

Legal Constraints on the Use of Race in Biomedical Research: Toward a Social Justice Framework

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I. Introduction: Law's Role in the Debate on Race in Biomedical Research

The scientific validity of racial categories has been the subject of debate among population geneticists, evolutionary biologists, and physical anthropologists for several decades.¹ After World War II, the rejection of eugenics, which had supported sterilization laws and other destructive programs in the United States, generated a compelling critique of the biological basis of race. The classification of human beings into distinct biological "races" is a relatively recent invention propped up by deeply flawed evidence and historically providing the foundation of racist ideology and inequities of power.² Social scientists' conclusion that race is socially constructed was confirmed by genomic studies of human variation, including the Human Genome Project, showing high levels of genetic similarity within the human species.³ Some scholars came to believe that the science of human genetic diversity would replace race as the preeminent means of grouping people for scientific purposes.⁴

Reports of the demise of race as a biological construct were premature. Debates about the scientific validity of race have reemerged in questions about the proper use of racial categories in genomic, biomedical, and biotechnology research. Some genetic and social scientists have recently expressed the view that clusters of genetic similarity correspond to social categories of race and that human racial differences are real and significant.⁵ But the debate is not a clear-cut battle between researchers who subscribe to a biological definition of race and those who believe that race is socially constructed. Rather, scientists are grappling with the confusing task of assigning the appropriate significance to race as a variable in research in the context of novel genomic tools for studying populations as well as government regulations and health disparities that track social categories of race.⁶

The evolution of race-based biotechnologies is occurring in the sociopolitical context of an equally heated contest over approaches to racial equality. Colorblindness and race consciousness compete as major frameworks for defining the proper treatment of race in social policy.⁷ The issues raised by race-based biotechnology, however, do not fit neatly into the ideological fault lines that mark social policy debates over race consciousness. Indeed, the use of race in biomedical research

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disrupts the prevailing opposition between colorblindness and race consciousness in significant ways. In the political realm, advocacy for colorblind policies is typically based on the assertion that racism has ceased to be the cause of social inequities, while race-conscious policies are promoted as a necessary means for remedying persistent institutional racism.

In contrast, one form of race consciousness in biomedical research – using race as a *biological* category – can reflect and reinforce racial stratifications as well as racist notions of inherent human differences. However, another form of race consciousness in this research – using race as a *social* category to study the impact of racism on health and on access to medical care – is critical to eliminating health inequities based on race.⁸ Even this distinction between scientists' use of race as a biological versus social variable is complicated further by the demand by members of minority groups for inclusion in clinical trials and access to biotechnologies that incorporate biological definitions of race to redress past discrimination.⁹

The law plays an important, though underexplored, role in this scientific and political debate about the proper use of race in biomedical research. The law is a critical aspect of the sociopolitical context that shapes and is shaped by the production and use of scientific knowledge.¹⁰ Legal rules directly regulate scientific research, and legal norms help to determine acceptable boundaries of scientific inquiry. This article addresses three questions concerning the legal regulation of the use of race as a category in biomedical research: How does the law currently *encourage* the use of race in biomedical research (Part II)? How does the existing legal framework *constrain* its use (Part III)? What *should be* the law's approach to race-based biomedical research (Part IV)?

Examining the legal regulation of race-based biomedical research reveals how the law both influences and potentially constrains the use of race as a research category.¹¹ Various federal agency regulations directly govern the conduct of race-based biomedical research and the marketing of its products. Legal definitions of race in federal funding guidelines help to determine the racial categories that scientists employ in this research. Civil rights and equal protection standards govern the legal permissibility of state and private racial classifications and therefore may place limits on race-based biomedical research and marketing. State tort law and legislation related specifically to biomedical research may also provide legal direction to researchers using racial categories.

In an effort to reverse the historic exclusion of nonwhites from biomedical research, federal funding and regulatory agencies require that researchers include members of diverse racial and ethnic groups in clinical trials.

I argue, however, that the law's relationship to race-based biomedical research extends beyond these forms of legal regulation. More fundamentally, legal notions of racial equality and justice should be central to determining the proper use of race in scientific research. I propose a social justice framework that encourages the use of race as a *social* category in research to understand and eliminate health inequities, but that discourages the use of race as a *biological* category that reinforces dangerous and unscientific definitions of race.

II. Current Legal Incentives for Race-Based Research

At present, several types of legal regulations encourage researchers to use race as a variable in biomedical research. Federal agencies have begun to address centuries-long discrimination against nonwhites in medicine and public health by mandating that biomedical researchers take race into account. In an effort to reverse the historic exclusion of nonwhites from biomedical research, federal funding and regulatory agencies require that researchers include members of diverse racial and ethnic groups in clinical trials. The federal government also requires that researchers record their findings about diseases and treatments according to racial categories, and solicits research that studies illness in particular racial groups in order to eliminate race-based disparities in health status. In addition, government regulation of pharmaceuticals provides incentives for private investment in race-based biomedical research even when federal funding is unavailable or prohibited.

A. Inclusion of Minorities in Clinical Trials

The NIH Revitalization Act of 1993 mandates the inclusion of women and minorities as subjects in federally-funded clinical research and the reporting of research findings according to racial categories.¹² Congress wanted to “ensure that all NIH-funded clinical research will be carried out in a manner sufficient to elicit information about individuals of...diverse racial and ethnic groups....”¹³ The Act also specifies that researchers must use the racial categories provided in U.S. Office of Management and Budget's (OMB) Direc-

tive No. 15 for all federal reporting. In 1977 the OMB issued “Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting” to give federal agencies a uniform standard for collecting data on race and ethnicity, including the U.S. Census.¹⁴ The most recent revision of Directive 15 provides five categories as “a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal reporting purposes”: American Indian or Alaska Native, Asian, Black or African-American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, and White.¹⁵ In October 2001, Congress updated the requirements for federally-funded research to conform to these OMB Directive 15 race/ethnicity categories.

Congress’s purpose was not simply to ensure that members of these racial groups were included as research subjects. Rather, Congress intended that researchers analyze and report their findings according to race. The NIH “Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research” explains, “[s]ince a primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, *it is imperative to determine whether the intervention or therapy being studied affects...members of minority groups and their subpopulations differently.*”¹⁶ Without further clarification, this language could easily be interpreted to treat racial classifications not only as social groupings but as biologically distinct populations whose health status and responses to therapies vary for biological reasons inherent in the group.

Other federal initiatives encourage race-based biomedical research in response to the glaring disparities in health status among racial groups. The Department of Health and Human Services’ (DHHS) “Healthy People 2010” initiative, for example, promotes race-specific research “to eliminate health disparities among different segments of the population.”¹⁷ Through its “Racial and Ethnic Approaches to Community Health” (REACH) program, the Centers for Disease Control (CDC) Office of Minority Health sponsors scientific studies that “target” diseases within particular racial and ethnic communities.¹⁸ Studies funded by the CDC pointedly display a race-conscious focus with titles such as “Improving Cancer Screenings for Asian-American/Pacific Islander (AAPI) Women” and “Preventing and Reducing Cardiovascular Disease and Diabetes in African-Americans.”¹⁹

Race consciousness in federal funding guidelines creates a perplexing paradox. While designed to correct historic discrimination against people of color, requiring that biomedical researchers use race as a variable risks reinforcing biological definitions of race

that have historically legitimized racial inequalities. Forcing biological or genetic findings from biomedical research into social categories for race threatens to make these categories seem biological.²⁰ A number of scholars have tried to guard against grafting new findings about population-specific genomics onto existing social categories of race in confusing ways.²¹ A project at the University of Minnesota, “Colliding Categories: Haplotypes, Race & Ethnicity,” for example, predicted that biological categories of population subgroups emerging from the international initiative to create a haplotype map of the human genome were on a collision course with preexisting social categories of race and ethnicity mandated by OMB Directive 15 for collection of data in federally-funded research.²²

Likewise, Congress’s use of race in biomedical research to increase inclusion of socially disadvantaged groups may help to reinscribe the very biological definitions of race these groups have challenged.²³ Although race consciousness is crucial for achieving justice in research, notes legal scholar and bioethicist Patricia King, “conscious attention to the health needs of African-Americans risks feeding into established negative stereotypes and bias that have historically oppressed and stigmatized them.”²⁴ In crafting a legal framework for the proper use of racial categories in biomedical research it is important to grapple with this paradox by distinguishing between the meaning of racial groupings as biological classifications – which have historically supported inequities of power and negative racial stereotypes – and as social constructs – which recognizes the cultural and sociopolitical effects of racism and racial identification in the United States. There remains the question whether or not attention to race as a social category promotes or hinders racial equality; I argue in Part IV that this kind of race-consciousness in research is needed to address health inequities.

B. Support for Race-Based Pharmacogenomics

Like the federal funding guidelines discussed above, the Food and Drug Administration’s (FDA) rules also require classifying research subjects in clinical trials of pharmaceuticals according to the OMB Directive 15 race/ethnicity categories.²⁵ More importantly, FDA rules and patent law provide powerful government incentives for private investment in biotechnology research even when federal funding is unavailable or prohibited. The FDA’s recent approval of BiDil, the first race-specific drug, and the issuance of a patent for BiDil by the U.S. Patent and Trademark Office (PTO) suggest federal law governing the testing and patenting of pharmaceuticals will promote the future use of race in biomedical research. By permitting biotech company NitroMed to market BiDil, the FDA gave a

huge commercial inducement to scientists to conduct race-conscious research on the treatment of diseases in particular racial and ethnic groups.²⁶ Legal scholar Jonathan Kahn examines “how law, commerce, science, and medicine interacted to produce a distinctive understanding of BiDil as an ethnic drug” and makes a compelling case that legal and commercial factors as much as biology influenced the ultimate production of BiDil as a therapy for African-Americans.²⁷

Because federal patent law permits the PTO to issue patents on “anything under the sun made by man”²⁸ race-based pharmaceuticals promise to be a lucrative field of invention. In *Diamond v. Chakrabarty*, the U.S. Supreme Court rejected the “moral utility” doctrine that gave the PTO leeway to reject patents for morally controversial biotechnologies and that might have provided a basis for scrutinizing the potential danger of race-based pharmaceuticals for reinforcing biological definitions of race.²⁹ Transforming BiDil from a raceless to a race-based therapy allowed its inventors to obtain a new patent that will not expire until 2020.³⁰ As Kahn notes, “[i]n the case of BiDil, patent law did not spur the invention of a new drug, but rather the re-characterization of an existing therapy for a particular segment of society – in short, the repackaging of the drug as ethnic.”³¹

III. Legal Constraints on Race-Based Research

As the foregoing survey of the relevant law shows, there is a great deal of legal encouragement for biomedical researchers to use race as a category in their studies. Not only are researchers required by federal funding agencies to identify research subjects by race and ethnicity, to include minorities in clinical trials, and to report their findings according to the racial and ethnic identity of research subjects, but federal patent law also gives lucrative incentives to create pharmaceuticals designed for particular racial and ethnic groups. Although the aim of federal policy may be to address health disparities that stem from race-based *social* inequities, the unfettered use of race in biomedical research often confuses social groupings with biological ones. Thus, the law’s promotion of race-based biomedical research may help to re-inscribe the discredited biological definition of race.

There are also, however, several legal regimes that could potentially constrain the use of race in biomedical research. The power of the President, Congress, and federal agencies to regulate federally-funded research could prohibit certain uses of race as easily as it has required the inclusion of minorities in research and reporting of race-based data. In addition, federal law promoting racial equality – the federal civil rights stat-

utes and the Equal Protection Clause of the U.S. Constitution – might bar racially discriminatory biomedical research. Finally, state legislation, referenda, and tort law provide additional ways to restrict biomedical scientists’ use of race in their research.

A. Regulation of Federally-Funded Research

Federal funding agencies’ control over the funding for biomedical research is a powerful basis for restricting the use of race in these studies. In 2003, the federal government allocated \$20 billion for biomedical research.³² Just as Congress used its funding power to encourage the inclusion of minorities in clinical studies in the NIH Revitalization Act, it could discourage the use of race in biomedical research that threatens to reinforce unscientific and harmful biological definitions of human classification. There are numerous examples of federal policies that restrict research that is considered socially harmful. DHHS requires researchers to abide by its informed consent, confidentiality, and other rules that protect human subjects and severely sanctions researchers who violate them.³³ University Institutional Review Boards have established elaborate and strictly enforced protocols to ensure that university personnel comply with federal ethical standards.³⁴ The President and Congress also prohibit federal funding for morally controversial biomedical research. For example, the “Dickie Amendment” to the DHHS and NIH appropriations bill, in effect since 1996, bans funds for certain research on human embryos.³⁵ In 2001, President Bush similarly issued a policy that restricts federally funded stem cell research to embryonic stem cell lines existing at the time the policy was announced.³⁶

B. Federal Racial Equality Law: Civil Rights Statutes and Equal Protection

Another source of legal constraints on the use of race in biomedical research is federal civil rights and constitutional law governing racial classifications and promoting racial equality in the United States.³⁷ Title VI of the Civil Rights Act of 1964 bans exclusion and discrimination on basis of race, color, or national origin in federally funded programs or activities.³⁸ Section 1981 of 42 U.S. Code guarantees that private parties afford to nonwhites the same right to contract as white citizens enjoy, as well as the “equal benefit of all laws.”³⁹ The Equal Protection Clause of the Fourteenth Amendment to the Constitution provides that no state shall “deny to any person within its jurisdiction the equal protection of the laws.”⁴⁰

Courts enforce the Equal Protection Clause prohibition of official discrimination by subjecting all racial classifications imposed by state government to “strict scrutiny” – such classifications pass constitutional

muster only if they are narrowly tailored to further a compelling state interest. According to the U.S. Supreme Court, the purpose of strict scrutiny is to “‘smoke out’ illegitimate uses of race by assuring that [government] is pursuing a goal important enough to warrant use of a highly suspect tool.”⁴¹ “Benign” or “remedial” classifications, such as temporary measures aimed at achieving racial equality or racial classifications used when there are no race-neutral alternatives, are distinguished from classifications that are based on notions of racial inferiority.⁴²

To date, courts have not applied racial equality law to biomedical research, but this body of law could potentially be used to create a framework limiting and guiding the use of racial categories in biomedical research. In their article, “The Law and Genetics of Racial Profiling in Medicine,” Erik Lillquist and Charles Sullivan survey the various legal regimes that bear on the use of race in medicine, propose a legal defense for the limited use of race in medical treatment, and recommend efforts to include racial groups in clinical trials.⁴³ They argue that the anti-discrimination framework provided by civil rights and equal protection law may prohibit “racial profiling” in a several biomedical contexts. Making race a qualification for admission to a clinical trial, for example, may constitute illegal racial discrimination.⁴⁴ Providing different treatment on the basis of race, such as prescribing different drugs or doses for whites than for nonwhites with the same illness, is another possible violation.⁴⁵ This application of antidiscrimination law to biomedical research might have prohibited the clinical trial of BiDil that tested the therapy’s effectiveness exclusively on African-American subjects. It might also prohibit physicians from prescribing BiDil exclusively to African-American patients, while failing to offer it on the basis of race to other patients suffering from the same heart ailment.

C. State Laws

State laws are also a potential source of restrictions on the use of race as a category in biomedical research. State legislatures could pass laws that specifically govern this practice. The citizens of twenty-four states, as well as many counties, cities, and towns, have the power to enact statutes and constitutional amendments through the initiative and referendum process that could also regulate this research.⁴⁶ The California Racial Privacy Initiative, for example, which was defeated by voters in 2003, barred the state from using racial classifications in its data collection and record keeping except “otherwise lawful classification of medical research subjects and patients.”⁴⁷ This initiative, backed primarily by conservatives such as Ward Connerly, an outspoken opponent of affirmative action,

would have limited the government’s ability to identify, monitor, and correct social inequities based on race while permitting the very type of racial classification that reinforces a biological meaning of race.

In addition, state tort law provides a potential basis for product liability or malpractice lawsuits seeking damages for harms caused by the marketing and prescription of race-based medical treatment. A patient who was harmed when her physician declined to prescribe a medication solely because of her race might have a medical malpractice cause of action.⁴⁸

IV. Proposals for a Legal Framework

Thus far I have discussed legal regulations that currently encourage the use of race in biomedical research as well as potential legal constraints on its use. Constructively deploying the law in this area, however, requires a normative framework. We need to evaluate what constitutes the responsible use of race in biomedical research that the law should promote and what steps will further social justice. More broadly, race-based biomedical research forces us to reconsider the meaning, utility, and justice of race consciousness in social policy.

A. The Underlying Political Debate

While science may disclaim any social objectives, the law properly pursues social goals. Those social goals, especially as they are related to race, are the subject of intense political contest. The strict scrutiny test in equal protection law asks the fundamental question, when does race consciousness in public policy legitimately further the state’s interest in racial equality? In the last two decades, this question framed controversial Supreme Court decisions on state affirmative action programs in employment and education.⁴⁹ One train of legal thought holds that official race consciousness is always pernicious and that the Constitution requires colorblindness, with no explicit attention paid to race in policy making.⁵⁰ Critical scholars have contested the colorblind approach to race equality as inadequate to address the effects of past racial discrimination and the structures that systemically create white privilege and black disadvantage.

Critical race theorists in particular have shown that racism is systematically embedded in U.S. institutions and culture and is commonly experienced by people of color.⁵¹ Legal scholar Derrick Bell has argued that whites have a material and psychological stake in discounting racism in order to hold on to the privileges they reap from it.⁵² Critical race theory therefore rejects colorblind solutions to racial inequality, recognizing that only aggressive, race-conscious remedies can

reverse the centuries-old institutionalization of white privilege and nonwhite disadvantage.⁵³

At the same time, critical race scholars have contributed significantly to the view of race as a social construction by demonstrating law's crucial role in creating and defining racial categories. In his book *White by Law: The Legal Construction of Race*, Ian Haney Lopez, for example, demonstrates how legal definitions of whiteness have changed over time in support of prevailing power arrangements.⁵⁴ Such legal studies show that the state has deployed stereotypes and policies to racialize minority groups at different points in history in response to labor market needs and political developments.⁵⁵ Thus, critical race theory supports race consciousness in public policy to address racial inequities while challenging biological definitions of race that have reinforced them.

research while taking steps to avoid the misuse of research findings? Second, does membership in socially constructed racial, or "racialized," groups, continue to affect health status, access to health care, and medical treatment, requiring race-conscious scientific investigation and legal remedies, or should public health research be colorblind? Third, should law and funding policies pursue the state's interest in racial equality through the regulation of biomedical research or should biomedical research be unconstrained by this governmental aim?

I propose that the legal regulation of race in biomedical research should aim to promote racial justice. This social justice approach holds that race is a socially constructed category without scientific basis that continues to produce health inequities, that these inequities require race-conscious legal remedies, and

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As noted above, the 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?

This constitutional debate mirrors a heated political contest over colorblindness and race consciousness as major frameworks for defining the proper treatment of race in social policy.⁵⁶ On one hand, advocacy for colorblind policies is typically based on the assertion that racism has ceased to be the cause of social inequities. On the other hand, race conscious policies are promoted as a necessary means for remedying persistent institutional racism. Some black political theorists argue, however, that "race" is an obsolete relic of racist domination unsuited for contemporary opposition to racism.⁵⁷ While this argument most faithfully acknowledges the scientific meaninglessness of "race," it is hard to see how researchers could investigate the effects of racism on health without using social categories of race.

B. A Social Justice Approach

Developing a normative framework for the legal regulation of race in biomedical research thus requires confronting underlying political tensions over the use of race in policy. Three underlying issues dominate the debate about the proper use of race in biomedical research. First, is race, defined biologically, an unscientific and pernicious category that should be eliminated from biomedical research? Or is it a scientific classification that may be validly employed in biomedical

that biomedical research should be subject to legal regulation that promotes racial justice. I distinguish a social justice framework from more cautious approaches to the legal regulation of race in biomedical research. Some proposals permit researchers to use race as a proxy for genetics, ancestry, socioeconomic status and/or environment, or they focus on safeguards against the negative consequences that can flow from biological definitions of race.⁵⁸ Rather than take an approach that is deferential to researchers' continued use of race as a scientific category, I wish to explore how the law might seriously enforce the view that race is an unscientific and pernicious classification of human beings at the same time that systemic racism produces health inequities.

The overall aim of a social justice approach to the use of race in biomedical research is to eliminate inequities based on racial hierarchy. It challenges the reification of "race" as a biological trait while addressing health inequities resulting from racism. The legal regulation of biomedical research, then, should *discourage* or *prohibit* the use of "race" as a genetic or biological category but *encourage* or *require* the use of "race" as a socio-political category to understand and investigate ways to reduce disparities in health status, access to health care, and medical treatment.

The state's interest in promoting racial justice is furthered by opposing biological notions of race, not only because they are unscientific but because they reinforce ideologies of racial subordination.⁵⁹ Moreover, race-based biomedical research may impede state efforts to address health disparities and racial inequality more broadly, by diverting attention from the structural causes of racial inequities toward biological and technological explanations and solutions.⁶⁰ In contrast, understanding the causes of and solutions to stark racial inequities in health status requires using racial and ethnic categories in research. Most basically, data on health conditions and medical care must be collected according to race to determine the sites and extent of disparities.⁶¹

Collecting such data is challenging, however. Researchers disagree about the function "race" can serve in identifying the causes of disease – as a social grouping with no biological meaning, as a proxy for other correlated genetic or non-genetic variables, or as a biologically distinctive category.⁶² As Pilar Ossorio and Troy Duster recently recommended, researchers should investigate the relationship between race and health by "discussing when and how best to use race as a variable rather than arguing about the categorical exclusion or inclusion of race in science."⁶³ According to Duster, "[t]he task is to determine how the social meaning of race can affect biological outcomes."⁶⁴

This task is complicated by the complex interaction of social, cultural, environmental, and economic causes with genetic components of disease.⁶⁵ In addition, an emerging field combining epidemiological and anthropological research is discovering *non-genetic biological* pathways through which social disparities in income, housing, education, and experiences of discrimination may produce inequities in health and well-being.⁶⁶ This new conceptual model disrupts the dichotomy between biological and environmental causes of health inequities by suggesting complex biological interactions between racism, socioeconomic disadvantage, and poor health. Nevertheless, this research need not employ the false definition of race as a biological classification.

C. Equal Protection Analysis as a Model

Equal protection analysis provides a useful model for a legal framework to evaluate the proper use of racial categories in biomedical research. As noted above, the 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? Racial classifications, as social groupings, are essential to studying and combating racial inequities in health status and care because there is no race-neutral alternative, but not to study, diagnose, or treat genetic conditions that have no scientific basis in race. Using race as a temporary, remedial classification "in the service of the goal of racial equality itself" can be distinguished from using race as a biological classification which tends to promote notions of inherent racial superiority and inferiority.⁶⁷

Under this analysis, on the one hand, federal-funding policy would support the use of race as a sociopolitical category in data collection and research to track, investigate, and address the social reasons for health inequities. This framework would also reject legal measures that bar collection of race-based data on health status as well as other indicia of racial inequality. On the other hand, using race as proxy for genetics in clinical testing of pharmaceuticals would not be narrowly tailored enough. "Race" is *not* a necessary category for genetic research because there is no scientific evidence of race-specific genetic differences (for example, evidence that all or only African-Americans have a particular allelic frequency associated with an illness or response to therapy). Moreover, there is a race-neutral alternative to using race as a proxy for a particular genetic variation: researchers can study directly patterns of genetic variation to identify alleles associated with developing or treating diseases.

Thus, the federal government might deny funding under Title VI to institutions that conduct race-based pharmaceutical trials and deny FDA and patent approval to race-specific pharmaceuticals. The law might also provide remedies, under 42 U.S.C. 1981, the Equal Protection Clause, and product liability and medical malpractice law, to people who are discriminated against in clinical trials and medical treatment on the basis of biological definitions of race.

V. Conclusion

In this article, I have proposed a basic framework for a social justice approach to determining the proper use of racial categories in biomedical research, and have suggested several tentative applications of this approach. Informed by critical race theory, a social justice approach aims to promote racial equality by supporting race consciousness in public policy in order to address systemic racial inequities, while rejecting biological definitions of race that have reinforced them. Thus, the legal regulation of biomedical research should *discourage* or *prohibit* the use of "race" as a genetic or biological category, but *encourage* or *require* the use of "race" as a socio-political category to understand and investigate

ways to eliminate disparities in health status, access to health care, and medical treatment. Equal protection analysis helps to explain this distinction by revealing that biological classifications of race are not narrowly tailored to further the state's compelling interest in racial equality and improved health.

I recognize that this is a rudimentary proposal that will require fine tuning to attend to the complexities of research on the interactions of socioeconomic, cultural, and environmental causes of health inequities with genetic factors, as well as the biological pathways through which racism affects health. Moreover, the legal constraints suggested by a social justice approach raise countervailing concerns about the potential negative consequences of prohibiting certain kinds of research. Is there a clear enough distinction between legitimate and illegitimate uses of race in research and should we trust the President, Congress, federal agencies, state legislatures, and judges to make this determination? Will restrictions on harmful race-based research chill helpful research on race-based health disparities?⁶⁸ Any framework for legal constraints on biomedical research must grapple with these questions to justify restricting research and minimize the potentially harmful consequences. Nevertheless, the unfortunate potential for biological definitions of race to reinforce unjust racial hierarchies and to steer research and public policy away from efforts to address the social causes of health inequities is a compelling reason to pursue a social justice framework for regulating the use of racial categories in biomedical research.

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 28. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
 29. *Id.*, at 316-317. In contrast, the Canadian court in *Harvard College v. Canada*, 2002 SCC 76, denied the patentability of higher life forms without express authorization from Parliament.
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 31. Kahn, *supra* note 11, at 32.
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 39. 42 U.S.C.A. § 1981 (2006).
 40. U.S. CONST. amend. XIV, § 1.
 41. *Grutter v. Bollinger*, 539 U.S. 306 (2003), quoting *Richmond v. J.A. Croson*, 488 U.S. 469, 493 (1989).
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 47. Cal. Sec'y of State, Official Voter Information Guide 45, § 32(a) (2003); see also Proposition 54 to amend Cal. Const. art. I (2003), available at <<http://vote2003.ss.ca.gov/voterguide/english.pdf>> (last visited July 7, 2006).
 48. Suppose, for example, a cardiologist prescribes BiDil as the only suitable therapy for an African-American patient and does not consider alternative therapies solely because of the patient's race. The patient may have a tort claim against the cardiologist if she is harmed by the cardiologist's failure to prescribe more effective medication on the basis of race alone.
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 67. *Grutter v. Bollinger*, 539 U.S. 306 (2003), quoting *Richmond v. J.A. Croson*, 488 U.S. 469, 510 (1989).
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