“RACIALLY-TAILORED” MEDICINE UNRAVELED

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ABSTRACT: In June 2005, the FDA approved BiDil, a heart failure medication that is labeled for use only by African-Americans and thus, is the first treatment of its kind. The drug likely portends a future of growing interest in “race-based” medicine. This phenomenon is emerging at the same time that scientists, in light of the Human Genome Project, are reaching an understanding that “race” has no biological meaning, and consequently, “racially-tailored” medicine is both puzzling and troubling.

This Article explores the reasons for the new focus on “racial-profiling” in medicine. It analyzes the risks and dangers of this approach, including medical mistakes, stigmatizations, discrimination, exacerbation of health disparities, and violation of anti-discrimination mandates. The author does not argue against the pursuit of attribute-based therapies, but cautions that the attribute or attributes at issue must be carefully determined and will not be equivalent to what is conventionally thought of as “race.” The article develops recommendations for safeguards that should be implemented by scientific review boards, IRBs, researchers, health care providers, and journalists involved with attribute-based research and therapeutic practices to ensure that this new approach promotes rather than diminishes public health and welfare.

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INTRODUCTION

F.D.A. Approves a Heart Drug for African-Americans.\(^1\) This June 2005 headline announced the arrival of BiDil, a heart failure medication that is approved for African Americans only.\(^2\) BiDil is the first drug in pharmaceutical history that will constitute standard therapy for only one particular “race.”\(^3\)

Health care professionals are becoming increasingly interested in “race-based” medicine in the research and therapeutic contexts.\(^4\) Many researchers are attempting to discern “racial” differences in disease manifestation, biological functioning, and therapeutic response rates.\(^5\) As this approach develops, physicians may prescribe different dosages of medication for people of separate “races”\(^6\) or may provide them with entirely different drugs. In light of the success of BiDil, investigators are also likely to

\(^{1}\) Stephanie Saul, F.D.A. Approves a Heart Drug for African-Americans, N.Y. TIMES, June 24, 2005 at C2.
\(^{2}\) Id.
\(^{3}\) Id. See also infra Part II.A.
\(^{4}\) C. Condit & B. Bates, How lay people respond to messages about genetics, health, and race, 68 CLIN. GENET. 97, 97 (2005) (stating that “[t]here is a growing movement in medical genetics research and practice to develop, implement, and promote a model of race-based medicine”).
\(^{5}\) See infra Part II.B.
\(^{6}\) Sally Satel, I Am a Racially Profiling Doctor, N.Y. TIMES, May 5, 2002 § 6 (Magazine), at 56.
pursue the development of additional “racially-tailored” medications. In fact, several academic and professional conferences have already devoted significant time to the discussion of “race-based” medicine. On April 18, 2005, the University of Minnesota hosted a conference entitled Proposals for the Responsible Use of Racial & Ethnic Categories in Biomedical Research: Where do we go from here? Likewise, the eighth world congress on clinical pharmacology and therapeutics, held in 2004 in Brisbane, Australia, devoted an afternoon to ethnopharmacology.

While “racial profiling” in medicine has generated significant discussion in medical and bioethics circles, it has thus far gained relatively little attention in the legal literature. This Article aims to develop the discourse concerning this important topic. It argues that “race-based” medicine is an inappropriate and perilous approach. The argument is rooted partly in the fact that based on medical science, the social sciences, and the law, the concept of “race” is elusive and has no reliable definition. Does “race” mean color, national origin, continent of origin, culture, or something else? What about the millions of Americans who are of mixed ancestral origins – to what “race” do they belong? To the extent that “race” means “color” in colloquial parlance, should physicians decide what testing to conduct or treatment to provide based simply on their visual judgment of the patient’s skin tone? “Race,” consequently, does not constitute a valid and sensible foundation for research or therapeutic decision-making.

Further, this Article contends that “racial profiling” in medicine can be dangerous to public health and welfare. A focus on “race,” whatever its meaning in the physician’s eye, can lead to medical mistakes if the doctor misjudges the patient’s ancestral identity or fails to recall that a particular condition affects several vulnerable groups and not just one “race.” The phenomenon can also lead to stigmatization and discrimination in the workplace and elsewhere if some “races” are perceived as more diseased or more difficult to treat than others. In addition, “racial profiling” could exacerbate health disparities by creating opportunities for health professionals to specialize in treating only one “race” or to provide different and inferior treatment to certain minorities as well as by intensifying African-Americans’ distrust of the medical profession. Finally, “race-based” medicine might violate numerous anti-discrimination

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7 See conference information available at http://lifesci.consortium.umn.edu/conferences/categories.php?ss=0.
10 See infra Part III.
11 See U.S. CENSUS BUREAU AMERICAN FACTFINDER, RACE, COMBINATIONS OF TWO RACES, AND NOT HISPANIC OR LATINO: 2000, available at http://factfinder.census.gov/servlet/QTTable?_bm=y&-geo_id=01000US&-qr_name=DEC_2000_S... (disclosing that in the 2000 census almost seven million Americans indicated that they were members of two or more “races”).
12 See infra Part IV.
provisions contained in federal law, state law, and federal research regulations and guidelines.\textsuperscript{13}

The Article does not argue that attribute-based research and treatment mechanisms should be abandoned. Rather, to the extent that a group-oriented approach is pursued, it should be attribute-based rather than “race-based,” and scientists should invest considerable effort in accurately identifying the attribute or attributes at issue. Health status and treatment response depend on a constellation of factors, all of which must be considered. The variables that might be relevant for a particular procedure or therapy could include socioeconomic status, diet, exercise, stress level, exposure to environmental toxins, cultural and religious barriers to treatment compliance, specific genetic alterations that influence disease course or vulnerability, and other factors.\textsuperscript{14} In the future, it is likely that affordable genetic technology will be widely available to screen individuals for thousands of genetic variations.\textsuperscript{15} It is hoped that the practice of medicine will become increasingly individualized, with physicians examining patients for multiple variables that will determine which therapy should be prescribed.\textsuperscript{16} With careful attention to accurate identification of the patient groups that will benefit from various treatment alternatives, attribute-based medicine could undoubtedly make a significant contribution to public health.

In order to safeguard against the hazards of “racially-tailored” medicine, certain precautions must be implemented. These involve careful scrutiny on the part of governmental and institutional reviewers of study protocols,\textsuperscript{17} vigilance and prudence on the part of medical practitioners, and restraint on the part of researchers, research institutions, and the media in communicating information concerning attribute-based studies and therapies to the public.

\textsuperscript{13} See infra Part V.

\textsuperscript{14} See Ian Hacking, \textit{Why Race Still Matters}, DAEDALUS Winter 2005 at 102, 109 (stating that BiDil might be particularly effective for African-Americans because of social factors, such as diet); Alexandra E. Shields et al., \textit{The Use of Race Variables in Genetic Studies of Complex Traits and the Goal of Reducing Health Disparities}, 60 AM PSYCH. 77, 96 (2005) (recommending measurement of “specific social dimensions known to have an impact on health and health outcomes”); Margaret A. Winker, \textit{Measuring Race and Ethnicity: Why and How?}, 292 JAMA 1612, 1614 (2004) (encouraging investigators to measure a number of different variables, including “socioeconomic status, education, urban vs. rural location, or income region by ZIP code” in order to determine the true reasons for the outcome at issue).

\textsuperscript{15} See Michael Malinowski, \textit{Law, Policy, and Market Implications of Genetic Profiling in Drug Development}, 2 HOUS. J. HEALTH L. & POL’Y 3140-41 (2002) (stating that DNA chips can be used to test the samples of individuals for the presence of thousand of identified genetic variations and, alternatively, to screen hundreds of thousands of individuals with a shared phenotype characteristic to isolate and identify shared genetic expression”).

\textsuperscript{16} See infra notes 70-71 and accompanying text. By “individualized” I do not mean that different medications will be developed for each individual patient, since this would obviously be impractical. Rather, several treatment options will be available (as they often are today), and the selection of the appropriate alternative will depend on a number of factors (e.g. diet, genetic make-up, prior medical history, etc.) for which each patient will be examined.

A few notes about terminology are in order. I have argued previously that the term “race” should be eliminated from the law because it is both meaningless and pernicious. In this paper, the emphasis is different. I will extensively analyze the risks and dangers of basing medical research and therapeutic decisions on “race.” Because the concept of “race” is amorphous and not precisely definable, I will place quotes around the term when its use is necessary to describe existing medical practices or attitudes. When I can avoid reference to “race” or “racial,” I will speak in terms of “ancestry,” “population,” “attribute-based” or some other appropriate term.

I have chosen the phrase “attribute-based medicine” to describe an approach that is preferable to “race-based” medicine. The attributes upon which researchers and healthcare providers might focus include genetic makeup, socio-economic status, health habits such as diet, exercise, or smoking, religious and cultural beliefs that could constitute barriers to treatment compliance, ancestry, and other factors. These characteristics are precisely and objectively definable, and their presence or absence in individuals can be verified through testing or inquiry. While “race” could be considered an attribute, I will explain at length why it should not be the focus of medical research and practice.

The Article will proceed as follows. Part II of the Article will describe “race-based” research and therapeutic practices and will examine the growing interest in “race-based” medicine and the reasons for it. Part III will argue that “race” is a concept that has no coherent meaning and that is potentially pernicious. Part IV will detail the dangers of “racially-tailored” medicine, and Part V will establish that the practice can potentially violate a variety of anti-discrimination mandates. Finally, Part VI will detail recommendations for the development of attribute-based medicine in a manner that will promote the health and welfare of all population groups.

II

“RACE-BASED” RESEARCH AND THERAPEUTIC PRACTICES

A. The Story of BiDil

BiDil is a combination of two drugs, hydralazine and isosorbide dinitratre (H/I). These drugs are vasodilators that dilate blood vessels in order to diminish the stress on the heart as it pumps blood. BiDil also is believed to increase nitric oxide levels in the blood, which benefits many heart failure patients.

The evolution of BiDil began with the first Vasodilator Heart Failure Trial (V-HeFT I), which was conducted from 1980 to 1985 and found that the H/I drug combination (BiDil’s components) reduced mortality, though the results were of

19 “Population” does not necessarily mean “inhabitants.” It can also be defined as a “set of individuals, items, or data from which a statistical sample is taken.” WEBSTER’S II NEW COLLEGE DICTIONARY 859 (1995).
20 Bowser, supra note __, at 1116 1117.
21 Kahn, supra note __, at 108.
“borderline statistical significance.” A second trial, V-HeFT II, took place between 1986 and 1991 and compared the H/I combination to enalapril, an ACE inhibitor. This study showed that enalapril was generally more effective than the H/I combination and established ACE inhibitors as the drugs of choice for heart failure, though twenty to thirty percent of congestive heart failure patients could not tolerate them or did not respond to them and, therefore, were found to be better treated by the H/I combination. The V-HeFT trials enrolled both Black and White subjects and did not scrutinize or report any racial distinctions in drug response rates. In 1989, Dr. Jay Cohn, one of the trials’ principal investigators, received a patent for the H/I drugs. His patent application did not mention race or indicate that the medications should be targeted for any particular ethnic population.

The H/I drugs were combined into one pill, known as BiDil, and Medco, which had acquired the intellectual property rights to BiDil from Cohn, submitted a new drug application to the FDA in 1996. The FDA, however, voted nine to three against BiDil’s approval because it lacked confidence in the biostatistical validity of the V-HeFT studies’ results. Medco thereafter allowed its intellectual property rights to revert to Cohn.

In an effort to revive the drug, Cohn reanalyzed the V-HeFT data, focusing on race. In 1999 Cohn and other scientists published a paper in which they wrote that “the H-I combination appears to be particularly effective in prolonging survival in black patients and is as effective as enalapril in this subgroup. In contrast, enalapril shows its more favorable effect on survival, particularly in the white population.”

In 1999 NitroMed Inc. acquired the intellectual property rights to BiDil from Jay Cohn. NitroMed amended BiDil’s new drug application to seek approval for the use of BiDil to treat African-American heart failure patients. In 2001 the FDA indicated that it would most likely approve the drug if a clinical trial proved its efficacy for Black

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22 Kahn, supra note __, at 112; Jay N. Cohn et al., Effect of Vasodilator Therapy on Mortality in Chronic Congestive Heart Failure: Results of a Veterans Administration Cooperative Study, 314 NEW ENG. J. MED. 1547, 1547 (1986).
23 Jay N. Cohn et al., A Comparison of Enalapril with Hydralazine-Isosorbide Dinitrate in the Treatment of Chronic Congestive Heart Failure 325 NEW ENG. J. MED. 303, 303-04 (1991). ACE inhibitors are drugs lower the blood pressure by inhibiting the formation of angiotensin II, a substance that causes the arteries to constrict. ACE inhibitors relax the arteries, thereby lowering blood pressure and improving the pumping efficiency of failing hearts. See MEDTERMS MEDICAL DICTIONARY available at http://www.medterms.com/script/main/art.asp?articlekey=2108.
24 Id. at 307-09; Bowser, supra note __, at 1117, Kahn, supra note __, at 112.
25 Cohn, supra note __, at 303-04.
26 Kahn, supra note __, at 113.
27 Id.
28 Bowser, supra note __, at 1118. In 1994 BiDil was tested to ascertain that it was as effective as the H/I drugs were when administered separately, and it was found to be efficacious. Id.
29 Id. The following day Medco’s stock plummeted by 25%. Id.
30 Id.; Kahn, supra note __, at 115-16.
31 Peter Carson et al., Racial Differences in Response to Therapy for Heart Failure: Analysis of the Vasodilator-Heart Failure Trials, 5 J. CARDIAC FAILURE 178, 182 (1999).
32 Bowser, supra note __, at 1119. NitroMed is a “Boston area biotech firm specializing in the development and commercialization of nitric oxide enhanced medicines” to treat heart disease. Id.
This conditional promise led to the African-American Heart Failure Trial (A-HeFT), which enrolled 1050 self-identified African-Americans and was supported by the Association of Black Cardiologists and $31.4 million raised from private venture capital firms.

On October 15, 2002, Cohn and his co-author, Peter Carson, obtained a new patent for the use of BiDil to treat African American patients and assigned the patent rights to NitroMed. The patent is “the first ever granted to a preexisting drug for a new, race-specific use.” While Cohn’s original 1989 patent for the H/I drugs is scheduled to expire in 2007, the second, race-based patent will not expire until 2020.

The study was halted early when it became evident that the addition of BiDil to standard therapy reduced “relative one-year mortality” by forty-three percent among the Black study participants. The investigators determined that it would be unethical to continue to deprive subjects in the control arm of the drug. The study results were published in the prestigious *New England Journal of Medicine* in November 2004, and BiDil was approved by the FDA in June 2005. The emergence of BiDil may well usher in a new era of racially-tailored medicine.

### B. Race-Based Research

The question of whether there are biological and medical differences among members of different races has long fascinated scientists. Biomedical researchers have conducted numerous clinical studies that focus on racial differences in disease manifestation, metabolism, and treatment response rates. Moreover, even when studies are not designed specifically to examine racial differences, data about the racial identities of subjects is nevertheless collected. Many of the findings, however, are controversial and are vigorously debated in medical circles.

For example, a 1999 study claimed that Blacks metabolize nicotine more slowly than Whites. Critics have argued that the study enrolled only fifty-one Blacks, that

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34 Anne L. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 NEW ENGL. J. MED., 2049, 2049 (2004).
36 Kahn, *supra* note __, at 118, 131-32; Bloche, *supra* note __, at 2036.
37 Bloche, *supra* note __, at 2036.
38 Id.
39 Taylor, *supra* note __, at 2049; Wade, *supra* note __, at 12
40 Wade, *supra* note __, at 12.
41 Taylor, *supra* note __, at 2049. The study has not been replicated by anyone without financial interests in BiDil.
42 Saul, *supra* note 1, at C2.
43 See infra Part III.A.
44 See Kahn, *supra* note __, at 116 (stating that “the V-HeFT investigators had been tracking data by race from the outset” long before they conceived of BiDil as a racially-tailored drug). The observation that race identification data is routinely collected in clinical trials is confirmed by the author’s personal experience as a member of an IRB.
45 Neal L. Benowitz et al., *Ethnic Differences in N-Glucuronidation of Nicotine and Cotinine*, 291 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1196 (1999). The study included 108 volunteers, 51 of whom were black and 57 were white. The subjects were “of similar age, gender distribution, and smoking history.”
Blacks are far more likely than whites to smoke menthol brands thereby skewing the comparison, and that the statistical difference was insubstantial. 46

Other studies have focused on hypertension and have purported to find that Blacks have higher rates of hypertension. 47 Upon careful scrutiny, however, it becomes evident that while African-Americans do demonstrate higher blood pressure measurements than North American Whites, Whites have higher levels than Nigerians and Jamaicans, and the data from Brazil, Trinidad, and Cuba show a much smaller blood pressure disparity than the statistics from North America. Overall, in the populations studied, between fourteen to forty-four percent of Blacks were found to have hypertension, while in Whites the prevalence rate ranged from twenty-seven to fifty-five percent. 48 Another epidemiological study found that even among African-Americans there are notable hypertension differences, with darker skinned American Blacks manifesting more serious symptoms than lighter skinned Blacks. 49 The researchers concluded that the differences could be explained by socioeconomic factors, since those with darker skin in America suffer more discrimination and deprivation than those with lighter skin. 50

In 1999 Peter Carson, Daniel Dries, and others coauthored a study whose results indicated that “there may be differences in the natural history of . . . left ventricular dysfunction between black and white patients” and thus in the evolution of progressive heart failure. 51 The authors also asserted that “[t]he population-based mortality rate from congestive heart failure is 1.8 times as high for black men as for white men and 2.4 times as high for black women as for white women.” 52 This study has been sharply criticized for failing to control adequately for socio-economic factors 53 and for reaching erroneous statistical results. Specifically, critics note that the study relied on data from 1981 even though the gap between Black and White mortality rates had significantly narrowed between 1980 and 1995. 54 Furthermore, the study examined only individuals between the ages of thirty-five and seventy four, even though among whites who die of heart failure,

46 Bowser, supra note __, at 1125 (stating that “there was only an 8% difference in the variable of interest”). The author claims that 57 of the subjects were African-American, but has apparently inverted the number of Black and White participants.
48 Duster, supra note __, at 1050; Cooper, supra note 47.
49 Michael J. Klag et al., The Association of Skin Color With Blood Pressure in US Blacks With Low Socioeconomic Status, 265 JAMA 599, 599 (1991).
50 Id. at 602.
51 Daniel L. Dries et al., Racial Differences in the outcome of Left Ventricular Dysfunction, 340 NEW ENG. J. MED. 609, 616 (1999).
52 Id. at 609.
53 Kahn, supra note __, at 119-120.
54 Id. at 120; Jonathan Kahn, Getting The Numbers Right, 46 PERSPECTIVES IN BIOLOGY AND MEDICINE 473, 477 (2003).
seventy-one percent do so after the age of seventy-four.\textsuperscript{55} According to one commentator, current data places “the age-adjusted ratio of black to white mortality from heart failure at something under 1.1:1 for 1999.”\textsuperscript{56}

In the world of “racially-tailored” research, the A-HeFT trial is a milestone.\textsuperscript{57} It was the first study that was designed specifically to prove the efficacy of a drug that would be recommended only for members of one “race.”\textsuperscript{58} The A-HeFT study has been particularly controversial.\textsuperscript{59} The trial included only self-identified African-Americans and compared a combination of BiDil and standard therapy (which includes ACE inhibitors) to standard therapy alone for this population.\textsuperscript{60} No trial has ever compared a combination of BiDil and ACE inhibitors to standard therapy among all populations, and therefore, according to critics, it is erroneous to conclude that BiDil combined with conventional therapy is the treatment of choice only for African-Americans.\textsuperscript{61} The V-HeFT trials that preceded A-HeFT\textsuperscript{62} compared BiDil, on its own, to conventional therapy that was used in the early 1980s and then to enalapril (an ACE inhibitor) alone.\textsuperscript{63} No previous trial ever tested a combination of BiDil and Ace inhibitors. Consequently, if non-Blacks are not given BiDil together with ACE inhibitors because the FDA has not approved it for them, they might be deprived of a beneficial treatment.\textsuperscript{64} On the other hand, if doctors prescribe BiDil off-label\textsuperscript{65} to non-Black patients, which might be what its manufacturers hope for, these individuals will be receiving a drug combination that was never tested within their population group.

C. A Growing Interest in “Race-Based” Medicine: Why Now?

\textsuperscript{55} Kahn, \textit{supra} note \_, at 121; Kahn \textit{supra} note 54, at 477; Duster, \textit{supra} note \_, at 1050 (noting that the “age group 45 to 64 only accounts for about 6\% of heart failure mortality, and for those over 65, the statistical difference between ‘African-Americans and Caucasians’ nearly completely disappears”).
\textsuperscript{56} Kahn, \textit{supra} note \_, at 121. \textit{See also}, Kahn \textit{supra} note 54, at 477.
\textsuperscript{57} \textit{See supra} Part II.A.
\textsuperscript{58} Bloche, \textit{supra} note \_, at 2035; Susan J. Landers, \textit{New drug combo intensifies race-based medicine debate}, AMNEWS, Dec. 6, 2004, available at \url{http://www.ama-assn.org/amednews/2004/12/06/hl111206.htm}. \textit{Other trials have been conducted to compare treatment outcomes between Black and non-Black patients with therapies that are marketed to all population groups. See e.g. Jackson T. Wright, Jr. et al., \textit{Outcomes in Hypertensive Black and Nonblack Patients Treated with Chlorthalidone, Amlodipine, and Lisinopril}, 293 JAMA 1595 (2005) (finding that “[w]hile the improved outcomes with chlorthalidone were more pronounced for some outcomes in blacks than in nonblacks, thiazide-type diuretics remain the drugs of choice for initial therapy of hypertension in both black and nonblack hypertensive patients”).}
\textsuperscript{59} Pilar Ossorio & Troy Duster, \textit{Race and Genetics}, 60 AM. PSYCH. 115, 116 (2005) (“The racialized nature of the BiDil trial and marketing is highly contested terrain”).
\textsuperscript{60} Taylor, \textit{supra} note \_, at 2049.
\textsuperscript{61} Bloche, \textit{supra} note \_, at 2035; Kahn, \textit{supra} note 54, at 481.
\textsuperscript{62} \textit{See supra} Part II.A.
\textsuperscript{63} \textit{See supra} Part II.A; Bowser, \textit{supra} note \_, at 1117. In the early eighties ACE inhibitors were not used.\textsuperscript{64} Bloche, \textit{supra} note \_, at 2036; Kahn, \textit{supra} note 54, at 481; Jonathan Kahn, \textit{Misreading race and genomics after BiDil}, 37 NATURE GENETICS 655 (2005); Saul, \textit{supra} note \_, at C2.
\textsuperscript{65} Off-label use of a drug is a use that was not explicitly approved by the FDA. Thus, a drug that was tested only on African-American adults and approved by the FDA only for use by this population, could be prescribed for Whites or children. \textit{See Dale E. Hammerschmidt, \textit{Understanding the FDA’s IND Process} in \textit{INSTITUTIONAL REVIEW BOARDS: MANAGEMENT AND FUNCTION} 324 (2002).}
As will be discussed below, scientists are developing an understanding that “race” is not a biological feature.\footnote{See infra Part III.A. See also THE UNEQUAL BURDEN OF CANCER: AN ASSESSMENT OF NIH RESEARCH AND PROGRAMS FOR ETHNIC MINORITIES AND THE MEDICALLY UNDERSERVED 38 (M. Alfred Haynes & Brian D. Smedley ed. 1999) (stating that “race” is not a biological reality but rather, a “social or cultural construct of human variability based on perceived differences in biology, physical appearance, and behavior”).} At the same time, however, there is also renewed and increasing interest in “ racially-tailored” medicine.\footnote{Condit & Bates, supra note __, at 97.} One must wonder why this is so.

One response is that this approach holds true promise for patients, whose treatment will thereby be considerably improved.\footnote{See Satel, supra note __, at 58; Armand Marie Leroi, A Family Tree in Every Gene, N.Y. TIMES, March 14, 2005, at A23 (arguing that “the recognition of race may improve medical care”).} Skeptics might point out, however, that there are also academic, commercial, and regulatory incentives to pursue “racial-profiling” in medicine.

The mapping of the human genome was achieved in 2003 as a result of the Human Genome Project.\footnote{Nicholas Wade, Once Again, Scientists Say Human Genome Is Complete, N. Y. TIMES, April 15, 2003 at F1.} The question now is how will the knowledge gained be applied to improve human health? There is much hope that it will ultimately lead to individualized genomic medicine, whereby physicians can test individual genetic samples to determine what treatment is best for each person.\footnote{See Bloche, supra note __, at 2036 (discussing the possibility of finding genetic variations and linking them to different therapeutic approaches); Kahn, supra note __, at 28 (commenting on the “promise of fully individualized genomic medicine”); David Neil & Jillian Craigie, The ethics of pharmacogenomics, 23 MONASH BIOETHICS REV. 9, 14 (2004) (providing the example of the “multi-drug resistance gene,” MDR1, “which is found in 70% of Kenyans, 32% of Chinese, 24% of UK Caucasians and 15% of Southwest Asians”).} This advance, however, is years if not decades away from becoming practical and widely accessible.\footnote{Kahn, supra note __, at 28; Shields, supra note __, at 80 (stating that “individualized medicine is still in the future”); Condit & Bates, supra note __, at 98 (noting the “fear that the promise of so-called ‘personalized’ genetic medicine is increasingly unlikely to be fulfilled in the near-term future”).} In the interim, developing a few different “race-based” treatment protocols that are justified by apparent “racial” disparities in treatment response rates might seem like a reasonable step in the right direction.\footnote{Bloche, supra note __, at 2036 (articulating the position that reliance on race is merely an interim step on the path to personalized pharmacotherapy”); Kahn, supra note __, at1 28.} Critics, however, would argue that “race” is a crude and inaccurate marker and that its use will lead to medical mistakes and potential exacerbation rather than alleviation of health disparities.\footnote{See infra Part IV (discussing the dangers of “racial profiling” in medicine); Bloche, supra note __, at 2036; Neil & Craigie, supra note __, at 14-15 (discussing the ethical implications of research that uses “ethnicity as a recruitment shortcut”).}

Pharmaceutical companies are also likely to be enthusiastic about developing certain “ racially-tailored” drugs. If a particular manufacturer can produce a drug that is marketed as the medication of choice for all Black, Asian, or Hispanic patients, it will be able to capture a significant percentage of the market and divert it away from competitors who produce the standard therapy. Moreover, drug companies engaging in research and development that is specifically designed to improve treatment outcomes for a minority
group might be able to obtain financial and political support for their endeavors, which would not be available for ordinary clinical studies.\textsuperscript{74}

By extension, regulatory advantages might also motivate pharmaceutical companies to pursue the development of “racially-tailored” medicine. Health disparities between Whites and Blacks in the U.S. have been the subject of much commentary and debate in recent years and have fueled a governmental interest in formulating an effective response.\textsuperscript{75} Guidelines issued by the National Institutes of Health (NIH) emphasize the importance of gathering data concerning treatment response differences among various minority groups in order to achieve “change in health policy or standard of care.”\textsuperscript{76} The NIH might thus be especially interested in funding research projects with potential to improve the health status of a minority group. The NIH guidelines also require the reporting of “racial” and ethnic treatment response differences.\textsuperscript{77} The policy may thereby encourage investigators to attribute differences to “race” and to respond to them in future projects by developing “racially-tailored” therapies.\textsuperscript{78}

Similarly, the FDA might be particularly willing to approve therapies that are depicted as likely to reduce health disparities. In the case of BiDil, NitroMed obtained the support of the Association of Black Cardiologists and the Congressional Black Caucus for purposes of obtaining FDA approval of the drug, and the FDA, which had declined approval when BiDil was presented as an alternative therapy for all populations, approved it as a drug for African-Americans despite vocal criticism on the part of some experts.\textsuperscript{79} It is also noteworthy that the United States Patent and Trademark Office (PTO) issued a “race-based” patent for BiDil even though an earlier patent already existed for the drug as a non- “racially-tailored” medication.\textsuperscript{80} Consequently, scientists may have incentives to conduct research that will prove the efficacy of a therapy in a particular population in order to seek new “race- specific” patents for existing products.

This Article does not argue that attribute-based medicine should be abandoned. Rather, it argues only that it is extremely important to identify accurately the attributes

\textsuperscript{74} Kahn, supra note __, at 123, 145 (reporting that NitroMed obtained the support of the Association of Black Cardiologists and the Congressional Black Caucus in its effort to obtain FDA approval for Bidil and that the drug became racialized in part because of commercial considerations); Bowser, supra note __, at 1120 (stating that NitroMed raised $31.4 million from private venture capital firms to support the A-HeFT study).


\textsuperscript{77} Id. at II.B.

\textsuperscript{78} For further discussion of the NIH Guidelines see infra, Part V.C.1.

\textsuperscript{79} Kahn, supra note __, at 123; Saul, supra note __, at C2.

\textsuperscript{80} See supra Part II.A; Kahn, supra note __, at 132. While the original patent will expire in 2007, the second patent will expire only in 2020. Id.
that are relevant for the proposed medical protocol. For this reason, the correct questions must be asked about the characteristics that are responsible for distinguishable disease vulnerabilities or treatment response rates. Is the difference based on geographic origin? Is it a specific genetic variation? Or is it socio-economic status that causes individuals to have poor nutrition, little opportunity for exercise, and excessive stress? Or is it a combination of factors? The concept of “race” is not helpful in this regard. Although it is likely to be more costly to consider all of the relevant factors rather than relying on the proxy of “race,” doing so is the only responsible way to proceed with medical research and to achieve accurate research outcomes. As will be developed in the next section, because “race” is incoherent and undefinable, medical researchers and practitioners cannot rely on it as a conclusively illuminating attribute for medical purposes.

III

DOES “RACE” MEAN ANYTHING?

This Article argues against substantial use of the concept of “race” in medical settings. A primary reason for this restriction is that “race” has no coherent meaning, and, therefore, reliance upon it for research or treatment purposes can be confusing at best and lead to significant adverse consequences at worst. This section will build the argument that based on medical science, the social sciences, and the law, “race” has no reliable definition or real meaning. Moreover, it is a pernicious concept that has been used to suggest that human beings can be divided into subspecies, some of which are morally, intellectually, and physically inferior to others. Thus, caregivers should focus on more precise and meaningful aspects of human identity rather than on the amorphous concept of “race.”

A. “Race” in the Medical and Social Sciences

As early as 1937 Jacques Barzun wrote that “[a]mong the words that can be all things to all men, the word race has a fair claim to being the most common, the most ambiguous, and the most explosive.” “Race” has been defined as a biological feature; a local geographic population; a group linked by common descent or origin; a population connected by a shared history, nationality, or geographic distribution; a “subspecies”; and a social and political construct. The word “race” has also been used

81 For a more extensive discussion of these arguments, see Hoffman, supra note 18.
82 JACQUES BARZUN, RACE A STUDY IN MODERN SUPERSTITION 3 (1937).
84 DVORA YANOW, CONSTRUCTING “RACE” AND “ETHNICITY” IN AMERICA 47 (2003) (citing the AMERICAN HERITAGE DICTIONARY 1488 (1992)).
85 Id. (citing the OXFORD ENGLISH DICTIONARY 69 (1991)).
86 Id. (citing WEBSTER’S II NEW RIVERSIDE UNIVERSITY 968 (1984)).
interchangeably with “ethnicity,” “ancestry,” “culture,” “color,” “national origin,” and even “religion.”

During the nineteenth and twentieth centuries, scientists attempted to classify racial groups through assessment of physiological characteristics. Samuel Morton, a prominent Philadelphia physician, collected over 800 skulls from around the world. From these, he attempted to calculate the skull capacities of different “races,” not surprisingly finding that Caucasians ranked highest, Native Americans ranked lower, and Blacks placed last. Morton’s results have been discredited by contemporary scholars, such as Stephen J. Gould, who have pointed out, for example, that skull size corresponds to body size and that body size does not necessarily correspond with intelligence level.

The Nazis focused on the science of “race” with renewed intensity. In order to identify Jews and Gypsies, who were targeted for extermination, they scrutinized hair and eye color, the shape of nostrils, the skull, jaws, earlobes, posture, the position of feet at rest, and even gait. Visitors to contemporary Holocaust museums can often see photographs of Nazi doctors measuring various features on people suspected of being Jews or Gypsies.

Of particular interest in the early twenty-first century, following the completion of the Human Genome Project’s mapping of the human genome, is the question of

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A U.S. study involving lay person focus groups concluded that African-Americans are more likely to have a broad and malleable understanding of “race,” which includes notions of self-identification and culture. Tasha N. Dubriwny et al., Lay Understandings of Race: Cultural and Genetic Definitions, 7 COMMUNITY GENETICS 185, 185, 194 (2004). The study involved 120 participants, including seven focus groups consisting of self-identified African Americans, seven groups of self-identified Whites, and one group of self-identified Hispanics. The participants were recruited from urban, suburban, and rural areas in Georgia. Id. at 186. By contrast, European-Americans were more likely to understand “race” in terms of physical characteristics, genetics, and geography. Id. at 185, 194.

91 Id. (citing SAMUEL MORTON, CRANIA AMERICANA (J. Dobson 1839)). Morton attempted to develop a scientific method for his study. He filled the skull cavity with white pepper seeds that he then transferred to a tin cylinder from which he read the volume of seeds in cubic inches. Id. He also repeated the experiment with lead shot. Id.; Samuel Morton, Observations on the Size of the Brain in Various Races and Families of Man, 4 THE PROCEEDINGS OF THE ACADEMY OF NATURAL SCIENCES OF PHILADELPHIA 221-224 (1848).
94 The Human Genome Project is an international research effort whose goal is to analyze the structure of DNA in human beings and other living creatures. Rothstein & Hoffman, supra note __, at 849.
whether “race” is a genetically valid concept. Scientists estimate that human beings share 98.56 percent of their genes with chimpanzees. 95 Human beings have approximately 30,000 to 35,000 genes, 96 and 99.9 percent of genes are identical in all individuals. 97 While there is variation in the remaining one tenth of a percent, ninety to ninety-five percent of variations, which are called alleles, 98 are found at equal rates in every “racial” population. 99 Consequently, only five to ten percent of all genetic variations (in the one-tenth of a percent of genes that actually vary) are distributed along geographical or continental lines. 100 This can be explained by the fact that human beings had to adapt to very different climates in different regions, and certain features, such as light or dark skin, are advantageous for particular environmental conditions. 101

Recently, researchers have been able to classify individuals into clusters based on similarities in particular sections of their genetic codes, and these classifications correspond statistically to the “races” by which those tested identified themselves. One study, led by Neil Risch, involved 3,636 subjects who identified themselves as White, African American, East Asian, and Hispanic. 102 Researchers analyzed three hundred twenty six microsatellite markers in their DNA samples and found that the analysis produced four major clusters that overwhelmingly corresponded to the subjects’ self-identified “race.” 103 These results, however, can be achieved only if the study includes participants whose recent ancestors all come from one distinct geographic area. 104

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95 J.W. Jamieson (no first name provided), The Reality of Race: Contra Biondi and Rickards, 42 MANKIND QUARTERLY 389, 399 (2002).
96 Guttmacher & Collins, supra note __, at 1514.
97 David Rotman, Genes, Medicine, and the New Race Debate, TECH. REV. (June 2003), at 41, 42.
98 An allele is an “alternative form of a gene.” Guttmacher & Collins, supra note __, at 1513.
99 Richard S. Cooper et al., Race and Genomics, 348 NEW ENG. J. MED. 1166, 1167 (2003); Noah A. Rosenberg et al., Genetic Structure of Human Populations, 298 SCIENCE 2381, 2381 (2002).
100 Michael J. Bamshad, Human Population Genetic Structure and Inference of Group Membership, 72 AM. J. HUM. GENET. 578, 578 (2003); Lynn B. Jorde & Stephen P. Wooding, Genetic variation, classification and ‘race,’ 36 NATURE GENET. SUPP. S28, S29 (2004) (stating that “~90% of total genetic variation would be found in a collection of individuals from a single continent, and only ~10% more variation would be found if the collection consisted of Europeans, Asians and Africans”).
101 See Kelly Owens & Mary-Claire King, Genomic Views of Human History, 286 SCIENCE 451, 453 (1999) (explaining that difference in skin and hair color, hair texture and facial features may be attributable to “differential selection by climate in various parts of the world”); Wang & Sue, supra note __, at 39 (“People from local population groups are typically more closely related than are members of groups who live greater distances apart”); Ossorio & Duster, supra note __, at 116 (stating that human “physical traits vary gradually, with groups that are close geographic neighbors being more similar than groups that are geographically separated”).
103 Id. at 268, 273-74. Only five subjects (0.14%) had genetic clustering indicative of a “racial” identity different from the one they had listed.
104 Id. at 273-274 (acknowledging that the study underrepresented “individuals with recent mixed ancestry” and that clustering success depends on “the homogeneity within groups relative to distance between groups” as well as indicating that the study’s Hispanic population was recruited from one location in Texas and consisted only of Mexican Americans). See also, Vence L. Bonham et al., Race and Ethnicity in the Genome Era, 60 AM PSYCH. 9, 12 (2005); Duster, supra note __, at 1050 (critiquing studies of human genetic diversity); Joseph L. Graves, What We Know and What We Don’t Know: Human Genetic Variation and the Social Construction of Race, available at http://raceandgenomics.ssrc.org/Graves/ (posted April 25,
Furthermore, the clustering can only be achieved through examination of microsatellites, which constitute a particular “class of non-functional DNA” that are “not typical of genes” but are selected because they are “maximally informative’ about group differences.”

Significantly, among the five to ten percent of variants in the tenth of a percent of variable genes that seem to be distributed differentially between geographical populations, there are no variants that are found in all members of one population group and not in any members of a different population group. In addition, commentators emphasize that intra-group genetic variation is dramatically greater than inter-group variation. Furthermore, Black people originating in Africa demonstrate more genetic variation than do people with recent ancestry from any other continent, so that two Black individuals are likely to be more dissimilar genetically than two members of any other “race.”

Moreover, variation in genetic makeup and physical features is gradual and continuous, so it is impossible to demarcate where one “race” ends and another begins. For example, skin color, produced by a pigment called melanin, slowly changes from one region to another so that people whose geographic distance from one another is small...
tend to look more alike than those living far apart. Also, individuals who share skin color often have radically different ancestries, as is the case for sub-Saharan Africans, New Guinea highlanders, and Australian aborigines, so that skin color, as a proxy for “race,” is an extremely unreliable indicator.

Like medical scientists, anthropologists and sociologists have long debated the significance of “race.” The American Anthropological Association (AAA) issued a 1997 statement urging the federal government to discontinue its use of the term “race” in the gathering of data, because “‘race’ has been scientifically proven to not be a real, natural phenomenon.” This position was articulated even more emphatically in 1998, when the AAA wrote that “[t]he ‘racial’ worldview was invented to assign some groups to perpetual low status, while others were permitted access to privilege, power, and wealth.”

In 2003, the American Sociological Association (ASA) issued its own statement on “race.” The ASA noted that “race” has a significant impact on individuals’ educational opportunities, employment, health status, place of residence and treatment within the social justice system. Consequently, the organization urged the continued pursuit of scholarship concerning “race,” asserting that “[r]efusing to acknowledge the fact of ‘racial’ classification, feelings, and actions, and refusing to measure their consequences will not eliminate ‘racial’ inequalities. At best, it will preserve the status quo.” The ASA, however, did not address the biological validity of “race” or attempt to define the concept’s meaning.

**B. Race and the Law**

During the eras of slavery and segregation, state legislatures struggled to create bright line rules in order to categorize people as White and Black. Different states developed the one-quarter rule, the one-eighth rule, the one-sixteenth rule, the one-thirty-

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111 Goodman, *supra* note __, at 1700. See also, Bamshad, *supra* note __, at 587 (Acknowledging that “[o]ur analysis is based on samples from regions of Africa, Asia, and Europe that are widely separated from one another. Accordingly, these samples also maximize the degree of genetic variation among populations.”).

112 Bamshad, *supra* note __, at 587.


117 *Id.*

118 *Id.* at Executive Summary.

119 *Pauli Murray, States’ Laws on Race and Color* (1950) (detailing the laws of all the states, including their definitions of “Negro”).
second rule, and the infamous one drop rule. Thus, a person could be considered White in one state and Black in another.

The courts also struggled to define who was White and who was non-White for purposes of determining questions of status, rights, and benefits. Predictably, the courts did not construct any systematic methodology for making these determinations. A published study of sixty-eight nineteenth century cases that were appealed to Southern state supreme courts showed that “race” was often determined as much by the way an individual “performed Whiteness” as by appearance, “blood,” or other presumably scientific evidence. Thus, courts often called for “reputation evidence,” judging men by their exercise of good citizenship, gentleman-like behavior, and fulfillment of obligations in the public sphere and judging women by their apparent purity and moral virtue.

The census provides a dramatic example of the fluidity of “racial” categories. The choices listed in answer to the questions about the respondent’s “race” have changed from decade to decade since 1870. In 1870 the list included only white, colored, Chinese, and Indian. In 2000, respondents could choose from the following “racial” categories: “White,” “Black, African Am., or Negro,” “Asian Indian,” “Chinese,” “Filipino,” “Japanese,” “Korean,” “Vietnamese,” “Native Hawaiian,” “Guamanian or Chamorro,” “Samoan,” “Other Pacific Islander,” “Other Asian,” and “Some other race.” It is noteworthy that many of these categories are not “races” in the traditional sense, but rather, refer to national origin (e.g. Korean, Japanese) or state/territory of origin (e.g. Native Hawaiian, Guamanian). “Hispanic” is not considered a “race” for purposes of the census, but rather an “ethnicity” and is addressed in a separate question concerning Hispanic identity.

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121 See e.g. Hudgins v. Wright, 11 Va. (1 Hen. & M.) 134, 143 (1806) (holding that appellees, who were of Native American descent, were entitled to freedom).
122 Peggy Pascoe, Miscegenation Law, Court Cases, and Ideologies of “Race in Twentieth-Century America, J. AM. HISTORY 44, 51 (June 1996) (asserting that “the criteria used to determine who fit in which category were more notable for their malleability than for their logical consistency”).
123 Ariela J. Gross, Litigating Whiteness: Trials of Racial Determination in the Nineteenth-Century South, 108 YALE L.J. 109, 120, 182-185 (1998). The cases involved criminal prosecutions, inheritance disputes, slaves suing for their freedom, slander claims, and slaveholders suing those who allegedly assisted runaway slaves passing as White. In each case the “racial” identity of a person was disputed, and a determination of whether the person was White or Black was relevant to the outcome of the litigation. Id. at 120-121.
124 Id.
126 DVORA YANOW, CONSTRUCTING “RACE” AND “ETHNICITY” IN AMERICA 56 (2003).
128 2000 Census; U.S. Census Bureau, United States Census 1990 [hereinafter 1990 Census].
129 For a discussion of the term “ethnicity” see infra note 147.
130 2000 Census, supra note __.
The categorization of people of mixed “race” has also constituted a conundrum for the Census Bureau. Until 1980, “multi-racial” individuals were required to identify themselves by the “race” of their non-White parent.\(^{131}\) In 1990, those who wrote “Black-White” in response to the inquiry about “race” were identified as Black, and those who wrote “White-Black” were classified as White.\(^{132}\) The 2000 census finally included the option of self-identification by more than one “race.”\(^{133}\) Almost seven million Americans chose two or more “races” by which to describe themselves.\(^{134}\) According to the Census Bureau, however, seventy-five percent of those who now identify themselves as Black could also correctly claim multiracial origins.\(^{135}\) In addition, according to scientists, on average, African-Americans have an admixture of ten to twenty percent white genetic ancestry, based on familial lineage.\(^{136}\)

C. Shifting the Focus Away from “Race”

When scrutinized carefully and studied through the lens of a number of disciplines, the concept of “race” has no coherent meaning. Moreover, it is a pernicious concept that suggests that human beings can be divided into subspecies, some of which are morally, intellectually, and physically superior to others.\(^{137}\) This misconception has led to the oppression, subjugation, and even extermination of millions of people, as evidenced by genocides such as the Nazi Holocaust and the slaughter in Rwanda.\(^{138}\)

\(^{131}\) Scales-Trent, supra note __, at 285.
\(^{132}\) Id.
\(^{133}\) Yanow, supra note __, at 72.
\(^{134}\) See U.S. Census Bureau American FactFinder, Race, Combinations of Two Races, and Not Hispanic or Latino: 2000, supra note __. More specifically, the responses are as follows: Two or more races - 6,826,228; Two races – 6,368,075; White: Black or African American – 784,764; White: American Indian and Alaska Native – 1,082,683; White: Asian – 868,395; White: Native Hawaiian and Other Pacific Islander – 112,964; White: Some other race – 2,206,251; Black or African American: American Indian and Alaska Native – 182,494; Black or African American: Asian – 106,782; Black or African American: Native Hawaiian and Other Pacific Islander – 7,328; American Indian and Alaska Native: Some other race – 93,842; Asian: Native Hawaiian and Other Pacific Islander – 138,802; Asian: Some other race – 249,108; Native Hawaiian and Other Pacific Islander: Some other race – 35,108; Three or more races – 458,153.
For a discussion of census data concerning Hispanics, see Greico & Cassidy, supra note __.
\(^{135}\) Bowser, supra note __.
\(^{137}\) Jayne Chong-Soon Lee, Review Essay: Navigating the Topology of Race, 46 STAN. L. REV. 747 (1994) (noting that physical traits are often associated with moral characteristics); Darren Lenard Hutchinson, Progressive Race Blindness?: Individual Identity, Group Politics, and Reform, 49 UCLA L. REV. 1455 (2002) (discussing the theory that “race consciousness breeds a culture of inferiority, victimization, and helplessness among persons of color”); Ossorio & Duster, supra note __, at 119 (stating that “[p]eople often interact with each other on the basis of their beliefs that race reflects physical, intellectual, moral, or spiritual superiority or inferiority”).
Even in contemporary intellectual circles, some are promoting theories concerning the inferiority of the Black “race.”\textsuperscript{139} For example, in 1994, Richard Herrnstein and Charles Murray published a book called \textit{The Bell Curve: Intelligence and Class Structure in American Life},\textsuperscript{140} which focused on the fact that on average, African-Americans score fifteen or sixteen points lower than Whites on IQ tests.\textsuperscript{141} Instead of critiquing the validity of IQ tests or the environmental factors that might contribute to the scoring disparities,\textsuperscript{142} the authors concluded that this population simply was less intelligent than others. Furthermore, the authors asserted that the ranks of the destitute, the criminal, the unemployed, those bearing children out of wedlock, and the socially maladjusted are populated by the unintelligent, and consequently, by a disproportionate number of African-Americans.\textsuperscript{143}

A second book, written by Michael Levin, \textit{Why Race Matters}, went a step further.\textsuperscript{144} The book argued that African-Americans are not only typically less intelligent than Whites, but also are more aggressive, assertive, and impulsive than Caucasians.\textsuperscript{145} Furthermore, according to the author, Blacks have a different moral orientation from Whites, are more likely to commit crimes, suffer from an absence of “conscience” and self-monitoring, and have less free will than Whites.\textsuperscript{146}

It should be emphasized that I do not argue that individuals should stop thinking of themselves as African-American, White, Hispanic, Jews, etc. These identities are central and empowering for many people, and I am not arguing that they should be expunged. However, deeming them to be “race” designations is not useful. More accurately, these relate to people’s continent of origin, color, national origin, religion, and culture.

Moreover, because “race” is an incoherent term that eludes clear definition and because its use reinforces misconceptions about biological differences among human populations, it should not be the focus of medical inquiry. Rather, in designing research and providing care, health professionals interested in a patient’s background should

\textsuperscript{139} \textit{See} Condit & Bates, \textit{supra} note __, at 98 (stating that “even today, beliefs in genetic variation among different ‘races’ are routinely used by racists as evidence in favor of discriminatory programs or against programs that ameliorate historical and structurally based discrimination”).

\textsuperscript{140} \textit{Richard J. Herrnstein & Charles Murray, The Bell Curve: Intelligence and Class Structure in American Life} 118-120 (1994).

\textsuperscript{141} \textit{Id.} at 276.

\textsuperscript{142} \textit{See} \textit{The Bell Curve Wars} (Steven Fraser ed. 1995) (criticizing Herrnstein and Murray for engaging in distortion of data and political advocacy rather than objective, scientific analysis); Robert J. Sternberg et al., \textit{Intelligence, Race, and Genetics}, 60 Am. PSYCH. 46, 52, 57 (2005) (explaining that “[a]lthough attempts have been made to establish genes for intelligence . . . none have been conclusively identified,” that intelligence is “ill defined,” and that “studies currently indicating alleged genetic bases of racial differences in intelligence fail to make their point”); David C. Rowe, \textit{Under the Skin}, 60 AM. PSYCH. 60 (2005)

\textsuperscript{143} \textit{Herrnstein & Murray, supra} note __, at 25-27, 63-64.

\textsuperscript{144} \textit{Michael Levin, Why Race Matters: Race Differences and What They Mean} (1997).

\textsuperscript{145} \textit{Id.} at 213.

\textsuperscript{146} \textit{Id.} at 213, 322. \textit{See also}, J. Philippe Rushton, \textit{Construct Validity, Censorship, and The Genetics of Race}, AM. PSYCH., January 1995, at 231, 242-247 (defending the concepts of “race” and “race” differences based on what the author finds to be reliable evidence of differences in “brain size, IQ, violent crime, testosterone, sexuality, and AIDS.”).
consider a combination of factors, among which might be an individual’s ancestry, socio-economic status, genetic make-up, health habits, cultural beliefs, and others.\footnote{The concept of “ethnicity,” which is often substituted for “race,” also has no fixed meaning and would not be a significant improvement over “race.” \textit{Id.} at 1148-49. To illustrate, one source quotes the following definitions of “ethnicity,” found in a variety of dictionaries: 

\begin{quote}
Of or pertaining to a social group . . . on the basis of complex, often variable traits including religious, linguistic, ancestral, or physical characteristics. 
(American Heritage Dictionary 1975, p. 450) 
1a. Of or pertaining to sizable groups of people sharing a common and distinctive \textit{racial}, national, religious, linguistic, or cultural heritage. (American Heritage Dictionary 1992, p. 630) 
Pertaining to \textit{race}; peculiar to a \textit{race} or nation; ethnological. (Oxford English Dictionary 1971, p. 313) 
2a. Pertaining to \textit{race}; peculiar to a \textit{race} or nation; ethnological. Also, pertaining to or having common \textit{racial}, cultural, religious, or linguistic characteristics…; hence (U.S. colloq), foreign, exotic. (Oxford English Dictionary 1991, p. 423) Of or relating to a religious, \textit{racial}, national or cultural group. (Webster’s II New Riverside University 1984, p. 445)
\end{quote}
\textsc{Yanow, supra} note __, at 47.} Generally, however, no single aspect of a person’s identity should be the sole basis for research or therapeutic decisions.

The term “race” obfuscates social discourse, policy-making, and medical decision-making because it subsumes so many different meanings. In the following section this Article will analyze the specific hazards of “racially-tailored” research and therapeutic practices.

IV

THE DANGERS OF “RACIAL PROFILING” IN MEDICINE

A. Medical Mistakes

Reliance on the concept of “race” can lead to unfortunate medical mistakes, which in turn, can generate medical malpractice claims.\footnote{In an ordinary medical malpractice case the plaintiff will allege that the health care provider was negligent in that she failed to use due care under the circumstances, thereby injuring the patient. \textsc{Marcia M. Boumil \& David J. Sharpe}, \textsc{Liability in Medicine and Public Health} 43 (2004); \textsc{Crossley, supra} note __, at 244 (explaining that malpractice suits are based on allegations that the physician “failed to conform to the standard of care” for “treating patients with the plaintiff’s condition”).} The problem is obvious in the diagnostic setting. If sickle cell anemia is thought of only as a “racial” disease that affects African-Americans, doctors will miss diagnoses in people with ancestry from Greece, Italy, and the Arabian Peninsula, who are also vulnerable to the illness.\footnote{\textsc{See Kahn, supra} note 9, at 139.} If cystic fibrosis is perceived as a disease that affects only people of Northern European descent, it will go undiagnosed in Black patients.\footnote{\textsc{See Richard S. Garcia, The Misuse of Race in Medical Diagnosis, CHRON. HIGHER EDUC., May 9, 2003, at B15 (relating the story of an African-American girl whose cystic fibrosis was not diagnosed until she reached the age of eight because the disease is much more common among Whites than among Blacks and thus her doctors overlooked its possibility in her case).} Similarly, a recent study examined counseling concerning testing for BRCA1 and BRCA2, which are largely associated with

\footnote{\textsc{Yanow, supra} note __, at 1148-49. To illustrate, one source quotes the following definitions of “ethnicity,” found in a variety of dictionaries: 

\begin{quote}
Of or pertaining to a social group . . . on the basis of complex, often variable traits including religious, linguistic, ancestral, or physical characteristics. 
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1a. Of or pertaining to sizable groups of people sharing a common and distinctive \textit{racial}, national, religious, linguistic, or cultural heritage. (American Heritage Dictionary 1992, p. 630) 
Pertaining to \textit{race}; peculiar to a \textit{race} or nation; ethnological. (Oxford English Dictionary 1971, p. 313) 
2a. Pertaining to \textit{race}; peculiar to a \textit{race} or nation; ethnological. Also, pertaining to or having common \textit{racial}, cultural, religious, or linguistic characteristics…; hence (U.S. colloq), foreign, exotic. (Oxford English Dictionary 1991, p. 423) Of or relating to a religious, \textit{racial}, national or cultural group. (Webster’s II New Riverside University 1984, p. 445)}
Ashkenazi Jewish women. It found that African American women with a first or second degree relative who had suffered breast or ovarian cancer were far less likely to get counseling concerning testing for the genetic abnormality than White women, even though their risk of having BRCA1/2 was no smaller.

The same concern applies to the treatment setting. Under the currently approved FDA label, individuals who appear to be non-Black might not be prescribed BiDil, even though they could benefit from it. Therapies that are developed in the future could similarly be tested on only a limited population group and, therefore, not be validated for all those who could be aided by them.

Because genetic variations are shared by multiple populations, though at times they appear in different frequencies, “race” is a crude and unreliable predictor of how an individual will respond to a particular therapy. Furthermore, treatment responses are often explained by both genetic and environmental influences, including poor diet, poverty, and excessive stress, which cross population lines. Consequently, it is inappropriate to make facile assumptions about medical treatment and prognosis based on “race.”

Furthermore, even if “race” were somehow a relevant variable, it is often difficult to accurately determine a person’s “race.” Health care providers often judge “race” identity through personal observation or through the patient’s self-identification. Because of the growing mixed-origin phenomenon in the United States, both of these methods can be very misleading. Individuals who look White can have eighty percent West African origins according to their genetic profiles, and those who look Black can

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151 Katrina Armstrong, et al., Racial Difference in the Use of BRCA1/2 Testing Among Women With a Family History of Breast or Ovarian Cancer, 293 JAMA 1729, 1734 (2005) (explaining that in the study’s sample of “women with a first- or second-degree relative with breast or ovarian cancer, the predicted probability of a BRCA1/2 mutation differed very little between African American and white women”). For background concerning BRCA 1 and 2 testing see Karen H. Rothenberg, Breast Cancer, The Genetic “Quick Fix,” and The Jewish Community, 7 HEALTH MATRIX 97, 98 (1997); Jacqueline Stevens, Racial Meanings and Scientific Methods: Changing Policies for NIH-Sponsored Publications Reporting Human Variation, 28 J. HEALTH POL’Y & L. 1033, 1044 (2003).

152 Id. __, at 1729.

153 See Saul, supra note __, at C2.

154 See supra Part III.A; Jorde & Woodying, supra note __ at S32.


156 Wang & Sue, supra note __, at 43. Some physicians may feel uncomfortable asking patients about their “racial” identity or might believe that their patient’s “race” is obvious and therefore not ask about it.
have primarily European ancestry. Therefore, those who look White or Black to a physician may not be so genetically, and those who experience themselves as African-American or Caucasian and self-identify as such, may be otherwise in genetic terms.

It follows that “racial profiling” is also alarming in the research context. If researchers test a new drug combination only on members of one “race,” the outcome will be flawed. First, if the subject population is based on individual self-identification, the study’s results could be skewed because many of the participants will actually be of mixed origins or predominantly of ancestry other than that which they reported. Second, if researchers test a treatment only on one population because of academic, commercial, or regulatory pressures or in order to facilitate recruitment or save costs and do not refine their research to determine exactly who will benefit from the therapy regardless of “race,” they would not be serving the general patient community as ably as possible.

B. Stigmatization and Discrimination

Public perception that scientific evidence has established that a particular “race” is more vulnerable to life-threatening illnesses than others or does not respond to medications that cure others may reinforce negative race-based stereotypes and misconceptions. Particular populations may be seen as diseased or incurable, which could fuel the belief that there are inferior human subspecies and biological differences among “races.”

To illustrate, when testing was first developed for the BRCA1/2 genetic abnormalities, there was concern among some Jewish advocates that it would lead to stigmatization. Commentators expressed anxiety that Jews would be generally considered to have defective DNA or bad genes, and this possibility raised the specter of the Holocaust and Nazi claims about Jewish inferiority in some minds.
Likewise, a study of lay people’s attitudes towards “racially varied pharmacogenomics,” revealed a significant amount of suspicion concerning “race-based prescription” and a preference for individualized genetic testing to determine the best course of treatment. The practice of basing treatment decisions on “race” was viewed as unwelcome “racial profiling.”

Stigmatization, in turn, can lead to discrimination in the workplace, and elsewhere. Some employers may seek to avoid hiring or promoting members of certain “races” because of a fear that they are at high risk of suffering from life-threatening diseases (e.g. cancer) or that they will be untreatable with conventional medicine if they are stricken with serious illnesses (e.g. heart disease). Employers will be concerned about excessive absenteeism, low productivity, and high insurance costs due to above-average medical expenses.

More sophisticated employers may try to avoid biased assumptions and actually test at-risk populations for the presence of genetic abnormalities but may exclude individuals from employment opportunities based on a misunderstanding of test results. In several documented cases employers singled out Black individuals for testing for the sickle cell trait, that is, for carrying one copy of the sickle cell gene, even though carrier status has absolutely no adverse health implications. From the early 1970s until 1981, the U.S. Air Force Academy excluded all Blacks with the sickle cell trait, and commercial air carriers did the same until well into the 1980s.

In the late 1990s, litigation was brought to challenge another employer’s program of collecting blood samples from Black employees and testing them for the sickle cell trait without disclosing that this was the intent of the blood test. The Ninth Circuit

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163 Jennifer L. Bevan et al., Informed lay preferences for delivery of racially varied pharmacogenomics, 5 GENETICS IN MEDICINE 393 (2003).
164 Id. at 393, 398.
165 Id. at 398. For a discussion of other studies about attitudes concerning “racial profiling” in medicine see Condit & Bates, supra note __, at 100-101
166 Bevan et al., supra note __, at 398; Kahn, supra note __, at 141.
167 Title VII of the Civil Rights Act of 1964 prohibits discrimination based on race, color, national origin, sex, and religion. 42 U.S.C. § 2000e-2(a) (2000). Employers might, however, consider it worthwhile to violate the law and risk prosecution because employment discrimination cases, based on the subjective intent of the employer, are very difficult to prove. See Sharona Hoffman, Preplacement Examinations and Job-Relatedness: How to Enhance Privacy and Diminish Discrimination in the Workplace, 49 KANSAS L. REV. 517, 552-55 (2001) for discussion of reasons for employment discrimination against individuals with actual or potential disabilities.
168 The Americans with Disabilities Act prohibits employment discrimination based on an individual’s disability, record of a disability, or perceived, disability. However, it does not clearly apply to genetic vulnerability to disease. 42 U.S.C. §§ 12102(2), 12112(a) (2000).
169 Those who carry the genetic variation for this disease do not themselves suffer from the illness. However, if they have a child with another carrier, the child could inherit a copy of the gene from each parent and thus acquire the ailment. Kahn, supra note __, at 138. In fact, having just one copy of the gene for sickle cell anemia may actually have health benefits since it is believed to increase the carrier’s resistance to malaria, a disease prevalent in Africa.
170 Kahn, supra note __, at 139.
171 See Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998). The employer, Lawrence Berkeley Laboratory, collected blood and urine samples during a mandatory physical exam and tested them for syphilis, sickle cell trait, and pregnancy.
held that such testing constituted an invasion of privacy under the California and U.S. constitutions and a violation of Title VII of the Civil Rights Act of 1964 because women and African-Americans were treated differently from other employees.\footnote{\textit{Id.} at 1275} Furthermore, according to a workplace testing survey conducted in 2001 by the American Management Association, 1.3 percent of employers acknowledged testing employees for sickle cell anemia.\footnote{See AM. MGMT. ASS’N, 2001 AMA SURVEY ON WORKPLACE TESTING: MEDICAL TESTING (2001).} The reported results did not specify whether the employers tested for the presence of disease symptoms or for the sickle cell trait and did not indicate whether only African-Americans were tested, though that is presumably the case.

Likewise, health insurers selling individual insurance policies\footnote{The Health Insurance Portability and Accountability Act of 1996 provides that insurers offering group plans cannot deny enrollment or charge higher premiums to any member of the group because of health status, medical history, or genetic information. 42 U.S.C. §§ 300gg(a), 300gg (b)(1)(B), and 300gg-1(b)(1) (2000). The law, however, does not extend to protect those seeking individual insurance plans. Such consumers might be subjected to discrimination in the form of exorbitant premium charges or complete denial of coverage. See Lori B. Andrews, \textit{A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models}, 79 WASH. U. L.Q. 221, 280 (2001). Approximately ten to fifteen percent of insured have individual policies. Rothstein & Hoffman, \textit{supra}, note __, at 869. But see infra Part V.B.5 for discussion of state insurance laws that prohibit “race” discrimination.} might use a person’s “race” as a mechanism for risk assessment and price-setting despite its unreliability.\footnote{Neil & Craigie, \textit{supra} note __, at 15 (mentioning the possibility of discrimination by insurers).} They may base decisions about issuing health insurance policies or determining premium amounts on general assumptions concerning the person’s “race” rather than on individualized assessments. They could, for example, assume that Black customers are generally at increased risk for high blood pressure or cannot be treated with inexpensive, conventional therapies for common diseases and, therefore, should be charged higher premiums or denied coverage altogether.\footnote{See \textit{supra} Part II.B for a discussion of “racially-tailored” research, its subtleties, and the controversy that surrounds them. See also \textit{supra} Part IV.A. and \textit{infra} Part VI.B, for discussion of the difficulty of determining individual “racial” identity.}

\textbf{C. Exacerbation of Health Disparities}

It is theoretically possible that if the practice of medicine becomes increasingly “racially-tailored,” minorities seeking care in largely White communities will be advised to go to doctors in other areas, such as economically disadvantaged neighborhoods in the inner city, who purportedly have more expertise in treating people of their ancestry. Just as today we have specialists who focus on particular ailments, such as oncologists and cardiologists, in the future we could have experts who specialize in treating different “races.” Thus, medical care could become more segregated, and disparities could grow rather than diminish as a result of the new approach.

Other commentators have further hypothesized that an emphasis on differences among “racial” groups could encourage health care givers to provide inferior treatment to minorities, as some are already accused of doing.\footnote{Condit & Bates, \textit{supra} note __, at 98.} If all patients with a particular illness cannot be treated the same, and there is no single standard of care, some doctors might, at least unconsciously, invest more effort and resources in serving White patients,
who can be given familiar, traditional treatments. “Race-based” medicine could also intensify the distrust that some African-Americans feel towards the medical profession in the aftermath of the Tuskegee syphilis trial and other scandals. African-Americans might absorb the message that medical professionals view them as biologically distinct from other groups and are looking for ways to exclude them from receiving mainstream, standard therapies.

V

VIOLATION OF ANTI-DISCRIMINATION PROVISIONS

“Race-based” medicine might also violate a variety of legal anti-discrimination mandates, including the Constitution, federal laws, state statutes, federal research regulations, and National Institutes of Health (NIH) Guidelines. If health care professionals and medical researchers rely upon the meaningless notion of “race” rather than basing decisions on more accurate and sound classifications, such as ancestry, national origin, socio-economic status, health-related habits, or genetic variation, they may run afoul of the law in a number of ways that are analyzed below.

A. The Constitution and Federal Civil Rights Laws

In a thorough and insightful article, Erik Lillquist and Charles Sullivan analyze a number of federal anti-discrimination provisions that could be violated by the practice of “race-based” medicine. Nevertheless, while these laws create potential causes of action for individuals subjected to “racial profiling” in medicine, they are not strong avenues for redress.

First, the Constitution’s Equal Protection provisions prohibit state and federal governmental entities from denying individuals the “equal protection of the laws.” This prohibition would apply to actions by governmental agencies, public hospitals, and public research institutions. The equal protection mandate might be invoked by individuals who feel they are treated differently in a medical setting because of their “race.”

However, plaintiffs asserting equal protection claims against governmental actors will face the hurdles of immunity. The Eleventh Amendment provides that states cannot be sued in federal court for constitutional violations.

\footnote{Id. For a description of the Tuskegee syphilis trial and other medical research abuses see Sharon Hoffman, Continued Concern: Human Subject Protection, The Institutional Review Board, and Continuing Review, 68 TENN. L. REV. 725, 729-31 (2001).}

\footnote{Lillquist & Sullivan, supra note __, at 443.}

\footnote{U.S. CONST. amend. V, XIV § 1. See also, Adarand Constructors v. Pena, 515 U.S. 200, 201 (1995) (explaining that while the Fourteenth Amendment applies to the states, the Fifth Amendment’s Due Process Clause is understood to impose an identical equal protection mandate on the federal government).}


\footnote{U.S. CONST. AMEND. XI. The text reads as follows: “The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.”}

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immunity has been interpreted to extend to cases asserting constitutional claims in state court as well\(^\text{183}\) and covers agencies and other arms of the state\(^\text{184}\). The amendment bars all suits for damages or retroactive relief against state governments that are sued by any party other than a different state or the federal government\(^\text{185}\). Likewise, the doctrine of federal sovereign immunity protects the United States from being sued without its consent\(^\text{186}\). Thus, state or federal institutions, such as hospitals or clinics, could not be sued for constitutional violations\(^\text{187}\).

In addition, the defense of qualified immunity shields federal and state government officials who are performing discretionary functions from liability for civil damages unless their conduct violates “clearly established statutory or constitutional rights of which a reasonable person would have known.”\(^\text{188}\) Consequently, individual governmental actors can be held liable only if they could be expected to have known that their actions would result in a violation of constitutional rights. Proving such knowledge is difficult, though not impossible.

A second federal law provision that might apply to “racially-tailored” medicine is 42 U.S.C. § 1981, which proscribes “race-based” discrimination with respect to contracts involving either public or private parties\(^\text{189}\). Section 1981, however, has rarely been successfully invoked in health care cases\(^\text{190}\). Furthermore, § 1981 plaintiffs must prove that the alleged wrong occurred in association with a “contract,” which could be a challenging task, especially in the research context\(^\text{191}\).

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\(^\text{183}\) Alden v. Maine, 527 U.S. 706, 712 (1999) (holding that “the powers delegated to Congress under Article I of the United States Constitution do not include the power to subject nonconsenting States to private suits for damages in state courts”).


\(^\text{186}\) Fallon, et al., supra note __, at 1001.


\(^\text{189}\) The statute provides that “all persons within the jurisdiction of the United States shall have the same right . . . to make and enforce contracts . . . as is enjoyed by white citizens . . . ” 42 U.S.C. § 1981(a) (2003); Runyon v. McCrary, 427 U.S. 160, 168 (1976) (holding that § 1981 applies to private conduct).


\(^\text{191}\) See Roger L. Jansson, Note, Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions, 78 Wash. L. Rev. 229, 242-43 (2003) (analyzing whether researchers have a special relationship with human subjects and noting that only one court has indicated
Third, Title VI of the Civil Rights Act of 1964 disallows “race” discrimination on the part of federally funded programs even if the funding recipient is a private institution.\textsuperscript{192} Nevertheless, Title VI has been held not to apply to doctors receiving Medicare payments because they are not federally-funded “programs” as defined by the law,\textsuperscript{193} though hospitals and long-term care facilities receiving federal funds are covered.\textsuperscript{194}

Finally, Title II of the Civil Rights Act of 1964\textsuperscript{195} forbids discrimination and segregation in places of public accommodation.\textsuperscript{196} The provision that defines “a place of public accommodation,” however, refers specifically to lodging, eating establishments, gasoline stations, and exhibition or entertainment facilities\textsuperscript{197} but not to medical facilities.\textsuperscript{198} Thus, it is not clear whether health care entities would constitute public accommodations under the law.\textsuperscript{199}

In short, federal law provides a number of potential causes of action for those aggrieved by “racially-tailored” medicine, but each has its shortcomings. Thus, sources other than the federal civil rights laws may provide stronger protection for patients.

\section*{B. State Laws Prohibiting Discrimination in the Medical Arena}

A number of different types of state laws prohibit discrimination by health care providers, some of which could apply to “race-based” medicine.\textsuperscript{200}

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\textsuperscript{192} 42 U.S.C. § 2000d (2000). The provision reads:
No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

Doctors receiving Medicare funding, however, are not “programs” under the statute. Lillquist & Sullivan, supra note __, at 445.


\textsuperscript{196} The text reads as follows:
All persons shall be entitled to the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of any place of public accommodation, as defined in this section, without discrimination or segregation on the ground of race, color, religion, or national origin.


\textsuperscript{197} 42 U.S.C. § 2000a(b) (2003).

\textsuperscript{198} 42 U.S.C. § 2000a(b) (2003); Bass v. Parkwood Hosp., 180 F.3d 234 (5th Cir. 1999) (finding that plaintiff lacked standing to assert a Title II claim against a hospital because even if he could prove that he suffered covered discrimination, the statute awards only prospective injunctive relief rather than damages, and he would not suffer continuing harm); Verhagen v. Olarte, No. 89 CIV. 0300(CSH), 1989 WL 146265, at *4 (S.D.N.Y. Nov. 21, 1989) (finding that hospitals are not covered by Title II); United States v. Med. Soc’y of S.C., 298 F.Supp. 145, 147-48 (D.S.C. 1969) (holding that a hospital was covered partly because it had a cafeteria and snack bar that served interstate travelers food).

\textsuperscript{199} Lillquist & Sullivan, supra note __, at 443.

\textsuperscript{200} See OFFICE OF MINORITY HEALTH, DEP’T OF HEALTH AND HUMAN SERVICES, EXECUTIVE SUMMARY: ASSESSMENT OF STATE LAWS, REGULATIONS AND PRACTICES AFFECTING THE COLLECTION AND
1. Civil Rights Statutes

The majority of states have civil rights statutes that proscribe discrimination based on race with respect to public accommodations. Arizona’s is a typical statute:

No person shall, directly or indirectly, refuse to, withhold from or deny to any person… accommodations, advantages, facilities or privileges thereof because of race, color, religion, sex, national origin or ancestry, nor shall distinction be made with respect to any person based on race, color, religion, sex, national origin or ancestry in connection with the price or quality of any item, goods or services offered by or at any place of public accommodation.\(^{201}\)

The states’ definitions of “public accommodation” vary. Twenty states consider “all establishments which cater or offer their services, facilities or goods to or solicit patronage from the members of the general public” to be places of public accommodation.\(^{202}\) One must look to each state’s common law to determine which types of health care facilities are covered.

Other states are more specific. California forbids discrimination “in all business establishments of every kind whatsoever.”\(^{203}\) Eleven states include clinics and hospitals in their statutory definitions of “public accommodation” but exclude private health care providers or insurance providers.\(^{204}\) Washington state covers any place “where medical service or care is made available,”\(^{205}\) and Nevada specifies that an “office of a provider of health care” is a place of public accommodation.\(^{206}\) Finally, the District of Columbia, Nevada, and Ohio include in their definitions of places of public accommodation insurers and insurance offices.\(^{207}\)
Other state laws are directed specifically at HMOs. To illustrate, Colorado’s statute establishes that “[n]o HMO shall unfairly discriminate against any enrollee based on...race.”

Medical facilities and health care providers who base treatment decisions on their assumptions about an individual’s “race” may be guilty of violating these civil rights laws if they cause harm by doing so. A provider who declines to consider various therapeutic options because of a patient’s apparent “race” may be a covered entity that is engaging in “race-based” discrimination under state law.

2. Hospital And Medical Facility Licensing Requirements

Massachusetts, Pennsylvania, Rhode Island, and Texas all require that medical facilities licensed to operate in the state agree to provide nondiscriminatory care. Pennsylvania’s statute, for example, mandates that “no provider shall discriminate in the operation of a facility on the basis of race...”. Rhode Island establishes that “[p]ersons and other entities providing health services in the state have a duty to provide those services to any person in need of health services without regard to the person’s race...” and that violators will be denied certification. Other states require compliance with Patients’ Bill of Rights laws that prohibit racial discrimination as a

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208 3 COLO. CODE REGS. § 4-7-2 (YYYY); FLA. STAT. ANN. § 641.22 (4) (West 2005) (“The procedures for offering comprehensive health care services... will not unfairly discriminate on the basis of age, sex, race...”); MD. CODE ANN., HEALTH–GEN. I § 19-710 (h) (West 2005) (“The procedures for offering health care services... may not discriminate unfairly on the basis of age, sex, race...”); MICH. COMP. LAWS ANN. 500.3519 (2) (West Supp. 2005) (A health maintenance organization contract... shall not discriminate on the basis of race...”); N.M. ADMIN. CODE tit. 13, §10.13.22 (A) (YYYY) (No health care insurer or health care facility or provider through which the health care insurer has made arrangements to provide health care services shall discriminate against any enrollee by... altering the terms of an existing health benefits contract and the quality of health care services rendered or to be rendered because of the enrollee’s gender, race...”); N.Y. COMP. CODES R. & REGS. tit. 10, § 98-1.11 (YYYY) (requiring that each HMO shall not discriminate in service provision on the basis of race); N.C. ADMIN. CODE tit. 11, r. 20.0202 (13) (MMM YYYY) (requiring that all contracts between providers and network plan carriers contain a provision that the provider “shall not discriminate against members on the basis of race...”); N.D. ADMIN. CODE § 45-06-07-05 (YYYY) (prohibiting HMOs from unfairly discriminating against enrollees or applicants on the basis of race); S.C. CODE REGS. 69-22 (YYYY) (prohibiting HMOs from discriminating against any enrollee or applicant on the basis of race); VA. ADMIN. CODE tit. 14, 5-210-80 (C) (1) (YYYY) (prohibiting HMOs from discriminating against any enrollee on the basis of race); W. VA. CODE ANN. § 33-25D-15 (Mitchie 2003) (prohibiting “prepaid limited health service organization[s]” from discriminating in the quality of services on the basis of race); W. VA. CODE ANN. § 33-25A-14a (d) (Mitchie Supp. 2005) (prohibiting HMOs from discriminating in the quality of services on the basis of race).

209 Similarly, in some states, an insurer that refuses to cover testing or treatment for an individual may be violating civil rights laws. See infra Part V.B.5.

210 Licensure is typically required “to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards in the construction, maintenance and operation of health care facilities.” 35 PA. CONS. STAT. ANN. § 448.801 (a) (West 2003)


condition of licensure. These statutes bind the facilities at issue even if they are not considered places of public accommodation for purposes of civil rights law.

3. Patients’ Bill of Rights Laws

Several states have Patient Bill of Rights laws that prohibit race discrimination in health care. Some states passed patient rights laws as individual statutes, while others placed patient rights provisions within more comprehensive laws. The Florida Patient’s Bill of Rights and Responsibilities is by far the most sweeping law of its kind. It provides in part that “[a] patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.” New Jersey’s law guarantees the right “[t]o treatment without discrimination as to race…” but applies only to patients in hospitals, while other laws cover long term care, surgical centers, and home health agencies.

Patients who are treated differently from others because of “race-based” practices and who suffer harm as a result might experience a violation of their rights under the law. Some patients’ rights statutes expressly authorize a private cause of action or have been deemed by the courts to include a right of private action. Other states provide only for administrative enforcement, while still others allow for patient grievances but fail to empower state agencies to fine violators or provide meaningful relief to aggrieved parties. In Michigan, while no private right of action exists, patients are entitled to reimbursement by the offending facility upon an administrative finding of a statutory violation. Florida requires that copies of the

213 NEB. ADMIN. CODE tit. 175, ch. 9, § 006 (2005); N.H. REV. STAT. ANN. § 151:21 (Supp. 2004); N.M. ADMIN. CODE tit. 7, § 7.7.2.19 (2005); N.M. ADMIN. CODE tit. 7, § 7.8.2.34 (2005); N.C. ADMIN. CODE tit. 10A, r. 13B.3302 (m) (March 2005); R.I. CODE R. 14 090 007 (2005).
216 FLA. STAT. ANN. § 381.026 (West Supp. 2005).
221 MICH. COMP. LAWS ANN. § 333.20203 (West 2001).
222 MICH. COMP. LAWS ANN. § 333.21799c (4) (West 2001) (stating that the Department of Health must order a facility in violation of the patient rights law to pay the patient $100.00 or reimburse patient for injuries or costs, whichever is greater).
patient’s bill of rights be available to patients, imposes penalties for those who violate this requirement,223 and enables patients to file grievances with the offending health care providers or the state licensing agency.224 Hospitals in Kansas must similarly inform patients of their rights during admission225 and “establish a mechanism for responding to patient complaints.”226 Delaware patients in long term care facilities can report mistreatment to the Patient Rights Unit227 or other agencies,228 and medical facilities must inform them in writing of their right to do so.229 North Dakota’s statute has a more limited scope, applying only to home health agencies and providing that they be monitored by the government to ensure compliance with the anti-discrimination mandate.230

4. Public Services Regulation

Many states prohibit discrimination on the basis of “race” in the distribution of state services, including Medicaid. Most of these states prohibit discrimination not only by state staff at public facilities, but also by any private provider or contractor who receives state funds to provide medical services and any health care facilities enrolled as state Medicaid providers.231 The statutes’ wording differs to some extent, with different laws addressing discrimination in enrollment, the provision of services, access to services, or separate treatment practices.232

To illustrate, Arizona mandates that “[a] contractor, provider, and nonprovider shall not discriminate against an eligible person or member because of race . . . .”233 Other states similarly prohibit “race” discrimination in the provision of services or denial

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224 FLA. STAT. ANN. § 381.026 (6) (West Supp. 2005) (stating that a patient can air grievances with the facility or provider serving her, as well as with the state licensing agency when a right has been violated).
225 KAN. ADMIN. REGS. 28-34-3b (10) (YYYY).
226 KAN. ADMIN. REGS. 28-34-3b (10) (b) (YYYY).
227 CODE DEL. REGS. § 40-700-014 (V) (I) (2004) (listing the phone number and address for county Patient Rights Units).
228 CODE DEL. REGS. § 40-700-014 (V) (1) (2004) (listing the Division of Public Health, State Human Relations Commission, Dept. of Health and Social Services, and Office of Civil Rights addresses to which patients can send correspondence regarding discriminatory practices).
229 CODE DEL. REGS. § 40-700-014 (III) (1), (2) (2004).
231 See e.g. MO. CODE REGS. ANN. tit. 19, § 10-2.010 (2002) (“This rule specifies civil rights compliance requirements for all health service providers and contractors who provide services for the Department of Health and for all hospitals and public health clinics that receive federal financial assistance or reimbursements for services provided”); ALA. ADMIN. CODE r. 560-X-1-.07 (2) (Supp. 1997) (“Compliance with Federal Civil Rights and Rehabilitation Acts is required of all providers participating in the Alabama Medicaid Program”); ARIZ. ADMIN. CODE R9-22-513 (2004) (“A contractor, provider, and nonprovider shall not discriminate against an eligible person or member because of race . . . .”); GA. COMP. R. & REGS. r.350-1-.05 (1989) (“[N]o individual shall be excluded from participation, or be denied benefits, or be subjected to any other form of discrimination by the Department or providers of medical assistance, by reason of handicap, race, color, sex, age, religion, or national origin”) (emphasis added).
232 See infra note 234.
of benefits. Covered physicians and medical facilities that make therapeutic decisions based purely on a patient’s “race” and thereby cause harm, could be acting in violation of these laws.

5. Insurance Codes

A few states explicitly prohibit race discrimination by insurers. Insurers who refused to cover diagnostic tests or treatments ordered by a health care provider because they did not consider them appropriate for someone of the patient’s race could be deemed to have violated these laws. New Jersey, for example, mandates that insurers may not make or permit any policy “which expresses, directly or indirectly, any limitation or discrimination as to race, creed, color, national origin or ancestry…”

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235 N.J. Stat. Ann. § 17:29B-4 (7) (c), (d) (West 2004). See also Cal. Health & Safety Code § 1365.5 (West 2000); (stating that terms of a health care service plan contract may “not be modified, and the benefits or coverage of any contract shall not be subject to any limitations, exceptions, exclusions, reductions, copayments, coinsurance, deductibles, reservations, or premium, price, or charge differentials, or other modifications because of the race…of any contracting party.”); Del. Code Ann. tit. 18, § 2304 (22) (a) (2000) (“It shall be unlawful practice for any insurance company licensed to do business in this state to discriminate in any way because of the insured’s race . . .”); 215 Ill. Comp. Stat. Ann. 5/424 (West Supp. 2005) (defining unfair methods of competition and unfair and deceptive acts or practices as: “Making or permitting, in the case of insurance . . . any unfair discrimination between individuals . . . because of the race . . . of such insurance risks or applicants.”); Ill. Admin. Code tit. 50, § 2051.55 (West YYYY) (requiring that all health insurance preferred provider agreements contain “A provision stating that the provider will provide health care services without discrimination against any beneficiary on the basis of . . . ethnicity . . . ”); Md. Code Ann., Ins. § 27-910 (b) (2002) (“A health network may not deny health care services to an enrollee on the basis of gender, race . . . ”); N.M. Stat. Ann. § 59A-16-12 (Mitchie 2000) (“No insurer shall, on the basis of the race . . . of any individual or group of persons: . . . treat any such applicant or insured differently than any other applicant or insured with respect to the terms, conditions, rates, benefits or requirements of any such insurance contract.”); Ohio Rev. Code Ann. §
Nevada’s insurance statute is somewhat narrower and provides that: “[r]isks may be classified in any reasonable way for the establishment of rates and minimum premiums, except that classifications may not be based on race, color, creed or national origin." The statute does not address denial of coverage for particular treatments based on a patient’s “race.” However, if an insurer issuing individual policies attempted to charge African-Americans as a class higher rates or premiums because they were all perceived as more prone to disease or less easily treatable by standard therapy, the insurer could be deemed to violate the law.

Nevertheless, state mandates will not protect patients enrolled in self-funded employee benefit plans because under a federal law called the ERISA, state laws regulating insurance are preempted with respect to self-funded plans and cannot be enforced. This exception is quite consequential because a growing number of employers are self-insured.

C. Violation of Research Regulations and Guidelines

The best source of protection for the American public might be NIH guidelines and federal research regulations that will govern many “racially-tailored” research studies. Clinical trials that include only one population or deliberately exclude particular population groups could violate NIH and federal agency rules.

1. NIH Policy and Guidelines

Researchers seeking NIH funding who include only members of one population in a clinical trial may violate the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. The Guidelines state the following:

1751.18 (2) (West Supp. 2005) (prohibiting any “health insuring corporation, or health care facility or provider through which the health insuring corporation has made arrangements to provide health care services” from discriminating against anyone in “the quality of health care services rendered” on the basis of race); S.D. CODIFIED LAWS § 58-6-10(2) (Mitchie 2000) (prohibiting government insurers that discriminate on the basis of race from transacting insurance in the state).

See supra note 174 and accompanying text for discussion of group versus individual insurance policies.

Employers who choose self funded plans pay their employees’ medical claims on their own rather than contracting with a commercial insurer that collects premiums and serves as a third party payer. Every medical claim translates into an out-of-pocket expense for these employers. They are thus known as self-insured employers. Mark A. Rothstein, The Law of Medical and Genetic Privacy in the Workplace, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 281, 293 (Mark A. Rothstein ed., 1997).


Mark A. Rothstein, The Law of Medical and Genetic Privacy in the Workplace, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 281, 293. (Mark A. Rothstein ed., 1997). In 1993, ninety-three percent of employers with more than 40,000 employees were self-insured, as were eighty-five percent of employers with 5,000-40,000 employees, and thirty-seven percent of those with 50-199 employees. Id.

NIH GUIDELINES, supra note __.
It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. . . . Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. 243

Researchers who seek to exclude particular minority groups from their clinical studies because they are attempting to develop therapy for a different “racial” population (e.g. only African-Americans or only Hispanics), risk violation of these guidelines and denial of NIH funding. Investigators would have to show that there are valid reasons for excluding all members of a particular minority. Because so many Americans are of mixed ancestral origin and because genetic variations are shared across population lines,244 the NIH should rarely, if ever, find a compelling justification for invoking the exception to the general rule of inclusion. The BiDil trial, for example, should have been deemed unacceptable if judged under these guidelines because there was no evidence that African-Americans are the only individuals who could benefit from a combination of BiDil and standard therapy.245

While NIH’s rule of inclusion is laudable, the NIH guidelines also feature a more troubling mandate, instructing researchers to report “race/ethnicity differences in the intervention effect” in appropriate circumstances.246 The guidelines provide the following choices for “ethnic categories”: Hispanic or Latino and Not Hispanic or Latino.247 The choices for “racial categories” are: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, and White.248 The NIH, therefore, encourages research that focuses on “racial” differences and requires analyses of “race-based” treatment response disparities even in research that is not intentionally designed to develop “racially-tailored” therapies. This approach has been criticized by other commentators and ought to be rejected.249 It could constitute an incentive for sloppy science in which response differences are attributed to

243 Id.
244 See supra Parts III.A. and III.B.
245 See supra Part II.A for a discussion of the BiDil trial.
246 See NIH GUIDELINES, supra note ___ (indicating the circumstances in which sex/gender and ethnic/racial analyses must be conducted and stating that “[i]nclusion of the results of sex/gender, race/ethnicity and relevant subpopulations analyses is strongly encouraged in all publication submissions”).
247 Id. It is not clear why Hispanic or Latino are considered “ethnic” categories while other classification are considered “racial.” For a discussion of the term “ethnicity” see supra note 147.
248 NIH GUIDELINES, supra note ___. The Guidelines further provide that “NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms “minority groups” and “minority subpopulations” are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.” The categories provided by NIH are consistent with those of the Office of Management and Budget Directive No. 15, which lists the basic “racial” and ethnic categories that the federal government is to utilize for purposes of statistical, administrative, and civil rights compliance reports. Office of Management and Budget, Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (1997), available at www.whitehouse.gov/omb/fedreg/ombdir15.html.
249 See Stevens, supra note ___, at 1033-1036; Lillquist & Sullivan, supra note ___, at 451-455.
the subjects’ self-selected “racial” identity without deeper analysis of more specific geographic origins, socio-economic conditions, and other factors.

A better alternative is one that has been adopted by several prestigious publications, including *Nature Genetics* and *JAMA*. Rather than encourage the use of “racial” categorization, these journals require authors who analyze data by subpopulation, to justify their doing so and to explain how they constructed their classifications.250 *JAMA* specifically encourages investigators to measure a number of different variables, including “socioeconomic status, education, urban vs. rural location, or income region by ZIP code” in order to determine the true reasons for the outcome at issue.251 In the words of the *Nature Genetics* editors, “this will raise awareness and inspire more rigorous design of genetic and epidemiological studies.”252

### 2. Federal Research Regulations

The federal research regulations govern a large portion of research studies that are conducted in the United States. The FDA regulations apply to clinical trials that are designed to develop new drugs, medical devices, and biological products, such as vaccines and blood products.253 Clinical trials that involve treatments other than drugs and devices, such as surgery or bone marrow transplants, are not within the jurisdiction of the FDA but are subject to HHS regulation if they are “conducted, supported or otherwise subject to regulation by any federal department or agency.”254

The federal regulations can be viewed as a further constraint upon “race-based” research. Both the FDA and HHS regulations instruct Institutional Review Boards (IRBs) that review and approve research projects255 to pay particular attention to the selection criteria for human subjects. Specifically, the regulations provide:

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as... economically or educationally disadvantaged persons.256

Investigators who design “racially-tailored” clinical trials that are federally regulated risk violating this mandate by selecting enrollees in an inequitable fashion. If members of only one minority are included in a high-risk study, that minority will

250 *Census, Race and Science*, 24 NATURE GENETICS 97, 98 (2000); Winker, *supra* note __, at 1614 (encouraging authors who analyze results by race to rely on self-designation but cautioning that such analysis has become a “knee jerk reflex” and must be justified).

251 Winker, *supra* note __, at 1614.

252 *Census, Race and Science*, *supra* note __, at 98.


255 The federal regulations mandate that all research that is conducted, supported, or regulated by HHS, the FDA, or another federal agency must be overseen by an IRB, a committee constituted to provide initial approval and periodic monitoring for biomedical research studies. 21 C.F.R. §§ 56.101, 56.102(g), 56.103 (2005); 45 C.F.R. §§ 46.101(a), 46.102(g) (2005). The IRB’s primary role is to safeguard the rights and welfare of human subjects.

disproportionately bear the burdens of the research. On the other hand, if the experimental treatment holds promise of significant benefit for participants, then all but the members of the selected minority will be deprived of the opportunity to enjoy that benefit during clinical trials.

Furthermore, if a study focusing on a particular minority will include a large number of economically or educationally disadvantaged individuals, investigators who are eager to recruit and retain subjects might be insensitive to their limitations and vulnerabilities. Extra care must be taken to ensure that potential subjects fully understand the trial and its implications and are not coerced into enrolling. These concerns will be acute if English is not the subjects’ first language (which may be the case for many Hispanics or Asians), if there is a placebo control arm in which subjects will be deprived of standard therapy, or if enrollees are offered generous financial incentives, which some may feel unable to decline.

D. Discrimination Theory

The law’s anti-discrimination mandates do not categorically prohibit differential treatment. Rather, with respect to certain conduct, the law requires that those who wish to treat individuals differently ask the right questions and do so with adequate justification. Likewise, attribute-based medicine, which can be discriminatory by nature if the attributes at issue are possessed primarily by members of a particular protected class, should not be conducted unless the patient group that will benefit from the treatment has been carefully and accurately identified.

To illustrate this principle I will focus on a few well known anti-discrimination laws and on two provisions that govern biomedical research, as discussed above. The Constitution’s Equal Protection Clause generally prohibits discrimination by governmental actors but allows it when a compelling governmental interest justifies the conduct at issue, and the conduct is narrowly tailored to achieve the compelling goal. Title VII of the Civil Rights Act of 1964 prohibits employment discrimination based on race, color, national origin, sex, and religion, but allows discrimination where “religion, sex, or national origin is a bona fide occupational qualification reasonably necessary to the normal operation of that particular business or

257 See Sharona Hoffman, The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?, 33 CONN. L. REV. 449, 484-490 (2001) (discussing the difficulties of obtaining meaningful informed consent from research participants and the flaws of the typical informed consent process).
258 See id. at 452-460 (discussing placebo controls and concerns about their use). For further discussion see infra Part VI.A (discussing safeguards that should be implemented for attribute-based research).
259 See National Bioethics Advisory Committee, Discussion and Recommendations on Undue Inducement, reprinted in Undue Influence and Coercion, http://alumni.imsa.edu/~jason/ethics_topics/undue.html (stating that monetary payments can induce subjects to participate in research; Office of Research Support Committees, The University of Texas Health Science Center at Houston, Guidelines for Payment/Reimbursement of Research Subjects, available at http://www.uth.tmc.edu/ut_general/research_acad_aff/orsc/cphs/guidelines/pay.htm (prohibiting “monetary inducements to be utilized to recruit subjects for studies involving significant risk or excessive pain or discomfort”).
260 See supra Part V.C.
261 See supra Part V.A.
Thus, an employer might be able to discriminate in hiring actors of a particular gender or national origin for the sake of depicting authentic and believable characters, to hire only females to serve as attendants in women’s dressing rooms out of respect for the privacy of female customers, and to employ only male guards in high security male prisons because of safety concerns. The Americans with Disabilities Act (ADA) prohibits employment discrimination based on disability, but authorizes employers to exclude a candidate or employee if she cannot be reasonably accommodated by the employer or will constitute a direct threat to the health or safety of himself or others in the workplace.

In the research arena, the NIH Guidelines mandate inclusion of minorities in clinical studies unless concern about “the health of the subjects or the purpose of the research” militates against inclusive selection criteria. Similarly, the federal regulations require equitable selection of subjects but enable IRBs to “take into account the purposes of the research and the setting in which the research will be conducted” in evaluating whether subjects are recruited properly.

While all of the above-described provisions generally constitute anti-discrimination mandates, they allow for selectivity, exclusion, or actions that adversely affect a protected class under particular, defensible circumstances. Likewise, this Article does not per se argue against attribute-based medicine. It does, however, contend that this approach must not be practiced in an irresponsible or unjustifiably discriminatory fashion. Basing research design or medical decisions solely on an individual’s “race” is not a sound methodology because “race” does not mean anything coherent. Medical researchers and health care providers must focus on more sophisticated and revealing classifications. It is clear that there are differences in treatment responses among individuals, and certainly these individuals can be categorized into groups. The proper classifications might involve genetic variation, geographic origin, socio-economic status, diet exercise, or other factors, and if these are meaningful predictors of illness or appropriate treatment course, they should certainly be considered. Medical decision-making that is exclusively “race-based,” however, is contrary to the ethical and legal norms that govern the practice of medicine.

264 42 U.S.C. § 2000e-2(e)(1) (2000). Note that “race” and color are not included in the list of allowable exceptions. However, in rare circumstances the BFOQ defense has been applied to race and color discrimination as well. JOEL WM. FRIEDMAN & GEORGE M. STRICKLER, JR., THE LAW OF EMPLOYMENT DISCRIMINATION 173-174 (5th ed. 2001) (discussing affirmative action programs, the hiring of actors for “race”-specific roles, and law enforcement positions that might require “racial” hiring).

265 FRIEDMAN & STRICKLER, supra note __, at 171-72 (discussing BFOQ defenses based on authenticity, privacy, and safety needs).


268 42 U.S.C. § 12113(b) (2000); Chevron v. Echazabal, 536 U.S. 73, 73 (2002) (holding that the direct threat defense applies to cases in which job performance would threaten the applicant’s or employee’s own health even if he did not pose a direct threat to anyone else in the workplace).

269 NIH GUIDELINES, supra note __.


271 See supra Part III.

272 See supra Part IV.A and infra Part VI.B.
VI
RECOMMENDATIONS

The advent of BiDil may well portend a future in which attribute-based medicine is enthusiastically pursued. This approach could hold great promise for improving human health, but it must be embraced cautiously. The following section will delineate several safeguards that should be implemented in order to address the risks and dangers of attribute-based medicine.

A. Review of Research Studies by Scientific Review Boards and IRBs

Prior to allowing a clinical trial involving human subjects to proceed, the FDA requires the study’s sponsor to submit an investigational new drug (IND) application. The proposal then undergoes an extensive scientific review process in which it is scrutinized by groups with expertise in medicine, chemistry, and pharmacology/toxicology to ascertain its scientific integrity and safety. Thus, attribute-based drugs or devices will be subjected to scientific review by the FDA. In addition, some study sponsors conduct their own, internal scientific reviews of research protocols. Finally, most clinical trials must be approved by IRBs, institutional entities that are charged with responsibility for safeguarding the welfare of research participants. Both scientific review boards and IRBs should subject attribute-based studies to particular scrutiny.

1. Scientific reviews

Scientific review boards should carefully review clinical trials that exclude particular populations in order to determine whether the trial design is justified by existing data. The BiDil study, for example, has been criticized for including only African-Americans and failing to examine whether the combination of BiDil and standard therapy will benefit non-African-Americans. Clinical trials should not be constructed to develop therapy for only one population group unless there is good reason to believe that others will not benefit from it. Moreover, as discussed below, if

273 See Bowser, supra note 20, at 1124 (stating that “[o]ther BiDils are sure to surface” because “researchers are mining through decades of old clinical trials data to find an overlooked differential racial response to drugs”).
274 Barbara Ann Binzak, How Pharmacogenomics will impact the Federal Regulation of Clinical Trials and the New Drug Approval Process, 58 FOOD & DRUG L.J. 103, 117 (2003); 21 C.F.R. § 312.22(c) (2005). In the IND application, the sponsor details the outcomes of animal studies, submits drug manufacturing data, and provides information concerning the study’s design. 21 C.F.R. § 312.23 (2005).
275 CDER HANDBOOK, supra note __, at 15-16.
278 See Kahn, supra note 54, at 481; Bloche, supra note __, at 2036.
only one population will be included, the contours of the population should be thoughtfully and accurately delineated.

Scientific review boards should encourage researchers who will rely on self-identification for purposes of inclusion criteria to take into account the limitations of this mechanism. In the 2000 census, almost seven million Americans indicated that they belonged to two or more “races.” In addition, many more individuals could consider themselves to be of mixed origin and have genetic admixtures. If a study that is designed to be population exclusive has numerous subjects with significant ancestral mixing, its results might be skewed and inaccurate. Moreover, self-identified “race” alone will rarely if ever be a scientifically valid criterion for study enrollment since it lacks meaning in genetic and biological terms. As a recent study concluded “significant population substructure differences exist that self-reported race alone does not capture.” Researchers who believe that geographic origin might be informative for research purposes should not only require self-identification but also ask subjects specific questions about their ancestries in order to gather more accurate information.

Furthermore, scientific review boards should require investigators to formulate careful hypotheses regarding factors that will influence treatment response. If applicable, they should control for psychosocial, economic-environmental, cultural, educational and other non-biological factors that might provide a partial or complete explanation for treatment response rate differences. These might include diet, exercise, stress, exposure to environmental toxins, or cultural and religious barriers that can affect protocol compliance.

A book by Anne Fadiman entitled *The Spirit Catches You and You Fall* highlights some potential social and belief-based hurdles to optimal health care. It follows an immigrant Hmong family, whose young daughter suffers from severe epilepsy, through years of encounters with the American medical and social service systems. Despite everyone’s best intentions, the daughter’s medical treatment fails time

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279 As noted in Part III.A, Neil Risch and his colleagues analyzed DNA samples and found that the samples clustered into four major groups that corresponded to the subjects’ self-identified “race.” The components they analyzed, however, were microsatellites, which are non-functional DNA that is highly illuminating with respect to group differences but not relevant to health status and other medical information. Furthermore, they did not focus on individuals of mixed “race” origins. See supra notes 102-105 and accompanying text.

280 See supra note 134 and accompanying text.

281 See supra note 135-136 and accompanying text.

282 Jill S. Barnholtz-Sloan et al., *Examining Population Stratification via Individual Ancestry Estimates versus Self-Reported Race*, 14 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1545 (2005). The study found that the risk genotype at issue “varied substantially within self-reported racial group by individual ancestry and case-control status.” Id. at 1550.

283 See Hacking, supra note ___ at 102, 109 (stating that BiDil might be particularly effective for African-Americans because of social factors, such as diet); Shields et al., supra note ___, at 96 (recommending measurement of “specific social dimensions known to have an impact on health and health outcomes”); Winker, supra note ___, at 1614 (encouraging investigators to measure a number of different variables, including “socioeconomic status, education, urban vs. rural location, or income region by ZIP code” in order to determine the true reasons for the outcome at issue).

284 See infra note 283. See also supra Part IV.A for discussion of purported “race-based” outcome differentials and the non-racial factors to which they might in truth be attributed.

and again. The family has difficulty obtaining adequate translations during doctors’ visits; the doctors, who are eager to improve the youngster’s condition, frequently alter medication dosages so that the parents are unable to follow the ever-changing instructions; and some of the parents’ religious beliefs impede both their comprehension of medical circumstances and their acceptance of particular recommended treatments.\footnote{Id. pp. 83-84, 110-113, 176-180, 186-190, 219-224.} This experience surely is not unique. Thus, while particular communities that are involved in clinical trials may demonstrate unusual therapeutic responses, these phenomena might have nothing to do with biological or genetic characteristics.\footnote{See Shankar Vedantam, Racial Disparities Found in Pinpointing Mental Illness, WASH. POST, June 28, 2005, at __ (reporting that Blacks in the U.S. were more than four times as likely to be diagnosed with schizophrenia as Whites, quoting an expert as stating that “there is a risk a psychiatrist with a different cultural experience than a patient can misinterpret the expression of a psychiatric symptom," and describing “‘focus units’ – inpatient psychiatric centers that focus on how culture and ethnicity influence psychiatric diagnosis and treatment”).} Although controlling for many variables will likely be more difficult and costly than differentiating subjects based only on “race,” it is the only way to achieve accurate study outcomes.

2. Institutional Review Boards

IRBs do not review the scientific validity of clinical trial proposals, but rather, are entrusted with safeguarding the welfare of human subjects.\footnote{21 C.F.R. §56.111 (2005); 45 C.F.R. § 46.111 (2005) (detailing “[c]riteria for IRB approval of research”).} IRBs should be particularly vigilant when reviewing attribute-based protocols that are targeted at particular population groups. The federal regulations mandate that the selection of participants be equitable.\footnote{21 C.F.R. §56.111(3) (2005); 45 C.F.R. § 46.111(3) (2005).} IRBs, like scientific review boards, should scrutinize population-specific protocols to ensure that the selection criteria are justified by scientific data. IRBs must not approve protocols in which one or more minority group will bear the burden of undergoing experimental treatments unless there is sufficient reason to believe that the particular minority or minorities will benefit from the therapy and that other groups are significantly less likely to respond positively to it.\footnote{See 21 C.F.R. §56.111(2) (2005); 45 C.F.R. § 46.111(2) (2005) (providing that “[r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result”).} Thus, clinical studies should not be limited to minorities without data supporting this decision, and the mere hope that an experimental medication will turn out to be an attribute-based drug that will generate high profits for the drug manufacturer should not justify discriminatory inclusion and exclusion criteria.

The problem is exacerbated if many of the minority subjects are likely to be economically disadvantaged. If that is the case, the informed consent process should be tailored to be comprehended by subjects with limited educations.\footnote{See also Hoffman, supra note 257, at 484-490 (discussing the difficulties of obtaining meaningful informed consent from human subjects); S. Grossman et al., Are Informed Consent Forms That Describe Clinical Oncology Research Protocols Readable By Most Patients and Their Families? 12 J.} The informed
consent process should include extensive verbal explanations, and the informed consent document should be kept as short as possible, with language that is targeted at an adequately low reading comprehension level. Furthermore, any financial incentives that are provided for enrollment must not be so generous that they are too tempting for potential subjects and thereby essentially coerce enrollment. 292

Finally, the informed consent process should clearly disclose to subjects that the clinical study is limited to particular population groups. Some individuals may be concerned about potential stigmatization, discrimination, or other adverse consequences of ancestry-based medical research and practice 293 and thus, will consider this information essential to their decision-making process.

B. Investigators and Health Care Providers

The above discussion of recommendations for scientific review boards and IRBs has already suggested guidelines for investigators who are designing attribute-specific clinical trials. 294 Researchers should not design studies to include only one population unless there is sufficient reason to believe that only that group will benefit from the therapy and that other groups are significantly less likely to respond well to it. Thus, the reasons for such a design must be medical rather than related to a desire for profit or recruitment shortcuts.

If research is to focus on a particular “race,” investigators must be aware of the limitations of self-identification and its inaccuracies. Furthermore, researchers should design studies that carefully control for psychosocial, economic, environmental, cultural, educational, and other non-biological factors. They must also do everything possible to obtain meaningful informed consent from subjects who might have limited educations, reading comprehension levels, and ability to process medical data. The informed consent process should include disclosure of the inclusion and exclusion criteria for the research project. Finally, investigators must offer only modest financial recruitment incentives, if any, so that payments do not become overly enticing and coercive for economically disadvantaged subjects.

A few words of caution should be added for medical personnel who do not design studies but employ attribute-based therapies in their practices. In order to avoid potential medical malpractice claims and violation of anti-discrimination mandates, health care providers should eschew making treatment decisions solely based on their judgment of a patient’s “racial” identity. Precise identification of ancestral origin is difficult if not impossible to make based on visual observation alone, and efforts to do so are prone to error. To illustrate, one study analyzed the “racial” designations of infants who died in their first year of life. The study showed that 4.3 percent of babies categorized as Black at birth were deemed to be other than Black on their death.

292 See supra note 259.
293 See supra Part IV for discussion of the risks and dangers of “racial profiling” in medicine.
294 See supra Part VLA.
certificates, and thirty-seven percent of those categorized as Native American on their birth certificates were classified differently on their death certificates. The confusion is often due to the mixed ancestral origins of so many Americans. Another study that asked respondents to identify “ambiguous-race faces” found only a sixty-eight percent correct identification rate.

Certainly, physicians should discuss genetic testing for the Tay Sachs allele with Jewish people who are contemplating having a child and genetic testing for the sickle cell allele with African-Americans who are considering pregnancy because of the prevalence of the diseases in these populations. However, physicians should not rely on the fact that an individual looks Black or Asian in deciding whether to discuss the topic. Instead, they should ask their patients specific questions about their ancestry.

Moreover, while one’s ancestry might be relevant to medical care in limited circumstances, physicians would be misguided to rely on this factor exclusively for most treatment decisions. Health status and therapeutic responses depend on socio-economic factors, specific alleles that are shared among all populations, or other elements, not on the color of one’s skin.

Health care givers who will use attribute-based medicine must carefully review current literature and emerging research results so that they understand its subtleties. Within their areas of expertise, health care providers must be familiar with the factors that influence health status and treatment response and be able to accurately identify the attributes at issue in order to best serve their patients.

C. Public Discourse Concerning Attribute-Based Medicine: The Responsibilities of Investigators, Institutions, and the Media

Scientists, research institutions, and the media must act cautiously and responsibly in generating public discourse about attribute-based medicine. Medical professionals and journalists should not convey information that is exaggerated or inflated. They must not fuel the fires of prejudice and ignorance by reinforcing stereotypes and misconceptions about biological differences among “races.”

Researchers might be tempted to rush to the media with preliminary, ambiguous, or questionable research results in order to obtain headlines that will

296 See supra notes 133-136 and accompanying text.
297 Otto H. MacLin & Roy S. Malpass, Racial categorization of faces: The ambiguous-race face effect 7 PSYCH., PUBLIC POL. & L. 98, 105-06 (2001) (reporting that in their study, “68% of the Black faces (ambiguous race face + Afro hair feature) were classified as Black, 7% as Hispanic, 1% Indian, 3% White, 2% Asian, and 19% as other” while of “Hispanic faces (ambiguous race face + Hispanic hair feature), 68% were classified as Hispanic, 1% as Black, 7% Indian, 3% White, 3% Asian, and 18% Other”). See also Raymond Bruyer et al., Ethnic categorization of faces is not independent of face identity, 33 PERCEPTION 169, 169 (2003) (finding that “ethnic decision was affected by face familiarity”); Peter N. Shapiro & Steven Penrod, Meta-Analysis of Facial Identification Studies, 100 PSYCHOLOGICAL BULLETIN 139, 139 (1986) (discussing the variables that influence facial identification).
298 See Feldman, supra note __, at 374 (stating that “race is both too broad and too narrow a definition of ancestry to be biologically useful” and that “[c]onfusing race and ancestry could be potentially devastating for medical practice”).
299 See supra Part IV.A.
promote their careers, enhance opportunities for further funding of their projects, or please sponsors who are supporting their studies. Investigators have been criticized for seeking publicity for “hot” research news prematurely either for personal gain or in order to promote “favourable science policy and the financial support required to sustain costly research facilities.” Even if individual researchers are restrained, their institutions might seek inappropriate media coverage and engage in hyperbole for the sake of financial and reputational advantage.

In 2001, the Office of Management and Budget (OMB) issued Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, which require federal agencies to develop mechanisms to safeguard the “objectivity, utility, and integrity” of the information they release. Thus, if governmental entities are involved in the research and are the ones to engage in media contact, there is greater likelihood that accuracy will be achieved. Academic institutions should consider developing similar guidelines to enhance the integrity of the data conveyed to the public.

At the same time, the media has been criticized for distortions in its reporting of scientific information. Reporters may not fully understand the data, may oversimplify research results in order to make them accessible to readers, or may embellish facts in order to foster readers’ interest. The media has also been criticized for reporting

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300 Dorothy Nelkin, An uneasy relationship: the tensions between medicine and the media, 347 THE LANCET 1600, 1601 (1996) (relating incidents in which scientists at the University of Utah approached the media with news of cold fusion, hoping to attract venture capital to their research; University of Minnesota behavioral psychologists sought press coverage for studies of identical twins that had been rejected by peer reviewed journals; and geneticists made dramatic and exaggerated statements to the media); Douglas G. Altman et al., Is there a case for an international medical scientific press council? 272 JAMA 166 (1994) (arguing that researchers have engaged in misconduct because of the pressure to publish and calling for a code of conduct for editors and an international council to consider grievances).


302 Id.

303 Id.

304 Id. (stating that “scientists and their institutions are increasingly seeking to define science news and to shape the content and style of science communication”); Timothy Caulfield, Biotechnology and the popular press: hype and the selling of science, 22 TRENDS IN BIOTECHNOLOGY 337, 338 (2004) (stating that “researchers, research institutions and reporters can be viewed as inadvertent ‘complicit collaborators’ in the subtle hyping of science stories”).

305 Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. 66 FED. REG. 49718-49725 (Sept. 28, 2001).

306 Id. at 49723.

307 The Guidelines have been criticized for failing to elucidate whether they bind university faculty conducting research with federal support and for creating potential grounds for “frivolous challenges and harassment.” Nils Hasselmo & C. Peter Magrath, AAU/NASULGC Letter to OMB on Proposed Guidelines on Research Data, August 13, 2001 available at www.aau.edu/research/OMBLtr8.13.01.html (written on behalf of the Association of American Universities and the National Association of State Universities and Land Grant Colleges).

308 Nelkin, supra note __, at 1601 (explaining that “[m]any accusations of inaccuracy can be traced to reporters’ efforts to present complex material in a readable and appealing way”).

309 Id.; Sarah A. Wilcox, Cultural context and the conventions of science journalism: drama and contradiction in media coverage of biological ideas about sexuality, 20 CRIT. STUD. MEDIA COMMUN. 225,
scientific data before it has been published in peer reviewed journals and thus, prior to its validation by experts in the field. Journalists may report results that they know to be preliminary, unclear, or dubious as definitive and groundbreaking. For example, a trial that shows that fifty-four percent of Whites responded well to a particular medication and forty-seven percent of Blacks reacted similarly to it may be reported as establishing that there are unmistakable and dramatic differences between Whites and Blacks with respect to the illness at issue and its course of treatment. In order to remain competitive in the market, journalists may sacrifice a degree of integrity for the sake of creating dramatic headlines by depicting research results as more promising than they are or skewing data to exaggerate health risks.

In the alternative, the media may tailor its reporting to its targeted audience. A recent study revealed that information about breast cancer was reported differently in Canadian newspapers known to be read by Jews and those read by other communities. The study found that forty-seven percent of the articles examined in Jewish newspapers identified genetics as a major risk factor, while only seventeen percent of stories in newspapers with more general readerships did the same. The authors also found many shortcomings in the way information was conveyed in both types of newspapers, including inconsistencies, data gaps, and confusing descriptions. If the press modifies its stories to appeal to its targeted audience’s presumed concerns and interests and distorts information, it can cause significant harm by inducing readers

236-38 (2003) (finding that journalists include sensationalistic, absolutist, and dramatic statements in their stories in order to gain newspaper space).

310 See C. Neal Stewart, Jr., Press before paper –when media and science collide, 21 NATURE BIOTECHNOLOGY 353, 353-54 (2003) (urging journalists not to report scientific findings before publication in peer-reviewed journals because it is only through such publication that the data can receive “second-tier …validation” upon “scrutiny by the scientific community,” can become open to rebuttal, and can be communicated carefully and accurately to journalists who are not experts in the field).

311 Condit, supra note __, at 1415 (stating that “an overly optimistic slant [in journalistic reporting] has been detected in most studies”). But see, Tania M. Bubela & Timothy A. Caulfield, Do the print media “hype” genetic research? A comparison of newspaper stories and peer-reviewed research papers, 170 CAN. MED. ASSOC. J. 1399, 1399 (2004) (examining 627 newspaper articles and finding that “the majority of newspaper articles accurately convey the results of and reflect the claims made in scientific journal articles” but that they overemphasize benefits and under-represent risks); Caulfield, supra note __, at 337 (stating that “in some circumstances, the media reporting of science is surprisingly accurate and portrays a message created by the scientific community” but that the message often contains an overly-optimistic, positive spin, possibly because of growing commercial pressures within the research environment).

312 See supra note 311; L. Donelle et al., Portrayal of genetic risk for breast cancer in ethnic and non-ethnic newspapers, 40 WOMEN HEALTH 93, 107 (2004) (discussing the possibility that journalists will exaggerate risks in order to “grab the attention of readers” and the pressures placed on reporters by editors whose mission it is to “increase circulation and distribution”).


314 Id. at 99. Jews were assumed to be more interested in genetic influences on cancer because of the BRCA1/2 genetic abnormality, which is associated with Ashkenazi Jews. See supra note 151 and accompanying text.

315 Id. at 107-09. See also, Laurie Hoffman-Goetz & Daniela B. Friedman, Disparities in the coverage of Cancer Information in Ethnic Minority and Mainstream Mass Print Media, 15 ETHNICITY & DISEASE 332 (2005) (reporting that “cancer coverage in ethnic and mainstream newspapers did not accurately reflect the leading causes of cancer death in Canada” and that cancer data should be collected by ethnic minority in Canada so that at-risk populations can be better served and educated).
or viewers to underestimate health risks or undervalue certain medical choices, such as genetic testing.

Some professional organizations such as the Society of Professional Journalists and the American Medical Writers Association have developed their own codes of ethics for journalists writing about science and medicine. These include the principles that journalists “should apply objectivity, scientific accuracy and rigor, and fair balance,” that journalists “[t]est the accuracy of information from all sources,” and that they “[a]void stereotyping by race” or other classifications. Although these ethical codes are not legally binding, every journalist would be wise to follow them.

Scientists, research institutions, and the media all bear responsibility for educating the public concerning scientific data. If information is distorted to indicate that there are significant biological differences among “races” and that some “races” are more diseased than others or less easily treatable, negative and dangerous stereotypes and prejudices could be reinforced. Furthermore, some may feel justified in discriminating against particular population groups in the workplace or elsewhere based on allegedly hard data. Finally, readers and viewers may make errors in seeking medical care and making medical choices based on what they believe they have learned about risks and treatments for their “race.” Consequently, all parties must be restrained and fastidious about accuracy when discussing scientific information, especially that which relates to attribute-based research and treatments.

One additional area of concern is direct-to-consumer (DTC) advertising, which is likely to include advertising concerning “racially-tailored” medications, as they become available on the market. A robust body of literature is emerging concerning DTC advertising, and an extensive analysis of this phenomenon is beyond the scope


317 CODE OF ETHICS OF THE AMERICAN MEDICAL WRITERS ASSOCIATION, supra note __.

318 SOCIETY OF PROFESSIONAL JOURNALISTS, CODE OF ETHICS, supra note __.

319 Id.


321 See Condit & Bates, supra note __, at 102 (discussing “empiric and contextual grounds for concern that messages that link race, genetics, and health can increase racism”).

322 See supra Part IV.B.

323 Condit, supra note __, at 1416 (proposing guidance for researchers who are communicating with the media, such as that “researchers must prepare for such interviews as carefully as they would prepare for a talk at a scientific conference”); Eliza Mountcastle-Shah, Assessing Mass Media Reporting of Disease-Related Genetic Discoveries, 24 SCIENCE COMMUNICATION 458 (2003) (developing an instrument to assess the “content and balance of media stories about genetic discoveries”).

324 Saul, supra note __, at C2.

325 See e.g. Michael C. Allen, Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct to Consumer Pharmaceutical Advertising on the Learned Intermediary, 20 CAMPBELL L. REV. 113 (1997);
of this Article. DTC advertising, however, is another arena that will need to be carefully watched and addressed if “race-based” therapies become a force in the marketplace.

VII

CONCLUSION

The medical community is demonstrating a growing interest in “racially-tailored” medical practice and research. “Racially-tailored,” however, is the wrong concept. To the extent that a group approach is appropriate, health care professionals should be thinking in terms of attribute-based medicine and taking great care to identify the relevant attributes correctly. “Race” is a concept with no coherent meaning, and disease vulnerabilities, the course of illness, and treatment responses do not depend on the shade of one’s skin color or the texture of one’s hair. Instead, medical professionals should focus on far more specific questions about ancestry and geographic origin, on socioeconomic and environmental conditions, on health habits, on factors affecting treatment compliance, and on specific alleles linked to the condition in question.

Concentrating on the issue of “race” in the therapeutic and research contexts can lead to medical mistakes, reinforcement of stereotypes, exacerbation of health disparities, and violation of various anti-discrimination provisions. In the words of one commentator, “[t]o use the rhetoric of science to sell the idea that historical inequity should be embraced as biological inevitability is an insult to those who value a common humanity.”

In order to guard against the dangers of attribute-based medicine, the FDA and research institutions should subject clinical studies that target only particular population groups to extensive scrutiny by scientific review boards and IRBs. Health care professionals should avoid making treatment decisions based solely on their visual judgment of a patient’s ancestral origins and should review literature that analyzes all factors contributing to different disease vulnerabilities and treatment response rates among patients. Furthermore, researchers, research institutions, and the media, must be constrained and responsible in communicating scientific data to the public so as not to reinforce stereotypes and prejudice or induce patients to make misguided decisions about their own care.

Finally, on a national policy level, policy officials should think carefully about the resources allocated to the development of attribute-based medicine. As discussed above, many experts attribute health disparities such as differences in hypertension rates to non-biological factors, including diet, environment, exercise, and stress. While developing attribute-based drugs might improve treatment for certain patients, it will not constitute a panacea that will eliminate all health disparities. Consequently, in light of Matthew N. Strawn, Recent Developments in Direct Consumer Advertising of Attention Disorder Stimulants and Creating Limits to Withstand Constitutional Scrutiny, 19 J. CONTEMP. HEALTH L. & POL’Y 495 (2003); Ernst R. Berndt, To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs, 352 N. Eng. J. Med. 325 (2005).

326 Richard S. Cooper, RACE AND IQ: Molecular Genetics as Deus ex Machina, 60 AM. PSYCH. 71, 75 (2005).

327 Kahn, supra note 54, at 479.
limited resources, prudent decisions need to be made concerning funding allocation between medical research endeavors and other initiatives in the areas of education, nutrition, environment, and job training that could do more to improve the health status of disadvantaged minorities.\textsuperscript{328} Despite the appeal of attribute-based medicine, resources should not be diverted away from projects intended to diminish socioeconomic injustice, which are at least as important for those adversely affected by health disparities.

It is only with careful thought and appropriate precautions that attribute-based medicine can become an approach that enhances treatment opportunities for all human beings and contributes significantly to public health and welfare.

\textsuperscript{328} See Kahn, \textit{supra} note 54, at 479.