas, J., concurring in part and dissenting in part) (rejecting a public law school's consideration of race in admissions as the functional equivalent of a quota to the extent that it did not allow for individual consideration and was therefore not narrowly tailored to achieve educational diversity); see also *Rice v. Cayetano*, 528 U.S. 495, 517 (2000) ("One of the principal reasons race is treated as a forbidden classification is that it demeans the dignity and worth of a person to be judged by ancestry instead of by his or her own merit and essential qualities."); Norton, *supra* note 161, at 208–09 (discussing the instrumentalist and moral dimensions of the Court's application of colorblindness).

¹⁶³ See, e.g., *City of Rome v. United States*, 446 U.S. 156, 177–78 (1980) (voting); *United Steelworkers of Am. v. Weber*, 443 U.S. 193, 208–09 (1979) (employment); *Regents of the Univ. of Cal. v. Bakke*, 438 U.S. 265, 403 (1978) (Blackmun, J., concurring) (education).

beginning in the 1970s, the Court began to gradually restrict the use of race-conscious policies as a means of correcting racial disparities.¹⁶⁴

The Court was subsequently divided over whether to accept the assumption of colorblindness that race should not be considered in government decisionmaking. Some Justices argued that much more needed to be done before victory could be declared in the effort to end racial discrimination.¹⁶⁵ Others contended that we have achieved a colorblind reality and that, “[i]n the eyes of government, we are just one race here. It is American.”¹⁶⁶

During the 1980s and 1990s, the Court moved steadfastly towards a colorblind approach to race-based classifications. For example, in *City of Richmond v. J.A. Croson Co.*,¹⁶⁷ the Court rejected a municipal program that required prime contractors on city-funded construction projects to award at least thirty percent of the contract amount to minority-owned subcontractors.¹⁶⁸ In so doing, the Court adopted strict scrutiny as the default standard of review in racial discrimination cases, regardless of whether the government action was intended to remedy or perpetuate discrimination on the basis of race, and regardless of the race of those burdened or benefitted by the particular state action.¹⁶⁹ Six years later, in *Adarand Constructors, Inc., v. Peña*,¹⁷⁰ the

¹⁶⁴ See, e.g., *Washington v. Davis*, 426 U.S. 229, 238–48 (1976) (upholding a District of Columbia police officer’s exam that disproportionately excluded African Americans from the police force and holding that state action will not be considered unconstitutional solely because it has a disparate impact upon certain racial groups; instead, the plaintiff must show discriminatory intent); *Keyes v. Sch. Dist. No. 1*, 413 U.S. 189, 198 (1973) (“[P]laintiffs must prove not only that segregated schooling exists but also that it was brought about or maintained by intentional state action.”); see also *Pers. Adm’r of Mass. v. Feeney*, 442 U.S. 256, 272 (1979) (“[E]ven if a neutral law has a disproportionately adverse effect upon a racial minority, it is unconstitutional under the Equal Protection Clause only if that impact can be traced to a discriminatory purpose.”).

¹⁶⁵ See, e.g., *Bakke*, 438 U.S. at 403 (Blackmun, J., concurring) (“I yield to no one in my earnest hope that the time will come when an ‘affirmative action’ program is unnecessary and is, in truth, only a relic of the past. I would hope that we could reach this state within a decade at most. But the story of *Brown v. Board of Education*, decided almost a quarter of a century ago, suggests that that hope is a slim one.”) (citation omitted).

¹⁶⁶ *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 239 (1995) (Scalia, J., concurring); see also *Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 759 (2007) (Thomas, J., concurring) (race-based classifications are “precisely the sort of government action that pits the races against one another, exacerbates racial tension, and ‘provoke[s] resentment among those who believe that they have been wronged by the government’s use of race’” (quoting *Adarand*, 515 U.S. at 241)); *Adarand*, 515 U.S. at 224 (“[A]ny person, of whatever race, has the right to demand that any governmental actor subject to the Constitution justify any racial classification subjecting that person to unequal treatment under the strictest judicial scrutiny.”).

¹⁶⁷ *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469 (1989).

¹⁶⁸ *Id.* at 500.

¹⁶⁹ *Id.* at 493–94, 498–500; see also *Adarand*, 515 U.S. at 227 (“[A]ll racial classifications,

Court examined a federal competitive bidding plan that provided incentives to government contractors to award subcontracts to small businesses owned by “socially and economically disadvantaged individuals” such as racial minorities.¹⁷¹ In a five-to-four vote, the Court remanded the case, holding that such race-based programs are subject to strict scrutiny, even if they are meant to remedy the effects of past discrimination.¹⁷²

The Court’s acceptance of colorblindness has culminated in its most recent decisions severely limiting the government’s ability to use race-based classifications to address centuries of state-sanctioned racial discrimination. In *Parents Involved in Community Schools v. Seattle School District No. 1*,¹⁷³ the Court held that race-conscious policies are “extreme measure[s]” that are presumptively invalid.¹⁷⁴ Justice Roberts famously concludes his opinion with the directive: “The way to stop discrimination on the basis of race is to stop discriminating on the basis of race.”¹⁷⁵ Most recently, in *Ricci v. DeStefano*,¹⁷⁶ the Court, for the first time, ruled that a public employer’s decision to acknowledge and address the racially disparate impact of its practices, in this case a firefighter’s exam, was itself unlawful discrimination.¹⁷⁷ This may portend a similar change in the Court’s equal protection jurisprudence.¹⁷⁸

C. Racial Pragmatism in the Court’s Jurisprudence

Many legal commentators over the years have noted a philosophical division on the Court regarding the role race should play in government decisionmaking. The prevailing framework for capturing this divide has been to cast the concerns motivating the Justices as cleaving according to antistatutory and anticlassification interests.¹⁷⁹

imposed by whatever federal, state, or local governmental actor, must be analyzed by a reviewing court under strict scrutiny.”).

¹⁷⁰ *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200 (1995).

¹⁷¹ *Id.* at 200, 227.

¹⁷² *Id.* at 235–39.

¹⁷³ *Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701 (2007).

¹⁷⁴ *Id.* at 728.

¹⁷⁵ *Id.* at 748.

¹⁷⁶ *Ricci v. DeStefano*, 129 S. Ct. 2658 (2009).

¹⁷⁷ *Id.* at 2681.

¹⁷⁸ *Id.* at 2683 (Scalia, J., concurring) (“[T]he war between disparate impact and equal protection will be waged sooner or later, and it behooves us to begin thinking about how—and on what terms—to make peace between them.”).

¹⁷⁹ See, e.g., Charles R. Lawrence, *Forbidden Conversations: On Race, Privacy and Community* (A Continuing Conversation with John Ely on Racism and Democracy), 114 *YALE L.J.* 1353, 1382 (2005) (asserting that the Equal Protection Clause “creates a new substantive value of

Those Justices who advance an antistatutory perspective understand the Equal Protection Clause as prohibiting government actions that, either by intent or effect, reinforce racial inequality.¹⁸⁰ In addition, these Justices, whose views have most recently been represented primarily in dissenting opinions, draw a distinction between laws that seek to remedy and laws that seek to perpetuate racism.¹⁸¹ Thus, they have consistently found that “[a]ctions designed to burden groups long denied full citizenship stature are not sensibly ranked with measures taken to hasten the day when entrenched discrimination and its aftereffects have been extirpated.”¹⁸² As a result, to these Justices, race-conscious government actions that seek to advance the interests of particular racial groups by addressing past state-sanctioned racial discrimination or alleviating racial stratification should be constitutionally permissible.¹⁸³

The Justices who adhere to an anticlassification approach, on the other hand, understand the Constitution as protecting individual and not group interests, and therefore eschew state actions that involve clustering people into racial categories.¹⁸⁴ According to advocates of this perspective: “[U]nder our Constitution there can be no such thing as either a creditor or debtor race. That concept is alien to the Constitution’s focus upon the individual . . . and its rejection of dispositions

‘non-slavery’ and antistatutory to replace the old values of slavery and white supremacy”); Jack M. Balkin & Reva B. Siegel, *The American Civil Rights Tradition: Anticlassification or Antistatutory?*, 58 U. MIAMI L. REV. 9, 10 (2003); Reva B. Siegel, *Equality Talk: Antistatutory and Anticlassification in Constitutional Struggles over Brown*, 117 HARV. L. REV. 1470, 1472–73 (2004).

¹⁸⁰ *Parents Involved*, 551 U.S. at 864 (Breyer, J., dissenting) (“The Equal Protection Clause, ratified following the Civil War, has always distinguished in practice between state action that excludes and thereby subordinates racial minorities and state action that seeks to bring together people of all races.”).

¹⁸¹ *Id.* at 799 n.3 (Stevens, J., dissenting) (“[A] decision to exclude a member of a minority because of his race is fundamentally different from a decision to include a member of a minority for that reason.”); see also *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 243 (1995) (Stevens, J., dissenting) (“There is no moral or constitutional equivalence between a policy that is designed to perpetuate a caste system and one that seeks to eradicate racial subordination.”); *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 551–52 (1989) (Marshall, J., dissenting) (“A profound difference separates governmental actions that themselves are racist, and governmental actions that seek to remedy the effects of prior racism or to prevent neutral governmental activity from perpetuating the effects of such racism.”).

¹⁸² *Gratz v. Bollinger*, 539 U.S. 244, 301 (2003) (Ginsberg, J., dissenting).

¹⁸³ See *Parents Involved*, 551 U.S. at 803 (Breyer, J., dissenting) (“[T]he Constitution permits local communities to adopt desegregation plans even where it does not require them to do so.” (emphasis omitted)).

¹⁸⁴ See Ian F. Haney López, “A Nation of Minorities”: *Race, Ethnicity, and Reactionary Colorblindness*, 59 STAN. L. REV. 985, 988 (2006–2007).

based on race”¹⁸⁵ Those on the Court who have championed this view reject all racial classifications, and this anticlassification perspective has fueled the Court’s move towards colorblindness.¹⁸⁶

This Section contends that focusing on these approaches precludes a full appreciation of the way the Court occasionally permits some substantive forms of race-conscious decisionmaking by government actors. That is, some significant uses of race appear to the Court to capture the social salience of race, while not producing or invoking the gallery of harms that the Court attaches to other forms of race-conscious decisionmaking. Indeed, the Court has evinced the most concern about the uses of race that group people into racial categories without acknowledging individual differences within the group, or what some scholars have referred to as “wooden racial classifications.”¹⁸⁷ The Court has also expressed strong aversion to abstracting from a racial category a set of assumptions about the entire group, which leads to racial stereotyping, among other harms.¹⁸⁸

Interestingly, despite finding that many uses of race carry these harms, some Justices have simultaneously acknowledged that under some circumstances, state actors can be race conscious and such race consciousness is also normatively appropriate to the extent that it allows the state to account for the social significance of race. In these cases, strict scrutiny will not be triggered, and hence there is no search for a compelling interest that would justify the necessary evil of considering race. Admittedly, those instances in the Court’s jurisprudence are rare. However, they do signal a nuance that the Court has brought to its analysis of race-conscious government action.

Some jurists apply racial pragmatist reasoning in a way that is attentive to equality concerns. Others, however, apply it in a more retrograde manner. The following Section illustrates this distinction by examining where and when courts seem to embrace a sort of pragmatism about race. Then, Part IV demonstrates the ways in which

¹⁸⁵ *Adarand*, 515 U.S. at 239 (Scalia, J., concurring in part and concurring in the judgment).

¹⁸⁶ *Parents Involved*, 551 U.S. at 748 (Thomas, J., concurring) (“Disfavoring a color-blind interpretation of the Constitution, the dissent would give school boards a free hand to make decisions on the basis of race—an approach reminiscent of that advocated by the segregationists in *Brown v. Board of Education*. This approach is just as wrong today as it was a half century ago.” (citation omitted)).

¹⁸⁷ Akhil Reed Amar & Neal Kumar Katyal, *Bakke’s Fate*, 43 *UCLA L. REV.* 1745, 1763–64 (1996) (describing how the Court rejects the use of “wooden racial classification[s]”).

¹⁸⁸ See *Shaw v. Reno*, 509 U.S. 630, 647 (1993) (excessive race-based reapportionment “reinforces the perception that members of the same racial group—regardless of their age, education, economic status, or the community in which they live—think alike, share the same political interests, and will prefer the same candidates at the polls”).

racial pragmatism can offer a useful framework for devising a more equality-enhancing vision of the regulation of race in science.

1. *Race as Additional Factor*

Consider the Court's racial gerrymandering line of cases. These cases raise the question of whether state legislators who redraw voting lines can do so in a race-conscious manner. A particularly interesting aspect of these cases is the way the Court adjudicates issues regarding the extent to which race can be considered without triggering strict scrutiny review.

Redistricting or reapportionment involves state legislatures redrawing electoral districts in response to the data obtained from the decennial census.¹⁸⁹ Normally, political gerrymandering is subject to rational basis review.¹⁹⁰ However, this process can implicate equal protection concerns if the "reapportionment plan rationally cannot be understood as anything other than an effort to segregate citizens into separate voting districts on the basis of race without sufficient justification."¹⁹¹

In a series of cases, beginning with *Shaw v. Reno*,¹⁹² plaintiffs challenged state redistricting plans, yet they did not argue that the facially neutral redistricting decisions were made with a discriminatory purpose (to disenfranchise a particular group) or that their right to vote was diluted.¹⁹³ Rather their argument was that race-conscious redistricting itself violated their right to participate in a "color-blind" electoral process¹⁹⁴ and led to alleged "representational harms," to the extent that the redrawn districts "convey the message that political identity is, or should be, predominantly racial."¹⁹⁵ Under equal protection analysis, such race-conscious decisionmaking by legislatures would trigger strict scrutiny review and require a compelling justification by government actors.¹⁹⁶ In these cases, however, the Court employed racial pragmatist reasoning to identify three factors

¹⁸⁹ See *id.* at 633.

¹⁹⁰ See *supra* note 163 and accompanying text (discussing the application of rational basis review to classifications other than gender or race).

¹⁹¹ *Shaw*, 509 U.S. at 652; see also Terry Smith, *Autonomy Versus Equality: Voting Rights Rediscovered*, 57 ALA. L. REV. 261, 274–75 (2005).

¹⁹² *Shaw v. Reno*, 509 U.S. 630 (1992).

¹⁹³ See Sheila Foster, *Intent and Incoherence*, 72 TUL. L. REV. 1065, 1162 (1998).

¹⁹⁴ See *Shaw*, 509 U.S. at 641.

¹⁹⁵ *Bush v. Vera*, 517 U.S. 952, 980 (1996).

¹⁹⁶ See *supra* note 150 and accompanying text.

that influence whether the invocation of race in the reapportionment process will be subject to strict scrutiny.

The question before the Court in *Shaw v. Reno* was whether legislative redistricting measures designed to benefit particular racial groups create a cause of action under the Fourteenth Amendment.¹⁹⁷ The Court held that a claim of excessive racial gerrymandering was indeed subject to equal protection analysis.¹⁹⁸ Although the decision was criticized rightfully as overly restrictive and, at first glance, appeared to impose a rigid norm of colorblindness, the Court expressed racial pragmatist concerns to the extent that it ruled that, while drawing district lines, legislatures must necessarily exercise a degree of race consciousness.¹⁹⁹ Writing for the majority, Justice O'Connor declared it "antithetical to our system of representative democracy" when "a district obviously is created solely to effectuate the perceived common interests of one racial group," yet she nevertheless found that "the legislature always is *aware* of race when it draws district lines, just as it is aware of age, economic status, religious and political persuasion, and a variety of other demographic factors. That sort of race consciousness does not lead inevitably to impermissible racial discrimination."²⁰⁰ Thus, when race is one among many factors, rather than employed by itself as a sufficient factor, the consideration of race in redistricting may be constitutionally acceptable.

Two years later, in *Miller v. Johnson*,²⁰¹ Justice O'Connor opined in a concurrence that "even though race may well have been considered in the redistricting process," such an invocation of race should not trigger strict scrutiny so long as "States have drawn the boundaries in accordance with their customary districting principles,"²⁰² such as "compactness, contiguity, and respect for political subdivisions."²⁰³ In addition, the Court held that strict scrutiny would be applied only where "race was the predominant factor motivating the legislature's decision to place a significant number of voters within or without a particular district."²⁰⁴ This exacting standard requires more than a demonstration simply that the legislature "committed from the outset to creating majority-minority districts," or "manipulated district lines"

¹⁹⁷ See *id.* at 633–34, 642.

¹⁹⁸ See *id.* at 649.

¹⁹⁹ See *id.* at 642.

²⁰⁰ *Id.* at 646, 648.

²⁰¹ *Miller v. Johnson*, 515 U.S. 900 (1995).

²⁰² *Id.* at 928–29 (O'Connor, J., concurring).

²⁰³ *Id.* at 916 (majority opinion).

²⁰⁴ *Id.*

to achieve its race-conscious goals, or “substantially neglected traditional districting criteria.”²⁰⁵ According to the “predominant motive” standard, race must be the driving factor in the legislative linedrawing process for strict scrutiny to be invoked.²⁰⁶

In *Easley v. Cromartie*,²⁰⁷ for example, the Court was asked to decide whether the North Carolina legislature relied upon “race *rather than* politics” in the drawing of a congressional district.²⁰⁸ Although race played a significant role in the legislature’s redistricting efforts, the Court held that the legislature’s race-conscious decisionmaking did not violate the Equal Protection Clause because race was not the predominant factor in the redistricting.²⁰⁹ In so doing, the Court noted the “undisputed evidence that racial identification is highly correlated with political affiliation in North Carolina,” as whites registered as Democrats crossed party lines to vote Republican more often than African Americans, who registered and voted Democratic between ninety-five percent and ninety-seven percent of the time.²¹⁰ As a result, according to the Court, those involved in the redistricting process can take account of race to capture political affiliation.²¹¹

Despite the Court’s avowed colorblind and anticlassification concerns that allowing states to engage in race-based reapportionment may reinforce “the perception that members of the same racial group—regardless of their age, education, economic status, or the community in which they live—think alike, share the same political interests, and will prefer the same candidates at the polls,”²¹² it has nonetheless recognized that race consciousness in this context does not necessarily cause these stereotyping harms, and, in so doing, has adopted a racial pragmatist perspective regarding the significance of race in American political life.

The Court implicitly acknowledges that the United States remains a highly segregated society and that the gerrymandering exercise will account for that.²¹³ The Court also implicitly appreciates that

²⁰⁵ *Bush v. Vera*, 517 U.S. 952, 962 (1996) (observing that any one of these factors is not “independently sufficient to require strict scrutiny,” even though together they “weigh in favor of the application of strict scrutiny”); *see also* *Foster*, *supra* note 193, at 1166–67 (observing that “race-consciousness does not automatically prove constitutionally problematic”).

²⁰⁶ *Miller*, 515 U.S. at 916.

²⁰⁷ *Easley v. Cromartie*, 532 U.S. 234 (2001).

²⁰⁸ *Id.* at 243.

²⁰⁹ *See id.* at 243–44.

²¹⁰ *Id.* at 243–45.

²¹¹ *Id.* at 245.

²¹² *Shaw v. Reno*, 509 U.S. 630, 650 (1992).

²¹³ *See Easley*, 532 U.S. at 243.

voters often cast ballots along racial lines, due in large part to their social experience of race or racial discrimination.²¹⁴ In addition, the Court recognizes that legislators are inevitably conscious of the deep and real connections between political affiliation and race.²¹⁵ This awareness that drives racial pragmatist reasoning tempers the Court's colorblind impulse. Indeed, while the application of strict scrutiny to explicit racial classifications is based in part on the presumption that race is not relevant to government decisionmaking, in the racial redistricting context, a majority of Justices agree that race is relevant and may be invoked in the creation of majority-minority districts without necessarily raising constitutional concerns.²¹⁶

2. *Race as Descriptive Factor*

As the previous Section demonstrated, in the voting rights context, racial pragmatist reasoning creates a space for race-conscious decisionmaking that appreciates the reality of racial stratification and the social experience of race. There are, however, some contexts in which the application of racial pragmatism can be more regressive. Race-based suspect identification represents one such example.

Although racial profiling by law enforcement has been broadly condemned as illegitimate and constitutionally suspect,²¹⁷ courts have uniformly accepted the practice of identifying criminal suspects based upon their race.²¹⁸ Racial profiling involves inferring a connection between an individual and a particular criminal offense based upon generalizations about the characteristics or behavior of others of the same racial group.²¹⁹ Criminal suspect identification, on the other hand, in-

²¹⁴ See *id.* at 245.

²¹⁵ See *id.*; see also, e.g., *Bush v. Vera*, 517 U.S. 952, 958–59 (1996); *Shaw*, 509 U.S. at 646.

²¹⁶ See Foster, *supra* note 193, at 1165–66.

²¹⁷ See DAVID COLE, *NO EQUAL JUSTICE: RACE AND CLASS IN THE AMERICAN CRIMINAL JUSTICE SYSTEM* 50 (1999); RANDALL L. KENNEDY, *RACE, CRIME, AND THE LAW* 162 (1997); Sheri Lynn Johnson, *Race and the Decision to Detain a Suspect*, 93 *YALE L.J.* 214, 257 (1983).

²¹⁸ See *United States v. Waldon*, 206 F.3d 597, 604 (6th Cir. 2000) (holding that police may consider race in stopping a person if a criminal suspect's description includes a racial identification); *Buffkins v. City of Omaha*, 922 F.2d 465, 467–68 (8th Cir. 1990) (holding that the detention of a black woman at an airport did not amount to racial discrimination under § 1981 because "her race matched the racial description of the person described in the tip," which was only that "a black person or persons arriving on a flight from Denver" would be carrying cocaine). The practice of race-based suspect identification is considered by many legal commentators to be a legitimate use of race. See COLE, *supra* note 217, at 50; KENNEDY, *supra* note 217, at 150; Johnson, *supra* note 217, at 242–43. The practice does, however, have its critics. See R. Richard Banks, *Race-Based Suspect Selection and Colorblind Equal Protection Doctrine and Discourse*, 48 *UCLA L. REV.* 1075, 1096 (2001).

²¹⁹ See Banks, *supra* note 218, at 1081.

volves a physical description of a perpetrator of a crime elicited by law enforcement from either a victim or witness to the criminal event.²²⁰

Law enforcement today routinely relies upon both practices, and although state and lower federal courts have held that racial profiling may violate the Equal Protection Clause,²²¹ when presented with a challenge to the use of a race-based suspect description, they have consistently evaded the issue by concluding that the official use of racial categories in this context is appropriate.²²² The Supreme Court has indicated in dicta that racial profiling warrants strict scrutiny review,²²³ but it has never suggested that race-based suspect descriptions are “racial classifications” that implicate equal protection concerns.

This is so notwithstanding the fact that the practice raises antisubordination, anticlassification, and colorblindness concerns.²²⁴ The use of race-based suspect classifications, like racial profiling, involves the intentional invocation of race by state actors and has the potential to disparately burden members of racial minority populations who have committed no wrongdoing.²²⁵ In *Brown v. City of Oneonta*,²²⁶ for example, the Second Circuit presided over a case in which an attempted assault victim described her assailant to police as a young, black male with a cut on his hand.²²⁷ Over the next five days, police officers detained for questioning and physical inspection every black person, male or female, they could locate in and around the city of Oneonta, New York, beginning with students at Oneonta University.²²⁸ During this sweep, the police pulled over cars with black occu-

²²⁰ See *id.*

²²¹ See, e.g., *Chavez v. Ill. State Police*, 251 F.3d 612, 635 (7th Cir. 2001); *Flowers v. Fiore*, 239 F. Supp. 2d 173, 178 (D.R.I. 2003).

²²² See, e.g., *Waldon*, 206 F.3d at 604 (“Common sense dictates that, when determining whom to approach as a suspect of criminal wrongdoing, a police officer may legitimately consider race as a factor if descriptions of the perpetrator known to the officer include race.”); *State v. Ampey*, 609 P.2d 96, 97 (Ariz. Ct. App. 1980) (race properly used as an “identifying characteristic”); see also *Brown v. City of Oneonta*, 221 F.3d 329, 333–34 (2d Cir. 2000); *United States v. Davis*, 200 F.3d 1053, 1054 (7th Cir. 2000); *United States v. Lopez-Martinez*, 25 F.3d 1481, 1487 (10th Cir. 1994); *Cartnail v. State*, 753 A.2d 519, 530 (Md. 2000).

²²³ See *Whren v. United States*, 517 U.S. 806, 813 (1996) (“We of course agree . . . that the Constitution prohibits selective enforcement of the law based on considerations such as race.”).

²²⁴ See, e.g., David A. Harris, *The Stories, the Statistics, and the Law: Why “Driving While Black” Matters*, 84 MINN. L. REV. 265, 298–305 (1999).

²²⁵ See *Banks*, *supra* note 218, at 1080.

²²⁶ *Brown v. City of Oneonta*, 221 F.3d 329 (2d Cir. 2000).

²²⁷ *Id.* at 334 (The victim told the police “that she could not identify her assailant’s face, but that he was wielding a knife; that he was a black man, based on her view of his hand and forearm; and that he was young, because of the speed with which he crossed her room . . . [and] that, as they struggled, the suspect had cut himself on the hand with the knife.”).

²²⁸ *Id.*

pants, obtained a list of all black students at the university, and even prevented black people from boarding public transportation unless and until they provided identification.²²⁹ In the end, more than two hundred black people were detained and questioned, but no suspect was apprehended.²³⁰ Despite these facts, the Second Circuit ultimately held that no equal protection violation had occurred as a result of the police actions,²³¹ and the Supreme Court denied a petition for certiorari.²³²

As *Brown v. City of Oneonta* demonstrates, race-based suspect descriptions appear to be racial classifications to the extent that law enforcement procedures require the collection of race data from witnesses, law enforcement virtually always delimits searches by race, and such searches can disparately burden innocent members of minority groups.²³³ Nevertheless, courts have uniformly held that the reliance upon racial categories by law enforcement in this context does not require equal protection strict scrutiny, and this determination seems to be driven by racial pragmatist considerations.

First, the use of race in suspect identifications appears not to raise equal protection concerns because race is offered as one among several elements in the suspect description, and therefore race is not the sole or predominant identifying characteristic.²³⁴ Second, courts have found that the use of racial categories in this context is constitutionally unproblematic because race is understood as appropriately describing or correlating with some underlying social reality.²³⁵ Thus, this use of

²²⁹ *Id.* at 334, 340–41.

²³⁰ *Id.* at 340–41.

²³¹ *Id.* at 341.

²³² *Brown v. City of Oneonta*, 534 U.S. 816 (2001).

²³³ *See Banks*, *supra* note 218, at 1109–12.

²³⁴ *See United States v. Martinez-Fuerte*, 428 U.S. 543, 563 (1976) (finding “no constitutional violation” when motorists near the border are singled out by law enforcement “largely on the basis of apparent Mexican ancestry”); *United States v. Brignoni-Ponce*, 422 U.S. 873, 885–89 (1975) (same); *Davis v. Mississippi*, 394 U.S. 721, 722–28 (1969) (upholding detention and fingerprinting of black suspect when “[t]he victim could give no better description of her assailant than that he was a Negro youth”); *Monroe v. City of Charlottesville*, 579 F.3d 380, 390 (4th Cir. 2009), *cert. denied*, 130 S. Ct. 1740 (2010) (holding that “[t]he use of race was but one ‘pertinent element’ or characteristic of the suspect” and further noting that “[b]ecause the description of the assailant included being a young-looking black male, it is no surprise that the officers’ investigation almost certainly produced a disparate but incidental impact on young, black males, even though the purpose of the investigation was to target neither African-Americans nor males”); *Brown*, 221 F.3d at 337–38 (“This description [of the suspect] contained not only race, but also gender and age, as well as the possibility of a cut on the hand.”).

²³⁵ *See Banks*, *supra* note 218, at 1092–93; *see also Brown*, 221 F. 3d at 337 (“They were questioned on the altogether legitimate basis of a physical description given by the victim of a crime.”); *Cartnail v. State*, 753 A.2d 519, 530 (Md. 2000) (“In looking at the description of the

racial categories does not implicate the Court's colorblindness approach and trigger strict scrutiny review.²³⁶

Although reliance upon race in a suspect identification may seem intuitive or natural, the fact that race is a fundamental part of suspect identifications is due largely to the immense relevance of race in American society. Individuals do not simply notice race, but rather are socialized to "recognize" and categorize the combination of physical, cultural, and linguistic traits historically associated with particular racialized groups in the United States, despite the fact that one's race isn't always obvious, unambiguous, or transparent. Indeed, according to Professor R. Richard Banks:

Race is salient, memorable, and useful because of its cultural and social significance. Other possible suspect description components are less salient, memorable, and useful because they are less socially and culturally significant We perceive what we are trained and motivated to perceive. Visual perception operates within culture, not outside of it.²³⁷

Relying upon skin color in a suspect description, for example, might group many African Americans, Native Australians, and some South Asians into one category, while using hair texture as a descriptor might produce differences among and within these same groups.²³⁸ Race, in contrast, captures particular combinations of physical and cultural features that have particular social significance in the United States at a specific historical moment.²³⁹ Thus, the judicial acceptance of race-based suspect identifications, notwithstanding that the reliance on race in this context is susceptible to abuse and error, appears to be a nod by courts to the sociocultural singularity and prominence of race in America.

Advocates of the antisubordination perspective may be appropriately concerned about the state eliciting and relying upon race-based suspect descriptions in a way that burdens minority populations,²⁴⁰ and the anticlassification or colorblindness proponent may object to

suspects, undoubtedly physical characteristics, such as race, gender, ethnicity, hair color, facial features, age, body build, or apparel of a suspect permits winnowing of innocent travelers.").

²³⁶ A frequent critique of racial profiling, however, is that the practice relies upon invidious stereotypes. See Harris, *supra* note 224, at 292–93.

²³⁷ Banks, *supra* note 218, at 1111. According to Professor Banks, we focus most on race in suspect identifications because "it is race *rather than physical features* that predominates in the development and use of suspect descriptions." *Id.* at 1112.

²³⁸ See *id.* at 1111.

²³⁹ See *id.*

²⁴⁰ See *supra* notes 224–39 and accompanying text.

any official use of racial categories.²⁴¹ According to racial pragmatist reasoning, however, this practice acknowledges the social reality of race in order to further a legitimate law enforcement objective, while avoiding the group-based pejorative stereotypes that demand equal protection analysis.

Brown v. City of Oneonta vividly illustrates the ways in which racial pragmatism can be problematically applied. The next Section demonstrates how jurists can employ racial pragmatist reasoning in a way that is more attentive to social justice concerns.

3. *Race as Necessary Means*

Even where the use of race carries the type of harms that trigger strict scrutiny (i.e., a racial classification), we can still find strands of racial pragmatist reasoning in the Justices' opinions. We see this most in the education context. Despite the fact that strict scrutiny is typically applied in these cases, the Court nonetheless finds that some government race consciousness—that which accounts for the social salience of race, yet does not invoke the gallery of harms with which a majority of the Court is so deeply concerned—can survive strict scrutiny.

For instance, despite her general opposition to state reliance upon racial categories in the distribution of benefits and burdens,²⁴² Justice O'Connor nevertheless cast the definitive vote in *Grutter v. Bollinger*,²⁴³ where the Court upheld a public law school's consideration of race as a "'plus' factor" for applicants in the admissions process as a means of increasing racial diversity.²⁴⁴ Her opinion for the Court betrays a racial pragmatist perspective, as according to Justice O'Connor, "[j]ust as growing up in a particular region or having particular professional experiences is likely to affect an individual's views, so too is one's own, unique experience of being a racial minority in a society, like our own, in which race unfortunately still matters."²⁴⁵

²⁴¹ See *supra* notes 184–86 and accompanying text.

²⁴² See, e.g., *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 226 (1995).

²⁴³ *Grutter v. Bollinger*, 539 U.S. 306 (2003).

²⁴⁴ *Id.* at 334, 343.

²⁴⁵ *Id.* at 333. Similarly, in *Adarand*, while holding that the federal government's policies encouraging the provision of subcontracts to minority-owned firms would be subject to strict scrutiny, Justice O'Connor's majority opinion still openly recognizes that "[t]he unhappy persistence of both the practice and the lingering effects of racial discrimination against minority groups in this country is an unfortunate reality, and government is not disqualified from acting in response to it." *Adarand*, 515 U.S. at 237.

Justice Kennedy eloquently articulated racial pragmatist reasoning most recently in his concurring opinion in *Parents Involved*.²⁴⁶ Justice Kennedy voted with the majority to strike down a school district's consideration of race as a factor in students' school assignments, based on his determination that the practice created race-based classifications.²⁴⁷ Still, his concurring opinion, which claimed at least five votes, evinces a decidedly racial pragmatist conviction. According to Justice Kennedy: "The enduring hope is that race should not matter; the reality is that too often it does."²⁴⁸

Acknowledging that race consciousness is sometimes necessary to overcome the contemporary consequences of the nation's long history of racial discrimination, Justice Kennedy observed:

The plurality opinion is too dismissive of the legitimate interest government has in ensuring all people have equal opportunity regardless of their race. The plurality's postulate that "[t]he way to stop discrimination on the basis of race is to stop discriminating on the basis of race" is not sufficient to decide these cases.²⁴⁹

According to Justice Kennedy:

The statement by Justice Harlan that "[o]ur Constitution is color-blind" was most certainly justified in the context of his dissent in *Plessy v. Ferguson*. The Court's decision in that case was a grievous error it took far too long to overrule. *Plessy*, of course, concerned official classification by race applicable to all persons who sought to use railway carriages. And, as an aspiration, Justice Harlan's axiom must command our assent. In the real world, it is regrettable to say, it cannot be a universal constitutional principle.²⁵⁰

Justice Kennedy's support for some state efforts that rely on race-conscious decisionmaking is a recognition that acknowledging the social significance of race is often a necessary means of achieving particular racial justice ends.²⁵¹ Thus, his analysis reflects the fundamental interests of racial pragmatism with respect to government actions that rely upon racial classifications.²⁵² Justice Kennedy believes that gov-

²⁴⁶ *Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 787–88 (2007) (Kennedy, J., concurring in part and concurring in the judgment).

²⁴⁷ *Id.* at 782–87.

²⁴⁸ *Id.* at 787.

²⁴⁹ *Id.* at 787–88 (citation omitted).

²⁵⁰ *Id.* at 788 (citation omitted).

²⁵¹ *Id.* at 782–98.

²⁵² *Id.*

ernment decisionmakers should remain “free to devise race-conscious measures to address the problem in a general way,” yet holds that they must do so “without treating each student in different fashion solely on the basis of a systematic, individual typing by race.”²⁵³ To achieve this objective, he articulates a broad scheme of concrete, race-conscious mechanisms that “do not lead to different treatment based on a classification that tells each student he or she is to be defined by race, so it is unlikely any of them would demand strict scrutiny to be found permissible.”²⁵⁴

Despite Kennedy’s decision to vote with the majority to strike down the policy, his concurring opinion’s racial pragmatist reasoning complicates the Court’s inclination towards colorblindness and illuminates the nuances of the Court’s normative commitments with respect to state race-conscious decisionmaking.

IV. RACIAL PRAGMATISM AND REGULATING THE USE OF RACE IN BIOMEDICAL RESEARCH

As has been shown, the Court has identified a set of harms that it believes accompany the use of race—harms which can vary with the context, the ways in which race is used (as a variable versus the sole category), and other factors. The Court has also mapped some principles to guide the use of race in government decisionmaking. These principles occasionally appear to hew closely to a commitment to colorblindness (or anticlassification) and other times to a more racial pragmatist view of the role of race in our society and its implications for government decisionmaking. This Part applies these principles to the current uses of race in biomedical research as a means of illustrating how adoption of racial pragmatist principles may allow the NIH and FDA to mandate the use of racial categories in biomedical studies in a way that promotes better science and health care.

A. *Why Race Is Still Relevant in Biomedical Research*

By permitting researchers to employ race as a proxy for geographic ancestry, notwithstanding that there are no meaningful genetic differences among the races, the NIH Revitalization Act and the FDA rules have enabled, if not encouraged, researchers to use racial

²⁵³ *Id.* at 788–89.

²⁵⁴ *Id.* at 789. These mechanisms include “strategic site selection of new schools; drawing attendance zones with general recognition of the demographics of neighborhoods; allocating resources for special programs; recruiting students and faculty in a targeted fashion; and tracking enrollments, performance, and other statistics by race.” *Id.*

categories in just the ways that the Supreme Court condemns.²⁵⁵ In *Adarand Constructors, Inc. v. Peña*, for example, the Court rejected a policy that used race as a proxy for social and economic disadvantage.²⁵⁶ In so doing, the Court made clear that this use of racial classifications will be subject to strict scrutiny review.²⁵⁷ The Court's concern about the use of race as a proxy is likely based upon its concern about the official reliance upon harmful generalizations or stereotypes. The Court has consistently sought to prohibit state actors from placing individuals into rigid race boxes out of which they cannot climb because the state is treating them as if all individuals inside the box share the same characteristics (and vulnerabilities), while members of the majority group not in the box share the same characteristics (and advantages). The Court has declared that “[s]tereotyping, which treats individuals on the basis of group generalizations that might not apply to any particular individual, perhaps represents the paradigmatic harm that antidiscrimination law, including [the] Equal Protection Clause, is thought to guard against.”²⁵⁸

NIH and FDA rules invite the now-frequent practice among biomedical researchers of grouping people who share certain visible characteristics into inflexible race boxes in a way that overlooks differences within the groups, and then making baseless generalizations about the particular health traits that the individuals in the group are presumed to possess due to their membership in the group. For instance, in the case of BiDil, the FDA approved the drug despite the fact that there was no clear evidence to support the belief that BiDil worked better or differently in self-described African Americans than in other populations.²⁵⁹ At the FDA approval hearing for BiDil, Steven Nissen, the hearing chair, declared that the effect of BiDil on self-identified African Americans was enough to satisfy what he called “biological plausibility,” and until a genetic marker could be identified for individual differences in drug responses, race could serve as a sufficient surrogate.²⁶⁰ This belief was shared by others. As one re-

²⁵⁵ See Amar & Katyal, *supra* note 187, at 1763 (describing how the Court rejects the use of “wooden racial classification[s]”).

²⁵⁶ *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 204–05 (1995).

²⁵⁷ *Id.* at 227 (“[A]ll racial classifications, imposed by whatever federal, state, or local governmental actor, must be analyzed by a reviewing court under strict scrutiny.”).

²⁵⁸ Banks, *supra* note 218, at 1091–92.

²⁵⁹ See *supra* notes 91–103 and accompanying text.

²⁶⁰ 2 Transcript of June 16, 2005 Meeting at 359–60, Food & Drug Admin., Ctr. for Drug Evaluation & Res., Cardiovascular & Renal Drugs Advisory Committee, <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4145T2.pdf>.

searcher opined: “Using race is a blunt instrument for identifying those who respond to the drug, but it’s the best tool we have right now . . . [therefore, i]t’s appropriate that BiDil is targeted at a particular population group. Further research will likely identify the basis for the effectiveness observed in African-Americans.”²⁶¹

1. *Race, Health, and the New “Social Darwinism”*

The NIH and FDA rules that encourage the use of race as a proxy for genetics burden minority communities in many ways. Scientifically unfounded generalizations that connect race, genetics, and disease have led some physicians to treat their patients differently because of the erroneous belief that there may be genetic differences among racial populations.²⁶² A national survey of physicians conducted after the release of BiDil revealed that 81% believed that race should be used as a “biological basis for determining ailments or diseases.”²⁶³ Similarly, the author of a *Boston Globe* article on NitroMed wrote: “Researchers theorize that BiDil works better among blacks because their bodies lack enough nitric oxide.”²⁶⁴ The concern is that physicians may interpret the advent of BiDil or other such drugs as evidence that race has independent genetic explanatory power and then harm their patients by rendering diagnostic decisions about a patient’s potential illness, disease, or treatment response based upon the patient’s race.

History is rife with grim examples of such racial stereotypes in the biomedical research context. Just as the Tuskegee Syphilis Study researchers believed that syphilis was a different disease in African Americans than whites, some researchers during the height of the HIV/AIDS crisis believed that the disease progressed differently among African Americans as compared to other groups, and that this might be explained by race-based genetic or biological variations.²⁶⁵

²⁶¹ Dutton, *supra* note 2, at 43 (quoting Dr. Mario Ehlers, Chief Medical Officer of Pacific Biometrics).

²⁶² See, e.g., Sally Satel, *I Am a Racially Profiling Doctor*, N.Y. TIMES MAG., May 5, 2002, at 56 (claiming that “[w]hen it comes to practicing medicine, stereotyping often works”).

²⁶³ Reverby, *supra* note 95, at 482.

²⁶⁴ Diedtra Henderson, *Distrust Overshadows Drug’s Promise*, BOSTON GLOBE, May 16, 2005, at C1; see also Ronald Bailey, Commentary, *When Medicine That Discriminates Is Good: Using Race and Ethnicity to Improve Health Care Is Anything But Racist*, CHI. SUN-TIMES, Dec. 18, 2005, at 2B (asserting that “blacks tend to have lower average amounts of nitric oxide”); Nicolas Wade, *Race-Based Medicine Continued . . .*, N.Y. TIMES, Nov. 14, 2004, at 12 (“BiDil is designed to increase levels of a chemical signal known as nitric oxide, which tends to be lower in Africans, possibly because low levels help retain salt for people living in hot climates.”).

²⁶⁵ Richard E. Chaisson et al., *Race, Sex, Drug Use, and Progression of Human Immu-*

Eventually, they came to understand that the virulence of the disease in this population was related to socioeconomic conditions, including limited access to health care, which exacerbated the effects of the disease.²⁶⁶

Current federal laws endow race with a false genetic essentialism, which further harms minority populations to the extent that their underlying health conditions are no longer understood as potentially attributable to their place in the economic or social world, but are rather explained exclusively as resulting from their molecular constitution.²⁶⁷ Indeed, today, there are a number of significant health disparities among racial groups that have a crippling effect on their ability to enjoy the full benefits of citizenship. According to the Centers for Disease Control and Prevention's 2010 national health report, the infant mortality rate for African Americans is up to three times higher than that of other races;²⁶⁸ blacks die of heart disease much more often than whites and die at younger ages;²⁶⁹ blacks, Hispanics, and American Indians, whether straight or gay, have higher rates of HIV infection than whites, while Asians had the lowest rates of infection;²⁷⁰ life expectancy for blacks lags behind that of whites by 4.8 years;²⁷¹ the mortality rate is 29% higher for blacks than for whites;²⁷² the age-adjusted death rate for the black population exceeds that for the white

odeficiency Virus Disease, 333 *NEW ENG. J. MED.* 751, 751 (1995) [hereinafter Chaisson, *Race, Sex, Drug Use*] (“The differences in survival between blacks and whites, men and women, and drug users and those who do not use drugs have led to speculation that HIV disease progresses more rapidly in some demographic groups than in others.”); Richard E. Chaisson et al., *Racial Heterogeneity of HIV Antigenemia in People with HIV Infection*, 5 *AIDS* 177, 179–80 (1991) [hereinafter Chaisson, *Racial Heterogeneity*] (reporting that black HIV patients had different levels of a certain antigen in their blood than whites and concluding that “it is possible that racial differences” result in different immune responses to HIV in blacks and whites).

²⁶⁶ Chaisson, *Race, Sex, Drug Use*, *supra* note 265, at 754 (“Our results provide strong evidence that earlier reports of differences in survival were a result of inadequate medical care rather than biologic differences in the natural history of HIV infection.”); Richard D. Moore et al., *Racial Differences in the Use of Drug Therapy for HIV Disease in an Urban Community*, 330 *NEW ENG. J. MED.* 763, 767 (1994) (concluding that “our results indicate that blacks may not have the same access as whites to recommended therapeutic care”); Richard M. Selik et al., *Racial/Ethnic Differences in the Risk of AIDS in the United States*, 78 *AM. J. PUB. HEALTH* 1539, 1541 (1988) (“[T]he higher risks of AIDS in Blacks and Hispanics are due primarily to behavioral and perhaps environmental differences between the racial/ethnic groups, rather than genetic differences.”).

²⁶⁷ See *supra* Part II.A–B.

²⁶⁸ NAT'L CTR. FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH, UNITED STATES, 2010, at 147–48 (2011), <http://www.cdc.gov/nchs/data/hus/hus10.pdf>.

²⁶⁹ *Id.* at 176–78.

²⁷⁰ See *id.* at 196–98.

²⁷¹ *Id.* at 152.

²⁷² See *id.* at 153.

population by 49% for stroke (cerebrovascular disease), 31% for heart disease, 21% for cancer, 108% for diabetes, and 810% for HIV disease;²⁷³ and diabetes is more prevalent among blacks and Mexican Americans than other groups.²⁷⁴

Once the health problems of a minority population are defined as genetic, they become an innately personal concern, rather than a social or collective issue, and much less a residual effect of the United States's legacy of state-sanctioned, race-based discrimination. This changes not only the social meaning of a health condition in the racialized group, but also shifts responsibility for the condition onto the individual and away from the collective. This undermines attempts to address the environmental or socioeconomic causes of the negative health outcomes experienced by minority populations, as well as efforts to devise and fund systemic solutions. In the same way that the Social Darwinists of the past relied upon science to support their position that social programs aimed at elevating the status of the poor and racial minorities contradicted their natural condition,²⁷⁵ so too may some policymakers today fail to fully address health conditions that disproportionately affect communities of color in the belief that they emerge from one's genes rather than from society.²⁷⁶

2. *Racial Discrimination and Health Disparities*

Some of the serious health disparities experienced by minority populations may be attributed to demographic variables such as income or education. Others, however, can be traced directly to the experience of discrimination. For example, rates of high blood pressure for African Americans are double those of whites.²⁷⁷ Curiously, African Americans, who are descended primarily from western and central Africans, are prone to hypertension, despite the fact that their

²⁷³ See *id.* at 156.

²⁷⁴ See *id.* at 228.

²⁷⁵ See *supra* notes 33–35 and accompanying text.

²⁷⁶ For example, as sociologist Troy Duster has noted, researchers have spent years searching for a genetic basis for the high rates of chronic conditions such as alcoholism among Native Americans. See Troy Duster, *Comparative Perspectives and Competing Explanations: Taking on the Newly Configured Reductionist Challenge to Sociology*, 71 AM. SOC. REV. 1, 3 (2006). While this appears to be a laudable goal, in reality, such efforts not only pathologize Native Americans, but may also divert needed research time and funds from examining the ways in which centuries of mistreatment and oppression, high unemployment, geographic displacement and isolation, and other aspects of Native Americans' general disenfranchisement may affect their consumption of alcohol. *Id.*

²⁷⁷ See NAT'L CTR. FOR HEALTH STATISTICS, *supra* note 268, at 268–69.

African ancestors were not.²⁷⁸ And researchers found that rates of hypertension differ even within the African American population, as darker-skinned blacks have on average higher blood pressure than lighter-skinned blacks.²⁷⁹ The researchers who conducted this seminal epidemiological study ultimately determined that the differential in rates of hypertension is not due to race as a genetically distinct factor in disease development, but rather to the fact that having a dark skin color in the United States renders one subject to more social stresses and fewer social and economic resources than those with lighter skin color.²⁸⁰

Numerous studies demonstrate that racial discrimination and race-related stress negatively impact health, including the onset, progression, and severity of illness or disease.²⁸¹ The effects of racial discrimination and race-related stress have been linked to the development of certain cancers and health problems manifest in the neuroendocrine, cardiovascular, and immune systems.²⁸² Racial discrimination and race-related stress also have been shown to affect pain sensitivity and chronic pain, low birth weight, and BMI/obesity.²⁸³ Today, race remains at the root of much discrimination in the United States, and many racial minority populations continue to suffer the effects of the nation's long history of racial discrimination. Studies have demonstrated that even after controlling for socioeconomic factors, members of racial minority groups experience higher levels of

²⁷⁸ Dutton, *supra* note 2, at 43.

²⁷⁹ Clarence C. Gravlee et al., *Skin Color, Social Classification, and Blood Pressure in Southeastern Puerto Rico*, 95 AM. J. PUB. HEALTH 2191, 2191 (2005).

²⁸⁰ *Id.* at 2194; *see also* Troy Duster, *Race and Reification in Science*, 307 SCIENCE 1050, 1050 (2005) (noting the “complex feedback loop and interaction effect” between skin color and health); Dutton, *supra* note 2, at 41 (“The prevalence for biological-based conditions is 2.5 times higher among African-Americans than among those with European ancestry and is based upon the relative harshness of the environment.”); Terry Smith, *Everyday Indignities: Race, Retaliation, and the Promise of Title VII*, 34 COLUM. HUM. RTS. L. REV. 529, 546–48 (2003) (discussing the health effects on African Americans of stress caused by racial discrimination).

²⁸¹ *See* David R. Williams & Selina A. Mohammed, *Discrimination and Racial Disparities in Health: Evidence and Needed Research*, 32 J. BEHAV. MED. 20, 27 (2009); *see also* Elizabeth Brondolo et al., *Race, Racism and Health: Disparities, Mechanisms, and Interventions*, 32 J. BEHAV. MED. 20, 21 (2009); Yin Paradies, *A Systematic Review of Empirical Research on Self-Reported Racism and Health*, 35 INT'L J. EPIDEMIOLOGY 888, 891–92 (2006).

²⁸² Shawn O. Utsey et al., *Effect of Ethnic Group Membership on Ethnic Identity, Race-Related Stress, and Quality of Life*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 366, 368 (2002).

²⁸³ *See* Williams & Mohammed, *supra* note 281, at 27; *see also* Brondolo et al., *supra* note 281, at 1; Paradies, *supra* note 281, at 891–92.

race-related stress than whites, and African Americans experience the most elevated stress rates.²⁸⁴

Although some of the health disparities between whites and racial minorities may correlate with other social factors, such as income or education, they cannot be attributed to these factors alone.²⁸⁵ The risk factors that affect the development of particular diseases are rarely single-locus, but instead are often very complex, involving many genetic and environmental influences.²⁸⁶ Hence, the experience of racism may impact health in a way that is distinct from other social and economic indicators. Indeed, the aggregate effects of a life's worth of racially informed experiences may result in specific physiological responses that are not determined by genetic differences among racial groups and are irreducible to other demographic factors or variables.²⁸⁷ Thus, a combination of genetic, environmental, and socioeconomic factors, including the effects of racial discrimination, may together yield physiologically discernible effects, including differences in overall health status and rates of disease incidence and prevalence, morbidity, and mortality.

B. *Operationalizing Racial Pragmatism in the Biomedical Research Context*

The government must continue to mandate the use of race as a variable in biomedical research, yet it must do so in a way that does not encourage researchers to uncritically attribute differences in disease progression, or drug or therapy response, to biological or genetic notions of race. The NIH guidelines currently provide little guidance on how and when the use of racial categories is warranted.²⁸⁸ This has caused problems of such significance that, in 2001, an editor of the *New England Journal of Medicine* recommended that all biomedical journals require authors who make racial or ethnic distinctions to “furnish a scientifically valid definition of the population under study” as a criterion for publication.²⁸⁹ Similarly, since 2000, the journal *Na-*

²⁸⁴ See Deidre Franklin-Jackson & Robert T. Carter, *The Relationships Between Race-Related Stress, Racial Identity, and Mental Health for Black Americans*, 33 J. BLACK PSYCHOL. 5, 6 (2007); Hope Landrine et al., *Conceptualizing and Measuring Ethnic Discrimination in Health Research*, 29 J. BEHAV. MED. 79, 79, 88 (2006); Utsey et al., *supra* note 282, at 368.

²⁸⁵ See BROOKS & KING, *supra* note 126, at 7–8.

²⁸⁶ Dutton, *supra* note 2, at 43.

²⁸⁷ See Ossorio & Duster, *supra* note 77, at 119; NAT'L INSTS. OF HEALTH, NAT'L INST. ON AGING, HEALTH DISPARITIES STRATEGIC PLAN: FISCAL YEARS 2009–2013, <http://www.nia.nih.gov/about/health-disparities-strategic-plan-fiscal-years-2009-2013>.

²⁸⁸ See NIH Guidelines, *supra* note 58, at 14,510.

²⁸⁹ Schwartz, *supra* note 65, at 1393.

ture Genetics has required authors to “explain why they make use of particular ethnic groups or populations, and how classification was achieved.”²⁹⁰

This Section demonstrates the ways in which racial pragmatist considerations can provide a framework for how researchers can employ racial categories in biomedical studies without jeopardizing health, producing flawed science, or reinforcing pernicious, antiquated, and stigmatizing conceptions of racial difference.

1. *Race as a Necessary Means*

Federal rules must enable the practical use of race in scientific studies, yet not in a way that leads to the normatively and constitutionally suspect “racial profiling” that can harm minority populations by allowing researchers to suggest that people who look a certain way share a similar genetic profile. Here, the application of racial pragmatist reasoning from the education and voting rights contexts is instructive.

As Justice Kennedy opined in *Parents Involved*, race consciousness is often a necessary means of addressing the consequences of racial discrimination.²⁹¹ However, state actors cannot employ racial categories in a way that tells an individual that “he or she is to be defined by race,” as was the case in the BiDil episode.²⁹² This approach is illustrated in the Court’s voting rights jurisprudence, where the Court makes clear that legislatures may consider race in the redistricting process as a means of capturing political affiliation because one’s social experience of racism and racial discrimination affects how one is likely to vote.²⁹³ Implicit in the Court’s racial pragmatist reasoning is a recognition that race is as much a social process as a social fact.²⁹⁴ In keeping with this truism, in the biomedical research context, race should be taken into account as a means of capturing the causes of the health differentials that exist among racial groups, because one’s social experience of racism and racial discrimination affects health outcomes.

²⁹⁰ Editorial, *Census, Race and Science*, 24 *NATURE GENETICS* 97, 97–98 (2000).

²⁹¹ See *supra* notes 246–53 and accompanying text.

²⁹² *Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 789 (2007) (Kennedy, J., concurring in part and concurring in the judgment).

²⁹³ See *supra* Part III.C.1.

²⁹⁴ In her opinion in *Grutter v. Bollinger*, 539 U.S. 306 (2003), Justice O’Connor also recognized that, “[j]ust as growing up in a particular region or having particular professional experiences is likely to affect an individual’s views, so too is one’s own, unique experience of being a racial minority in a society, like our own, in which race unfortunately still matters.” *Id.* at 333.

Indeed, the NIH and FDA rules must make clear that race represents a complex amalgamation of social processes that can have physiological effects. Race is part of a fluid and dynamic feedback loop according to which social factors can drive biological outcomes that have social consequences. Thus, the FDA and NIH rules must ensure that researchers are self-consciously aware of the constructed nature of race, and acknowledge it as a socially manufactured identity maker, while recognizing racism as an interactive process that can inflict harms that manifest biologically. This understanding of race as a construct and a process will not only preclude researchers from employing race as a biological or genetic category in biomedical research, but will also enable researchers to more clearly identify and articulate how and why race is being utilized in their studies.

2. *Race as Descriptive Factor*

When determining how race will be assigned in biomedical studies, researchers can employ either closed racial designations (e.g., black, African American, Afro Caribbean; white, European American, etc.) or open-ended descriptions (providing a limitless range of racial identity options by allowing individuals to choose how to identify themselves). In making the decision of which type of designation to adopt, racial pragmatist reasoning from the criminal suspect identification context can provide guidance.

Courts' determinations that race may be used in identifying a suspect are based, in part, on a tacit understanding that, due to the social significance of race in the United States, most individuals in this country have been socialized to recognize the combination of physical, cultural, and linguistic traits historically associated with particular racialized groups.²⁹⁵ Although one's racial identification is not always self-evident to an observer, and racial categories can vary by context, historical moment, and geographic locale,²⁹⁶ individuals in the United States believe that they can accurately identify race, and they act upon this assumption by, for example, describing individuals by race or engaging in racially discriminatory acts.

Observer-identified race, to be sure, plays a central role in racial discrimination. Therefore, racial pragmatist reasoning from the suspect identification context can be useful in biomedical research: several studies have shown that the health disparities observed among minority populations can be linked to stress caused by discrimination

²⁹⁵ See *supra* note 237 and accompanying text.

²⁹⁶ See *supra* note 239 and accompanying text.

based upon the perceptible combination of characteristics that have historically been ascribed to certain groups.²⁹⁷ Thus, depending on the hypothesis under investigation, scientists may be better served by utilizing closed, rather than open-ended, racial designations, guided loosely by the Directive No. 15 categories. In so doing, researchers should disclose clearly the racial category options made available to the study participants.

Moreover, while open-ended racial designations allow individuals to more accurately express their personal understanding of their racial identity, the increased (though imperfect) definitional clarity provided by a closed racial designation will enable researchers to more effectively build and rely upon the data produced by others. This practice obviously requires race-conscious decisionmaking by regulators. However, here, as in the criminal suspect identification context, race appropriately correlates with or describes some underlying social reality. As a result, this use of race in the biomedical research context should not lead to the type of stigmatizing and stereotyping that raises constitutional concerns and leads to bad science.

3. *Race as Additional Factor*

To the extent that the challenge for researchers and clinicians is to understand and evaluate disease onset, progression, and severity, as well as to determine causality in drug efficacy and therapy response, using race, along with any number of other variables in research, may provide a more nuanced understanding of the effects of racism and racial discrimination on health and therapy response. Indeed, because researchers may not know whether a particular health outcome can be attributed primarily to environment, culture, or the social consequences of race, they should measure for each factor.

As recognized in the voting rights and criminal suspect identification contexts, race operates as an independent variable that is irreducible to other factors. The state, therefore, must enable researchers to consider race as one among other measurable variables that may impact health outcomes, such as family health history, income, age, environment, gender, education, or diet. Conversely, focusing on race alone may occlude other social, cultural, environmental, and physiological factors that can influence health outcome. As in the voting rights and suspect identification contexts, race should not be the “pre-

²⁹⁷ See *supra* notes 279–84 and accompanying text.

dominant” factor in the analysis²⁹⁸ and should be employed in accordance with “customary” or “traditional” research principles.²⁹⁹

Current FDA rules require researchers conducting Phase III clinical trials to look for possible variations in treatment responses among different groups.³⁰⁰ These rules, however, offer little additional guidance. If a statistically significant link is found between race and treatment response or between race and a particular condition or disease, researchers should be encouraged to engage in further study on the racial population at issue—but they must not be permitted to assume that the noted distinction is necessarily genetic. Rather, federal rules should mandate the use of additional research methods, such as genetic testing, if appropriate, instead of permitting reliance upon race as a surrogate for genetics or other factors, or allowing researchers to impute their prejudices, biases, or financial considerations into science. This will enable the research community to identify the effects of race on health without abstracting particular traits or characteristics that individuals in each racial group are presumed to possess, which may lead to the reinforcement or creation of invidious racial stereotypes.

CONCLUSION

The NIH Revitalization Act and FDA rules were enacted to address the effects of past, institutionalized racial discrimination in clinical research. Today, however, they are often employed in ways that harm minority populations and reinforce pejorative biogenetic notions of racial difference. The assumptions of biomedical researchers that allow for the linking of race to genetics can be traced back to the very origin of race in research as scientists today employ racial categories in their studies in ways reminiscent of the early “race scientists.”³⁰¹ Race consciousness on the part of regulators and lawmakers is, therefore, necessary to curtail the current misuses and to address the effects of past abuses of race in biomedical clinical research. Lawmakers and regulators, however, must proceed with care lest their actions allow for the geneticization of race.

While some legal commentators have argued that federal regulations and research funding guidelines should preclude researchers

²⁹⁸ See *supra* notes 204–06 and accompanying text.

²⁹⁹ See *supra* note 202–03, 205 and accompanying text.

³⁰⁰ See POLICY STATEMENT ON INCLUSION OF RACE AND ETHNICITY IN DHHS DATA COLLECTION ACTIVITIES, *supra* note 59.

³⁰¹ See *supra* Part I.A.

from using racial categories in their studies, this Article argues that federal regulations must allow for the use of racial categories in biomedical studies. However, they must do so in a way that does not allow researchers to jeopardize individual and public health or reify outmoded, pejorative, and stigmatizing notions of racial distinctions. This Article demonstrates the ways in which the racial pragmatist reasoning identified in federal courts' equal protection jurisprudence can enable regulators to effectively protect public health, promote racial justice, and restore scientific integrity by improving the way researchers employ racial categories in biomedical research. Indeed, application of racial pragmatist reasoning in the biomedical research context challenges scientists to spend as much time elaborating on their use of race in their studies as they spend on their datasets and regressions. This would preclude them from conflating phenotype with genotype or using race as a surrogate for disease and a stand-in for unexplained processes in the formulation of targeted medical treatments.

Moreover, while addressing the current abuses of race in biomedical studies, these guidelines, informed by racial pragmatist considerations, also would enable the biomedical research community to produce scientific data that could be used by health officials to determine and thereby alleviate the true causes of the disparate health outcomes that exist among racial groups. Further, this racial pragmatist framework empowers government to engage in the kind of race-conscious decisionmaking necessary to ameliorate the effects of past and ongoing racial discrimination, without creating racial classifications that offend the Constitution and trigger strict scrutiny review. This is the racial pragmatist imperative, because, as Justice O'Connor so aptly acknowledged, "race unfortunately still matters."³⁰²

³⁰² Grutter v. Bollinger, 539 U.S. 306, 333 (2003).