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## "Racially-Tailored" Medicine Unraveled

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# "Racially-Tailored" Medicine Unraveled

## **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.

## **Keywords**

BiDil, Federal Drug Administration, Race, Medicine, Discrimination, Race-based Medicine, Racially-tailored Medicine, Attribute-based Medicine, Racial Profiling, Institutional Review Boards, Scientific Review Boards

## “RACIALLY-TAILORED” MEDICINE UNRAVELED

SHARONA HOFFMAN \*

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#### INTRODUCTION

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

Health care professionals are becoming increasingly interested in “race-based” medicine in the research and therapeutic contexts.<sup>4</sup> Many researchers are attempting to discern “racial” differences in disease manifestation, biological functioning, and therapeutic response rates.<sup>5</sup> As this approach develops, physicians may prescribe different dosages of medication for people of separate “races”<sup>6</sup> or may provide them with entirely different drugs. In light of the success of BiDil, investigators are also likely to pursue the development of additional “racially-tailored” medications.<sup>7</sup> In fact, several academic and professional conferences have

1. Stephanie Saul, *F.D.A. Approves a Heart Drug for African-Americans*, N.Y. TIMES, June 24, 2005, at C2.

2. *Id.*; see also BiDil Package Insert, p. 9 (on file with author) (stating that “BiDil is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status”).

3. *Id.* See generally *infra* notes 36-43 and accompanying text (detailing the history and development of BiDil as a “racially-tailored” drug).

4. See C. Condit & B. Bates, *How Lay People Respond to Messages About Genetics, Health, and Race*, 68 CLINICAL GENETICS 97, 97 (2005) (observing 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* text accompanying notes 49-66 (appraising several studies that focus on “racial” differences).

6. See Sally Satel, *I Am a Racially Profiling Doctor*, N.Y. TIMES, May 5, 2002, § 6, at 56 (describing certain circumstances under which “race” is considered in determining treatment).

7. Cf. Jonathan Kahn, *How a Drug Becomes “Ethnic”: Law, Commerce, and the Production of Racial Categories in Medicine*, 4 YALE J. HEALTH POL’Y L. & ETHICS, 1, 25

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?*<sup>8</sup> Likewise, the Eighth World Congress on Clinical Pharmacology and Therapeutics, held in 2004 in Brisbane, Australia, devoted an afternoon to ethnopharmacology.<sup>9</sup>

While "racial profiling" in medicine has generated significant discussion in medical and bioethics circles, it has thus far gained relatively little attention in legal literature.<sup>10</sup> 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 the concept of "race" is elusive and has no reliable definition in medical science, the social sciences, and the law.<sup>11</sup> 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<sup>12</sup>—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.<sup>13</sup> A focus on "race," whatever its meaning in the physician's eye, can lead to medical mistakes if the doctor

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(2004) (arguing that correlating disease and "race" is growing in popularity as drug companies seek to tailor therapies to the genetic profiles of both individuals and groups).

8. See Conference at the University of Minnesota, *Proposals for the Responsible Use of Racial and Ethnic Categories in Biomedical Research: Where Do We Go From Here?* (Apr. 18, 2005), <http://lifesci.consortium.umn.edu/conferences/categories.php?s=0> (critically examining both the current and historical use of "racial" and "ethnic" categories in biomedical and pharmaceutical research).

9. Taslin Rahemtulla & Raj Bhopal, *Pharmacogenetics and Ethnically Targeted Therapies*, 330 BRIT. MED. J. 1036-37 (2005).

10. A Westlaw search revealed very few major law review articles discussing BiDiL. See Kahn, *supra* note 7; Rene Bowser, *Race As A Proxy for Drug Response: The Dangers and Challenges of Ethnic Drugs*, 53 DEPAUL L. REV. 1111, 1112 (2004); Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391 (2004); Kevin Outterson, *Tragedy and Remedy: Reparations for Disparities in Black Health*, \_\_\_ DEPAUL J. HEALTH CARE L. \_\_\_ (2005).

11. See *infra* text accompanying notes 101-106 (demonstrating the historical ambiguity of the term "race").

12. See U.S. CENSUS BUREAU, RACE, COMBINATIONS OF TWO RACES, AND NOT HISPANIC OR LATINO: 2000 [hereinafter U.S. CENSUS BUREAU, RACE], <http://factfinder.census.gov/servlet/SAFFPeople?sse=on> (follow "Race, Combinations of Two Races" hyperlink) (last visited Oct. 9, 2005) (disclosing that in the 2000 census almost seven million Americans indicated that they were members of two or more "races").

13. See *infra* notes 171-175 and accompanying text (underscoring the dangers of "racial profiling" in diagnosing and treating illness).

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 the public perceives certain "races" 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. It could also intensify African-Americans' distrust of the medical profession. Finally, "race-based" medicine might violate numerous anti-discrimination provisions contained in federal law, state law, and federal research regulations and guidelines.<sup>14</sup>

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 disease vulnerability, and other factors.<sup>15</sup> In the future, it is likely that affordable genetic technology will be widely available to screen individuals for thousands of genetic variations.<sup>16</sup> Ideally, the practice of medicine will become increasingly individualized, with physicians

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14. See *infra* Part IV (discussing the legality of "racially-tailored" medicine under various anti-discrimination laws).

15. See Ian Hacking, *Why Race Still Matters*, 134 DAEDALUS 102, 109 (2005) (stating that BiDil's success with the African-American population may have "less to do with the inherent constitution of their cardiovascular systems than with a mixture of social factors"); see also Alexandra E. Shields et al., *The Use of Race Variables in Genetic Studies of Complex Traits and the Goal of Reducing Health Disparities: A Transdisciplinary Perspective*, 60 AM. PSYCHOL. 77, 96 (2005) (recommending direct measurement of "specific social dimensions known to have an impact on health and health outcomes" instead of using "race" as a blanket category for "social, economic, and environmental factors that disproportionately affect minority populations in the United States"); Margaret A. Winker, *Measuring Race and Ethnicity: Why and How?*, 292 J. AM. MED. ASS'N 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 accurately assess the outcome at issue).

16. See Michael Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, 2 HOUS. J. HEALTH L. & POL'Y 31, 40-41 (2002) (stating that small chips embedded with DNA "can be used to test the samples of individuals for the presence of thousands 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").

examining patients for multiple variables that will determine which therapy should be prescribed.<sup>17</sup> 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,<sup>18</sup> 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.<sup>19</sup>

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.<sup>20</sup> In this Article 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 health care 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, and other factors.<sup>21</sup> These characteristics are precisely and objectively definable, and their presence or absence in individuals can be verified through testing or inquiry. While "race" could

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17. See *infra* notes 80-82 and accompanying text (defining "individualized" medical treatment as a method of medical evaluation in which several treatment options will be available for a given condition). The selection of the appropriate alternative will depend on a number of factors, such as diet, genetic make-up, and prior medical history. "Individualized" medical treatment does not mean, however, that medications will be developed for each individual patient, since this would obviously be impractical.

18. See THE CENTER FOR DRUG EVALUATION AND RES., CDER HANDBOOK 15-16 (1998), available at <http://www.fda.gov/cder/handbook/> (describing the FDA's role in the drug approval process). See also 21 C.F.R. §§ 56.107-56.111 (2005); 45 C.F.R. §§ 46.107-46.111 (2005) (describing the function and scope of Institutional Review Boards and their authority).

19. See *infra* notes 360-367 and accompanying text (cautioning researchers and the media that information about "racial" differences is often distorted).

20. See Sharon Hoffman, *Is There A Place for Race As A Legal Concept?*, 36 ARIZ. ST. L.J. 1094 (2005) (arguing that "race" is a vague and unreliable term without value as a legal concept).

21. See *supra* note 15 and accompanying text.

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 I 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 II will argue that “race” is a concept that has no coherent meaning and that is potentially pernicious. Part III will focus on the dangers of “racially-tailored” medicine, and Part IV will analyze a variety of anti-discrimination mandates that could potentially be violated by the practice. Finally, Part V will detail recommendations for the development of attribute-based medicine in a manner that will promote the health and welfare of all population groups.

## I. “RACE-BASED” RESEARCH AND THERAPEUTIC PRACTICES

### A. *The Story of BiDil*

BiDil is a combination of two drugs, hydralazine and isosorbide dinitrate (“H/I”).<sup>22</sup> These drugs are vasodilators that dilate blood vessels in order to diminish the stress on the heart as it pumps blood.<sup>23</sup> BiDil also increases nitric oxide levels in the blood, which is believed to benefit many heart failure patients.<sup>24</sup>

The evolution of BiDil began with the first Vasodilator Heart Failure Trial (“V-HeFT I”),<sup>25</sup> 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 “borderline statistical significance.”<sup>26</sup> A second trial, V-HeFT II, took place between 1986 and 1991 and compared the H/I combination to enalapril, an ACE inhibitor.<sup>27</sup> This study showed that

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22. See Saul, *supra* note 1, at C2 (discussing BiDil and its components).

23. Bowser, *supra* note 10, at 1116-17.

24. See Kahn, *supra* note 7, at 8 (emphasizing that nitric oxide is generally considered to be beneficial to patients suffering from heart failure); see also NitroMed, Background on BiDil, <http://www.nitromed.com/bildil/docs/heartfailur.html> (last visited Nov. 3, 2005) (postulating that heart failure can be associated with nitric oxide deficiency).

25. 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).

26. Kahn, *supra* note 7, at 12; see Cohn et al., *supra* note 25, at 1547.

27. See 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). Angiotensin converting enzymes, or ACE inhibitors, as they are commonly called, are drugs that lower blood pressure by inhibiting the formation of angiotensin, a substance that causes the arteries to constrict. See Mary Duenwald, *Familiar Blood Pressure Drug Finds an Array of Novel Uses*, N.Y. TIMES, June 25, 2002, at F1 (describing the many uses and benefits of ACE inhibitors); *Angiotensin-converting Enzymes (ACE) Inhibitors (Systemic)*, MedlinePlus, available at <http://www.nlm.nih.gov/>



enalapril was generally more effective than the H/I combination and established ACE inhibitors as the drugs of choice for heart failure,<sup>28</sup> 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.<sup>29</sup> The V-HeFT trials enrolled both Black and White subjects and did not scrutinize or report any "racial" distinctions in drug response rates.<sup>30</sup> In 1989, Dr. Jay Cohn, one of the trials' principal investigators, received a patent for the H/I drugs.<sup>31</sup> His patent application did not mention "race" or indicate that the medications should be targeted for any particular ethnic population.<sup>32</sup>

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 Food and Drug Administration ("FDA") in 1996.<sup>33</sup> 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.<sup>34</sup> Medco thereafter allowed its intellectual property rights to revert to Cohn.<sup>35</sup>

In an effort to revive the drug, Cohn re-analyzed the V-HeFT data, focusing on "race."<sup>36</sup> 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."<sup>37</sup>

In 1999 NitroMed Inc. acquired the intellectual property rights to BiDil from Jay Cohn.<sup>38</sup> NitroMed amended BiDil's new drug application to seek

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medlineplus/druginfo/uspdi/202044.html. ACE inhibitors relax the arteries, thereby lowering blood pressure and improving the pumping efficiency of failing hearts. *Id.*

28. Cohn et al., *supra* note 27, at 307-09.

29. *Id.*; see Kahn, *supra* note 7, at 12 (noting that current guidelines still recommend the H/I combination for the 1.5 million patients annually who do not respond well to ACE inhibitors).

30. See Cohn et al., *supra* note 27, at 303-04.

31. Kahn, *supra* note 7, at 13.

32. See *id.* (specifying that Cohn applied for a patent on a "method of reducing mortality associated with congestive heart failure using hydralazine and isosorbide dinitrate"). Cohn's patent contained no mention of "race." *Id.*

33. Bowser, *supra* note 10, at 1118. In 1994, BiDil was tested to ascertain whether the new pill was as effective as the H/I drugs when administered separately. *Id.*

34. *Id.* On the day following the FDA's decision, Medco's stock plummeted twenty-five percent. *Id.*

35. See Kahn, *supra* note 7, at 15-16 (describing Medco's decision to abandon BiDil after the FDA's rejection of the drug).

36. 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).

37. *Id.*

38. Bowser, *supra* note 10, 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.*

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 patients.<sup>39</sup> This conditional promise led to the African-American Heart Failure Trial (“A-HeFT”), which enrolled 1,050 self-identified African-Americans<sup>40</sup> and was supported by the Association of Black Cardiologists and \$31.4 million raised from private venture capital firms.<sup>41</sup>

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.<sup>42</sup> The patent is “the first ever granted to a preexisting drug for a new, race-specific use.”<sup>43</sup> 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.<sup>44</sup>

The study was halted early when it became evident that the addition of BiDil to standard therapy reduced one-year mortality by forty-three percent among the Black study participants.<sup>45</sup> The investigators determined that it would be unethical to continue to deprive subjects in the control arm of the drug.<sup>46</sup> The study results were published in the prestigious *New England Journal of Medicine* in November 2004,<sup>47</sup> and BiDil was approved by the FDA in June 2005.<sup>48</sup> 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

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39. Gregg M. Bloche, *Race-Based Therapeutics*, 351 NEW ENG. J. MED. 2035, 2036 (2004).

40. See Anne L. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 NEW ENG. J. MED. 2049, 2050 (2004) (describing the study’s exclusion and inclusion criteria). The study also defined “black” as being of African descent. *Id.*; cf. *infra* note 131 and accompanying text (explaining that skin color is an unreliable indicator of an individual’s ancestry).

41. Nicholas Wade, *Race-Based Medicine Continued . . .*, N.Y. TIMES, Nov. 14, 2004, § 2, at 12; see *NitroMed Completes \$31.4 Million Private Financing*, PR Newswire, June 14, 2001 (reporting that the money was raised primarily to support clinical and regulatory development and enabled NitroMed to complete the A-HeFT study).

42. Kahn, *supra* note 7, at 31-32; see U.S. Patent No. 6,465,463 (filed Sept. 8, 2000) (issued Oct. 15, 2002) (naming Cohn and Carter as the inventors and NitroMed, Inc. as the assignee of the patent).

43. See Bloche, *supra* note 39, at 2036 (emphasizing the financial benefit that lured NitroMed to pursue the manufacture of a “race-specific” drug).

44. *Id.*

45. Taylor, *supra* note 40, at 2049; accord Wade, *supra* 41, § 2, at 12.

46. See Wade, *supra* note 41, § 2, at 12 (reporting that the study had to be stopped because the drug was so effective that it seemed unethical to deny it to members of the control group).

47. See Taylor, *supra* note 40, at 2049 (stating that the study has not been replicated by anyone without financial interests in BiDil).

48. Saul, *supra* note 1, at C2.

among members of different “races” has long fascinated scientists.<sup>49</sup> Biomedical researchers have conducted numerous clinical studies that focus on “racial” differences in disease manifestation, metabolism, and treatment response rates.<sup>50</sup> Moreover, even when studies are not designed specifically to examine “racial” differences, data about the “racial” identities of subjects is often collected.<sup>51</sup> Many of the findings, however, are controversial and are vigorously debated in medical circles.<sup>52</sup>

For example, a 1999 study claimed that Blacks metabolize nicotine more slowly than Whites.<sup>53</sup> Critics pointed to several flaws in the study, including the enrollment of only fifty-one Blacks, the likelihood that Blacks smoked menthol cigarettes in far greater numbers than Whites, and the insubstantial statistical difference.<sup>54</sup>

Other studies have focused on hypertension and have purported to find that Blacks have higher rates of hypertension.<sup>55</sup> 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<sup>56</sup> and Jamaicans, and the data from Brazil, Trinidad, and Cuba show a much smaller blood pressure disparity than the statistics from North America.<sup>57</sup> Overall, in the populations studied, between fourteen and forty-four percent of Blacks were found to have hypertension, while in Whites, the prevalence rate ranged from

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49. See *infra* notes 99-112 and accompanying text (describing the history of the medical profession’s fascination with the concept of “racially-tailored” medicine).

50. See Lillquist & Sullivan, *supra* note 10, at 393 (highlighting two studies that focused on the possible differences in drug responses based on “race,” while noting that other examples are readily available).

51. See Kahn, *supra* note 7, at 16 (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.

52. See generally Lillquist & Sullivan, *supra* note 10, at 393 nn.15-17 (citing several studies evaluating a range of claims regarding “racial” differences).

53. 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, fifty-one of whom were Black and fifty-seven of whom were White. The subjects were similar in age, gender distribution, and smoking history. *Id.*

54. See Bowser, *supra* note 10, at 1125 (stating that the differences in metabolism were not substantial, and that “there was only an eight percent difference in the variable of interest”). Bowser claims that fifty-seven of the subjects were African-American, but has apparently inverted the number of Black and White participants. Benowitz et al., *supra* note 53.

55. Richard S. Cooper et al., *An International Comparative Study of Blood Pressure in Populations of European vs. African Descent*, 3 BMC MED. 2 (2005), available at <http://www.biomedcentral.com/> (follow “journals A-Z” hyperlink; then follow “BMC Medicine” hyperlink; then follow Article 3:2 hyperlink); Troy Duster, *Race and Reification in Science*, 307 SCI. 1050, 1050 (2005); Gregory M. Lamb, *A Place For Race in Medicine?*, THE CHRISTIAN SCI. MONITOR, Mar. 3, 2005, at 14.

56. Cooper et al., *supra* note 55.

57. Duster, *supra* note 55, at 1050.

twenty-seven to fifty-five percent.<sup>58</sup> 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 African-Americans.<sup>59</sup> 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.<sup>60</sup>

In 1999 Peter Carson, Daniel Dries, and others coauthored a study, the results of which 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.<sup>61</sup> 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.”<sup>62</sup> This study has been sharply criticized for failing to control adequately for socioeconomic factors<sup>63</sup> 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.<sup>64</sup> Furthermore, the study examined only individuals between the ages of thirty-five and seventy-four, even though among Whites who die of heart failure, seventy-one percent do so after the age of seventy-four.<sup>65</sup> According to one commentator, current data places “the age-adjusted ratio of black to white mortality from heart failure . . . under 1.1:1 for 1999.”<sup>66</sup>

In the world of “racially-tailored” research, the A-HeFT trial is a milestone.<sup>67</sup> It was the first prospective study designed specifically to

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58. Cooper et al., *supra* note 55.

59. Michael J. Klag et al., *The Association of Skin Color With Blood Pressure in U.S. Blacks With Low Socioeconomic Status*, 265 J. AM. MED. ASS'N 599, 599 (1991).

60. *See id.* at 602 (studying whether the association of skin color with blood pressure is linked to the social and economic stress faced by many individuals with darker skin color).

61. Daniel L. Dries et al., *Racial Differences in the Outcome of Left Ventricular Dysfunction*, 340 NEW ENG. J. MED. 609, 616 (1999).

62. *Id.* at 609.

63. *See* Kahn, *supra* note 7, at 19-20 (expressing concern that Dr. Dries' study failed to include variables such as diet, environment, exercise, and stress, many of which have a strong correlation with “race”).

64. *Id.* at 20; Jonathan Kahn, *Getting the Numbers Right*, 46 PERSP. IN BIOLOGY & MED. 473, 477 (2003).

65. *See* Kahn, *supra* note 7, at 21 (contending that Dr. Dries' failure to include the age-specific qualification of the study from which he took his data compromised the significance of his findings); *see also* Duster, *supra* note 55, at 1050 (noting that “[t]he 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”).

66. Kahn, *supra* note 7, at 21; Kahn, *supra* note 64, at 477.

67. *See supra* notes 41-43 and accompanying text (describing the A-HeFT trial and the FDA's approval of BiDil).

prove the efficacy of a drug that would be recommended only for members of a single “race.”<sup>68</sup> The A-HeFT study has been particularly controversial.<sup>69</sup> 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.<sup>70</sup> 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.<sup>71</sup> The V-HeFT trials that preceded A-HeFT<sup>72</sup> compared BiDil, on its own, to conventional therapy that was used in the early 1980s and then to enalapril (an ACE inhibitor) alone.<sup>73</sup> 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.<sup>74</sup> On the other hand, if doctors prescribe BiDil off-label<sup>75</sup> 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.

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68. Bloche, *supra* note 39, at 2035; accord Susan J. Landers, *New Drug Combo Intensifies Race-Based Medicine Debate*, AM. MED. NEWS, Dec. 6, 2004. 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., *Outcomes in Hypertensive Black and Nonblack Patients Treated with Chlorthalidone, Amlodipine, and Lisinopril*, 293 J. AM. MED. ASS'N 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”).

69. See Pilar Ossorio & Troy Duster, *Race and Genetics*, 60 AM. PSYCH. 115, 116 (2005) (emphasizing that the “racialized” nature of the BiDil trial remains very controversial).

70. Taylor, *supra* note 40, at 2049.

71. See Bloche, *supra* note 39, at 2035 (commenting that by only enrolling self-identified blacks, the A-HeFT study did nothing to test whether or not adding the H/I combination to conventional therapy would benefit other population groups); see also Kahn, *supra* note 64, at 481 (noting that the A-HeFT study provided no data with which to determine whether BiDil is effective in non-African Americans).

72. See *supra* Part I.A (describing the V-HeFT trials).

73. Bowser, *supra* note 10, at 1117; see *supra* notes 26-27 (summarizing the V-HeFT studies). The use of ACE inhibitors to prevent heart failure is a recent development, even though they have been used to control blood pressure for over twenty years. Duenwald, *supra* note 27, at F1.

74. E.g., Bloche, *supra* note 39, at 2036; Kahn, *supra* note 64, at 481; Jonathan Kahn, *Misreading Race and Genomics After BiDil*, 37 NATURE GENETICS 655 (2005); Saul, *supra* note 1, at C2.

75. 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. See Dale E. Hammerschmidt, *Understanding the FDA's IND Process*, in INSTITUTIONAL REVIEW BOARDS: MANAGEMENT AND FUNCTION 324 (Robert Amdur & Elizabeth Bankert eds., 2002).

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

As will be discussed below, scientists are developing an understanding that “race” is not a genetic feature.<sup>76</sup> At the same time, however, there is also renewed and increasing interest in “racially-tailored” medicine.<sup>77</sup> 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.<sup>78</sup> 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.<sup>79</sup> 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.<sup>80</sup> This advance, however, is years if not decades away from becoming practical and widely accessible.<sup>81</sup> 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.<sup>82</sup> Critics, however, would argue that “race” is a crude and inaccurate marker and that its use

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76. See *infra* Part II.A (indicating that genetic variations between all human beings remain nominal); see also INST. OF MED., 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 eds., 1999) (stating that “race” is not a biological reality, but rather is a “social or cultural construct of human variability based on perceived differences in biology, physical appearance, and behavior”).

77. See Condit & Bates, *supra* note 4, at 97 (recognizing that the movement toward “race-based” medicine may, in fact, aggravate health disparities).

78. See Satel, *supra* note 6, at 58 (arguing that “race” may play a vital role in the diagnosis and treating of certain diseases); Armand Marie Leroi, *A Family Tree in Every Gene*, N.Y. TIMES, Mar. 14, 2005, at A21 (asserting that “the recognition of race may improve medical care”).

79. See Nicholas Wade, *Once Again, Scientists Say Human Genome Is Complete*, N.Y. TIMES, Apr. 15, 2003, at F1 (reporting on the status of the Human Genome Project).

80. See Bloche, *supra* note 39, at 2036 (discussing the possibility of finding genetic variations and linking those variations to different therapeutic approaches); David Neil & Jillian Craigie, *The Ethics of Pharmacogenomics*, 23 MONASH BIOETHICS REV. 9, 14 (2004) (describing the “multi-drug resistance gene,” MDR1, “which is found in seventy percent of Kenyans, thirty-two percent of Chinese, twenty-four percent of UK Caucasians and fifteen percent of Southwest Asians”).

81. See Kahn, *supra* note 7, at 28 (estimating that “individualized genomic medicine is decades away . . .”); Shields, *supra* note 15, at 80 (observing that “individualized medicine is still in the future . . .”); Condit & Bates, *supra* note 4, at 98 (cautioning that “the promise of so-called ‘personalized’ genetic medicine is increasingly unlikely to be fulfilled in the near-term future”).

82. See Bloche, *supra* note 39, at 2036 (articulating the position that “reliance on race is merely an interim step on the path to personalized pharmacotherapy”); Kahn, *supra* note 7, at 28 (explaining that resource and technological constraints impede the development of individual genetic profiles).

will lead to medical mistakes and potential exacerbation rather than alleviation of health disparities.<sup>83</sup>

Pharmaceutical companies are also likely to be enthusiastic about developing certain “racially-tailored” drugs.<sup>84</sup> 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.<sup>85</sup> Moreover, drug companies engaging in research and development that is specifically designed to improve treatment outcomes for an underserved minority group might be able to obtain financial and political support for their endeavors, which would not be available for ordinary clinical studies.<sup>86</sup> NitroMed, for example, obtained the support of the Association of Black Cardiologists and the Congressional Black Caucus, who were eager to have BiDil approved as a drug for African-Americans suffering from heart failure.<sup>87</sup>

By extension, regulatory advantages might also motivate pharmaceutical companies to pursue the development of “racially-tailored” medicine.<sup>88</sup> Health disparities between Whites and Blacks in the United States have been the subject of much commentary and debate in recent years and have fueled a governmental interest in formulating an effective response.<sup>89</sup> The National Institutes of Health (“NIH”) issued guidelines emphasizing the importance of gathering data concerning treatment response differences among various minority groups to achieve “change in health policy or

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83. See Bloche, *supra* note 39, at 2036 (noting that the use of “race” could stigmatize some ethnic groups); Neil & Craigie, *supra* note 80, at 14-15 (explaining the ethical implications of research that uses “ethnicity as a recruitment shortcut”).

84. See Editorial, *The First Race-Based Medicine*, N.Y. TIMES, June 19, 2005, § 4, at 11 (illustrating the economic advantages of developing and marketing “racially-tailored” prescription medicine).

85. Cf. Kahn, *supra* note 7, at 24-25 (observing that many companies currently seek to develop “ethnic niche marketing”).

86. See *id.* at 23 (reporting that BiDil became “racialized” in part because of commercial considerations); Bowser, *supra* note 10, at 1120 (stating that NitroMed raised \$31.4 million from private venture capital firms to support the A-HeFT study).

87. Kahn, *supra* note 7, at 23.

88. See Kahn, *supra* note 7, at 31 (positing that the regulatory system steered the researchers of BiDil towards developing a “racially-tailored” drug to achieve FDA approval).

89. See Rene Bowser, *Racial Profiling in Health Care: An Institutional Analysis of Medical Disparities*, 7 MICH. J. RACE & L. 79, 125-26 (2001) (noting that the past two administrations have shown a desire to diminish health disparities); Ichiro Kawachi et al., *Health Disparities By Race and Class: Why Both Matter*, 24 HEALTH AFF. 343, 347-51 (2005) (arguing that society must address the injuries of both class and race in order to reduce health disparities); David Satcher et al., *What If We Were Equal? A Comparison of The Black-White Mortality Gap in 1960 and 2000*, 24 HEALTH AFF. 459, 462-63 (2005) (observing that the elimination of significant health disparities between Black and White Americans could prevent thousands of premature deaths per year); see also Mary Crossley, *Infected Judgment: Legal Responses to Physician Bias*, 48 VILL. L. REV. 195, 211-23 (2003) (positing that some physicians may have biases based on “race”).

standard of care.”<sup>90</sup> The NIH might thus be especially interested in funding research projects with potential to improve the health status of a minority group.<sup>91</sup> The NIH guidelines also require the reporting of “racial” and ethnic treatment response differences.<sup>92</sup> The policy may thereby encourage investigators to attribute differences to “race” and to respond to these differences by developing “racially-tailored” therapies.<sup>93</sup>

Similarly, the FDA might be particularly willing to approve therapies that are depicted as likely to reduce health disparities. In the case of BiDil, the FDA declined approval of the drug as an alternative therapy for all populations, but approved it for the use of African-Americans, despite criticism on the part of some experts.<sup>94</sup> 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.<sup>95</sup> 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.<sup>96</sup>

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 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 a specific genetic variation? 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 to rely on the proxy of

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90. NAT'L INST. OF HEALTH, OFF. OF EXTRAMURAL RES., NIH POLICY AND GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH [hereinafter NIH GUIDELINES] (Oct. 2001), [http://grants2.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants2.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

91. *See id.* (contending that health disparities between Whites and Blacks should be eliminated).

92. *Id.*

93. *See infra* Part IV.C.1 (analyzing the NIH policy).

94. *See* Kahn, *supra* note 7, at 16 (explaining that after BiDil was rejected for use in the general population, researchers began to analyze the effects of the drug on different “racial” groups); Saul, *supra* note 1, at C2 (reporting the approval of BiDil as a “racially-tailored” drug).

95. *See* Kahn, *supra* note 7, at 32 (noting that while the original patent will expire in 2007, the second patent will not expire until 2020); *supra* notes 25-37 and accompanying text (emphasizing that Dr. Cohn focused on “race” in analyzing the V-HeFt data only after he failed to obtain approval for a “race” neutral drug).

96. *See* Bloche, *supra* note 39, at 2036 (contending that commercial and regulatory incentives have precipitated “racially-tailored” drug manufacturing).



"race," comprehensive analysis is the only responsible way to proceed with medical research and to achieve accurate research outcomes.

## II. 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 can lead to significant adverse consequences at worst.<sup>97</sup> 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, medical professionals should focus on more precise and meaningful aspects of human identity rather than on the amorphous concept of "race."<sup>98</sup>

### 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."<sup>99</sup> "Race" has been defined as a biological feature;<sup>100</sup> a local geographic population;<sup>101</sup> a group linked by common descent or origin;<sup>102</sup> a population connected by a shared history, nationality, or geographic distribution;<sup>103</sup> a "subspecies";<sup>104</sup> and a socio-political construct.<sup>105</sup> The word "race" has also been used interchangeably with "ethnicity," "ancestry," "culture," "color," "national

97. See *infra* Part III (discussing the dangers of "racial-profiling" in medicine).

98. See Hoffman, *supra* note 20, at 1094 (maintaining that scientists should not rely on the confused and incoherent idea of "race").

99. JACQUES BARZUN, *RACE: A STUDY IN MODERN SUPERSTITION* 3 (1937).

100. See JONATHAN MARKS, *HUMAN BIODIVERSITY: GENES, RACE, AND HISTORY* 108 (1995) (explaining that "race" was seen as a dominant feature of human biology).

101. See DVORA YANOW, *CONSTRUCTING "RACE" AND "ETHNICITY" IN AMERICA* 47 (2003) (defining "race" as a "local geographic or global human population distinguished as a more or less distinct group by *genetically transmitted* physical characteristics" (citing AMERICAN HERITAGE DICTIONARY 1488 (1992))).

102. See *id.* (defining "race" as a group "connected by *common* descent or origin" (citing OXFORD ENGLISH DICTIONARY 69 (1991))).

103. See *id.* (explaining that a group linked by national origin or geography constitutes a "race" (citing WEBSTER'S II NEW RIVERSIDE UNIVERSITY 968 (1984))).

104. See Sandra Soo-Jin Lee et al., *The Meanings of "Race" in the New Genomics: Implications for Health Disparities Research*, 1 YALE J. HEALTH POL'Y L. & ETHICS 33, 39 (2001).

105. See Hiroshi Fukurai, *Social De-Construction of Race and Affirmative Action in Jury Selection*, 11 LA RAZA L.J. 17, 31 (1999); Miranda Oshige McGowan, *Diversity of What?*, in RACE AND REPRESENTATION: AFFIRMATIVE ACTION 237-38 (Robert Post & Michael Paul Rogin eds., 1998).

origin,” and even “religion.”<sup>106</sup>

During the nineteenth and twentieth centuries, scientists attempted to classify “racial” groups through assessment of physiological characteristics.<sup>107</sup> Samuel Morton, a prominent Philadelphia physician, collected over 800 skulls from around the world.<sup>108</sup> 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.<sup>109</sup> Morton’s results have been discredited by contemporary scholars, such as Stephen J. Gould, who have pointed out, for example, that skull size correlates with body size and that body size does not necessarily correlate with intelligence level.<sup>110</sup>

The Nazis focused on the science of “race” with renewed intensity. In

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106. See, e.g., Soo-Jin Lee, *supra* note 104, at 54 (noting that the terms used in association with “race” vary widely and remain ambiguous); Fukurai, *supra* note 105, at 31 (noting that the use of “race” differs from country to country); ALAIN F. CORCOS, *THE MYTH OF HUMAN RACES* 10-11 (1997) (asserting that there is no basis for the concept of “race” in science since all humans are of one species); see also Ortiz v. Bank of America, 547 F. Supp. 550, 560 (E.D. Cal. 1982) (declaring that “the notion of ‘race’ as contrasted with national origin is highly dubious”); Donald E. Muir, *Race: The Mythic Root of Racism*, in *THE CONCEPT OF “RACE” IN NATURAL AND SOCIAL SCIENCE* 96 (E. Nathaniel Gates ed., 1997) (contending that “[b]ecause of sexual selection, individuals sharing national origin (for example, Japanese), culture (for example, Gypsies), or religion (for example, Jews) also tend to share physical traits and thus may have come to be considered a race.”); Thuy N. Bui, *The Difference Between Race and Color: Implications for Changing the Racial Discourse*, 38 SANTA CLARA L. REV. 629, 631, 638 (1998) (discussing “race” as a notion of culture and color consciousness); Atwood D. Gaines, *Race and Racism*, in 4 *ENCYCLOPEDIA OF BIOETHICS* 2191, 2193-94 (Warren Thomas Reich ed., 1995) (positing that the use of religion as a criterion for “race” is erroneous). One study conducted in the United States 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. See Tasha N. Dubriwny et al., *Lay Understandings of Race: Cultural and Genetic Definitions*, 7 *COMMUNITY GENETICS* 185, 194 (2004). The study involved 120 participants, including seven focus groups consisting of self-identified Blacks, seven groups of self-identified Whites, and one group of self-identified Hispanics. *Id.* at 186. The participants were recruited from urban, suburban, and rural areas in Georgia. *Id.* By contrast, European-Americans were more likely to understand “race” in terms of physical characteristics, genetics, and geography. *Id.* at 185, 194.

107. See generally Hoffman, *supra* note 20, at 1113-16 (stating that many early researchers looked to physiological differences to demonstrate the inferiority of Blacks and the superiority of Whites).

108. WILLIAM H. TUCKER, *THE SCIENCE AND POLITICS OF RACIAL RESEARCH* 18 (1994).

109. See *id.* (citing SAMUEL MORTON, *CRANIA AMERICANA* (1839)). Morton attempted to develop a scientific method for his study. *Id.* 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 *PROCEEDINGS ACAD. NAT. SCI. PHILA.* 221-24 (1848).

110. TUCKER, *supra* note 108, at 19-20. Stephen J. Gould reanalyzed Morton’s original measurements and found many serious errors, miscalculations, and omissions. See, e.g., JOSEPH L. GRAVES, JR., *THE EMPEROR’S NEW CLOTHES: BIOLOGICAL THEORIES OF RACE AT THE MILLENNIUM* 46-47 (2001) (finding that Morton made a critical error in not distinguishing samples by sex or physique); Stephen J. Gould, *Morton’s Ranking of Races by Cranial Capacity*, 200 *SCI.* 503, 503-09 (1978) (discussing flaws in Morton’s work).

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.<sup>111</sup> 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,<sup>112</sup> is the question of whether "race" is a genetically valid concept. Scientists estimate that human beings share 98.56% of their genes with chimpanzees.<sup>113</sup> Human beings have approximately 30,000 to 35,000 genes,<sup>114</sup> and 99.9% of genes are identical in all individuals.<sup>115</sup> While there is variation in the remaining one tenth of a percent, ninety to ninety-five percent of variations, called alleles,<sup>116</sup> are found at equal rates in every "racial" population.<sup>117</sup> 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.<sup>118</sup> 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.<sup>119</sup>

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111. Judy Scales-Trent, *Racial Purity Laws in the United States and Nazi Germany: The Targeting Process*, 23 HUM. RTS. Q. 259, 279 (2001).

112. The Human Genome Project is an international research effort devised to analyze the structure of DNA in human beings and other living creatures. See Mark Rothstein & Sharona Hoffman, *Genetic Testing, Genetic Medicine, and Managed Care*, 34 WAKE FOREST L. REV. 849, 849 (1999).

113. J.W. Jamieson, *The Reality of Race: Contra Biondi and Rickards*, 42 MANKIND Q. 389, 399 (2002).

114. Alan Guttmacher & Francis Collins, *Genomic Medicine*, 347 NEW ENG. J. MED. 1512, 1514 (2002).

115. David Rotman, *Genes, Medicine, and the New Race Debate*, TECH. REV., June 2003, at 41, 42.

116. An allele is an "alternative form of a gene." Guttmacher & Collins, *supra* note 114, at 1513.

117. 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 SCI. 2381, 2381 (2002).

118. See Michael J. Bamshad, *Human Population Genetic Structure and Inference of Group Membership*, 72 AM. J. HUM. GENETICS 578, 578 (2003); Lynn B. Jorde & Stephen P. Wooding, *Genetic Variation, Classification and 'Race'*, 36 NATURE GENETICS (SUPP.) S28, S29 (2004) (stating that "ninety percent of total genetic variation would be found in a collection of individuals from a single continent, and only ten percent more variation would be found if the collection consisted of Europeans, Asians and Africans").

119. See Kelly Owens & Mary-Claire King, *Genomic Views of Human History*, 286 SCI. 451, 453 (1999) (explaining that differences in skin and hair color, hair texture, and facial features may be attributable to "differential selection by climate in various parts of the world"); Vivian Wang & Stanley Sue, *In the Eye of the Storm*, 60 AM. PSYCHOL. 37, 39 (2005) ("People from local population groups are typically more closely related than are members of groups who live greater distances apart."); see also Ossorio & Duster, *supra* note 69, at 116 (stating that human "physical traits vary gradually, with groups that are close

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.<sup>120</sup> One study, led by Neil Risch, involved 3,636 subjects who identified themselves as White, African-American, East Asian, and Hispanic.<sup>121</sup> 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.”<sup>122</sup> Such statistics, however, can be achieved only if the study includes participants whose recent ancestors all come from one distinct geographic area.<sup>123</sup> 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.”<sup>124</sup>

Significantly, among the five to ten percent of variants in the tenth of a

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geographic neighbors being more similar than groups that are geographically separated”); Michael J. Bamshad, *Genetic Influences on Health: Does Race Matter?*, 294 J. AM. MED. ASS’N 937, 940 (2005) (concluding that “[r]ace reflects the varied geographic ancestry of modern humans who have been partially isolated from one another throughout part of their evolutionary history”).

120. See Hua Tang et al., *Genetic Structure, Self-Identified Race/Ethnicity, and Confounding in Case-Control Association Studies*, 76 AM. J. HUM. GENETICS 268, 271 (2005).

121. *Id.* at 269-70.

122. See *id.* at 268, 273-74 (remarking that only five subjects (0.14%) had genetic clustering indicative of a “racial” identity that differed from the one they had listed).

123. See *id.* at 273-74 (acknowledging that the study underrepresented individuals who had recent mixed ancestry, that clustering success depends on a group’s homogeneity relative to the distance between groups, and that the study’s Hispanic population was recruited from one location in Texas and consisted only of Mexican-Americans); Vance L. Bonham et al., *Race and Ethnicity in the Genome Era*, 60 AM. PSYCHOL. 9, 12 (2005) (noting that a significant percentage of individuals do not have ancestry from only one geographic region); see also Duster, *supra* note 55, 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*, IS RACE “REAL”?, Apr. 25, 2005, <http://raceandgenomics.ssrc.org/Graves/>. Graves’ article, posted on a web forum entitled *Is Race “Real”?* that was organized by the Social Science Research Council, explains that

To accurately represent the genetic diversity of the world’s people would require a systematic collection along geographic distance between world regions. In addition, within each region, suitable numbers of individuals would have to be examined, particularly to discover genetic variants that are present in low frequency. For example, studies by American drug companies often recruit people with ancestry from three regions, African-Americans (representing sub-Saharan Africa), European-Americans (representing various parts of Europe), and various Asian-American groups. Sampling in this way ensures that individuals from these specific regions will cluster into three groups, simply because individuals from other portions of the spectrum of human genetic variation have been excluded from the study.

*Id.*

124. Richard C. Lewontin, *Confusions About Human Races*, IS RACE “REAL”?, Apr. 20, 2005, <http://raceandgenomics.ssrc.org/Lewontin/>.

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.<sup>125</sup> In addition, commentators emphasize that intra-group genetic variation is dramatically greater than inter-group variation.<sup>126</sup> For instance, 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.”<sup>127</sup>

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.<sup>128</sup> For example, skin color, produced by a pigment called melanin,<sup>129</sup> 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.<sup>130</sup> Also, individuals who share skin color may 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.<sup>131</sup>

Like medical scientists, anthropologists and sociologists have long debated the significance of “race.”<sup>132</sup> The American Anthropological

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125. Leda Cosmides et al., *Perceptions of Race*, 7 TRENDS IN COGNITIVE SCI. 173, 173 (2003); Bonham et al., *supra* note 123, at 12.

126. Alan H. Goodman, *Why Genes Don't Count (for Racial Differences in Health)*, 90 AM. J. PUB. HEALTH 1699, 1700 (2000); Morris W. Foster & Richard R. Sharp, *Race, Ethnicity, and Genomics: Social Classifications as Proxies of Biological Heterogeneity*, 12 GENOME RES. 844, 848 (2002), available at <http://www.genome.org/cgi/reprint/12/6/844>; see Marcus W. Feldman et al., *A Genetic Melting-Pot*, 424 NATURE 374, 374 (2003) (stating that “most genetic diversity occurs within groups, and that very little is found between them”).

127. Ossorio & Duster, *supra* note 69, at 118.

128. See Goodman, *supra* note 126, at 1700; Seymour Garte, *The Racial Genetics Paradox in Biomedical Research and Public Health*, 117 PUB. HEALTH REP. 421, 421 (2002) (“On a genetic level, human variation is a smooth continuum with very little evidence for sharp racially defined heterogeneities.”); Wang & Sue, *supra* note 119, at 39 (“[P]hysical anthropologists and geneticists agree that traits (e.g., skin color) do not cluster in rigidly bounded populations but gradually change in frequency from one geographic region to another.”).

129. Richard A. Sturm et al., *Human Pigmentation Genetics: The Difference Is Only Skin Deep*, 20 BIOESSAYS 712, 712 (1998); see also THE BANTAM MEDICAL DICTIONARY 262 (1990).

130. Goodman, *supra* note 126, at 1700; see also Bamshad, *supra* note 118, 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.”).

131. See Bamshad, *supra* note 118, at 587.

132. See, e.g., Matt Cartmill, *The Status of the Race Concept in Physical Anthropology*, 100 AM. ANTHROPOLOGIST 651, 652 (1999) (detailing the arguments of proponents and opponents of the “race” concept); Audrey Smedley & Brian D. Smedley, *Race as Biology Is Fiction, Racism as a Social Problem Is Real*, 60 AM. PSYCHOL. 16, 16-17 (2005) (reviewing the historical and anthropological origins of the concept of “race” and arguing for the

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.”<sup>133</sup> The AAA more emphatically articulated this position when, in 1998, it 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.”<sup>134</sup>

In 2003, the American Sociological Association (“ASA”) issued its own statement on “race.”<sup>135</sup> 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.<sup>136</sup> 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.”<sup>137</sup> The ASA, however, did not address the biological validity of “race” or attempt to define the concept’s meaning.<sup>138</sup>

### 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.<sup>139</sup> Different states developed the one-quarter rule, the one-eighth rule, the one-sixteenth rule, the one-thirty-second rule, and the infamous one drop rule.<sup>140</sup> Thus, a person could be considered White in one state and Black in another.<sup>141</sup>

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continued assessment of “racial” and ethnic inequality).

133. AM. ANTHROPOLOGICAL ASS’N, RESPONSE TO OMB DIRECTIVE 15: RACE AND ETHNIC STANDARDS FOR FEDERAL STATISTICS AND ADMINISTRATIVE REPORTING (Sept. 1997) [hereinafter AAA RESPONSE TO OMB DIRECTIVE 15], <http://www.aaanet.org/gvt/ombdraft.htm>.

134. AM. ANTHROPOLOGICAL ASS’N, STATEMENT ON “RACE” (1998), <http://www.aaanet.org/stmts/racepp.htm>.

135. AM. SOCIOLOGICAL ASS’N, STATEMENT OF THE AMERICAN SOCIOLOGICAL ASSOCIATION ON THE IMPORTANCE OF COLLECTING DATA AND DOING SOCIAL SCIENTIFIC RESEARCH ON RACE 1 (2003), [http://www.asanet.org/galleries/defaultfile/asa\\_race\\_statement.pdf](http://www.asanet.org/galleries/defaultfile/asa_race_statement.pdf).

136. *Id.*

137. *Id.* at 4.

138. *Id.* at 3.

139. See PAULI MURRAY, STATES’ LAWS ON RACE AND COLOR (1950) (detailing the laws of all the states, including their definitions of “Negro”).

140. See Carrie Lynn H. Okizaki, Comment, “What Are You?”: *Hapa-Girl and Multiracial Identity*, 71 U. COLO. L. REV. 463, 473-74 (2000) (examining the development of the “one-drop” rule which defined the Black “race” to include all those with any form of African ancestry); State v. Treadaway, 52 So. 500, 502-10 (La. 1910) (noting that statutory definitions of the word “Negro” varied from state to state).

141. See Luther Wright Jr., Note, *Who’s Black, Who’s White, and Who Cares: Reconceptualizing the United State’s Definition of Race and Racial Classifications*, 48

The courts also struggled to define who was White and who was non-White for purposes of determining questions of status, rights, and benefits.<sup>142</sup> Predictably, the courts did not construct any systematic methodology for making these determinations.<sup>143</sup> 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 the individual's appearance, "blood," or other presumably scientific evidence.<sup>144</sup> Thus, courts 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."<sup>145</sup>

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.<sup>146</sup> In 1870 the list included only "white," "colored," "Chinese," and "Indian."<sup>147</sup> 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."<sup>148</sup> It is noteworthy that many of these categories are not "races" in the traditional sense, but rather, refer to

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VAND. L. REV. 513, 524 (explaining that an individual with a Black great-grandparent would have been considered Black in states such as South Carolina or Florida, but the same individual would have been considered White in a state such as Indiana, which had a different statutory definition of "race").

142. See *Hudgins v. Wright*, 11 Va. (1 Hen. & M.) 134, 143 (1806) (holding that slaves of Native-American descent were entitled to freedom).

143. See Peggy Pascoe, *Miscegenation Law, Court Cases, and Ideologies of "Race" in Twentieth-Century America*, 83 J. AM. HIST. 44, 51 (1996) (asserting that "the criteria used to determine who fit in which category were more notable for their malleability than for their logical consistency").

144. See Ariela J. Gross, *Litigating Whiteness: Trials of Racial Determination in the Nineteenth-Century South*, 108 YALE L.J. 109, 120, 182-85 (1998) (examining cases involving 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 120-21.

145. *Id.* at 147-48, 157.

146. MARGO J. ANDERSON, *THE AMERICAN CENSUS: A SOCIAL HISTORY* (1988); see *THE POLITICS OF NUMBERS* 229-32 (William Alonso & Paul Starr eds., 1986).

147. YANOW, *supra* note 101, at 56.

148. U.S. CENSUS BUREAU, *UNITED STATES CENSUS 2000*, 1 (2001) [hereinafter U.S. CENSUS BUREAU, 2000 CENSUS], available at <http://www.census.gov/dmd/www/pdf/d02p.pdf>. Ninety-seven percent of those who marked "some other race" indicated that they were Hispanic. Elizabeth M. Greico & Rachel C. Cassidy, *Overview of Race and Hispanic Origin: Census 2000 Brief 2* (2001), available at <http://www.census.gov/prod/2001pubs/c2kbr01-1.pdf>, at 11.

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,<sup>149</sup> but rather an “ethnicity”<sup>150</sup> and is addressed in a separate question concerning Hispanic identity.<sup>151</sup>

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.<sup>152</sup> 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.<sup>153</sup> The 2000 census finally included the option of self-identification by more than one “race.”<sup>154</sup> Almost seven million Americans chose two or more “races” by which to describe themselves.<sup>155</sup> According to the Census Bureau, however, seventy-five percent of those who now identify themselves as Black could also correctly claim multiracial origins.<sup>156</sup> In addition, according to

149. *Id.* at 1 (“The Federal Government considers race and Hispanic origin to be two separate and distinct concepts.”).

150. The concept of “ethnicity,” which is often substituted for “race,” also has no fixed meaning and would not be a significant improvement over “race.” To illustrate, one source quotes the following definitions of “ethnicity,” found in a variety of dictionaries:

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 *racial*, national, religious, linguistic, or cultural heritage. (American Heritage Dictionary 1992, p. 630)

Pertaining to *race*; peculiar to a *race* or nation; ethnological. (Oxford English Dictionary 1971, p. 313)

2a. Pertaining to *race*; peculiar to a *race* or nation; ethnological. Also, pertaining to or having common *racial*, cultural, religious, or linguistic characteristics. . . ; hence (U.S. colloq), foreign, exotic. (Oxford English Dictionary 1991, p. 423) Of or relating to a religious, *racial*, national or cultural group. (Webster’s II New Riverside University 1984, p. 445).

YANOW, *supra* note 101, at 47.

151. U.S. CENSUS BUREAU, 2000 CENSUS, *supra* note 148, at 3.

152. Scales-Trent, *supra* note 111, at 285.

153. *Id.*

154. YANOW, *supra* note 101, at 72.

155. See U.S. CENSUS BUREAU, RACE, *supra* note 12. More specifically, the responses were 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. *Id.*; see also Elizabeth M. Greico & Rachel C. Cassidy, *Overview of Race and Hispanic Origin: Census 2000 Brief 2* (2001), available at <http://www.census.gov/prod/2001pubs/c2kbr01-1.pdf> (discussing census data concerning Hispanics).

156. Bowser, *supra* note 10, at 1113-14.



scientists, on average, African-Americans have an admixture of ten to twenty percent white genetic ancestry, based on familial lineage.<sup>157</sup>

### 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.<sup>158</sup> 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.<sup>159</sup>

Even in contemporary intellectual circles, some are promoting theories concerning the inferiority of the Black “race.”<sup>160</sup> For example, in 1994, Richard Herrnstein and Charles Murray published a book called *The Bell Curve: Intelligence and Class Structure in American Life*,<sup>161</sup> which focused on the fact that on average, African-Americans score fifteen or sixteen points lower than Whites on Intelligence Quotient (“IQ”) tests.<sup>162</sup> Instead of critiquing the validity of IQ tests or the environmental factors that might contribute to the scoring disparities,<sup>163</sup> the authors concluded

157. See Esteban J. Parra et al., *Estimating African-American Admixture Proportions by Use of Population-Specific Alleles*, 63 AM. J. HUM. GENETICS 1839, 1839 (1998) (finding that European genetic ancestry in ten U.S. populations of African descent ranged from 6.8% in Jamaicans to 22.5% in those from New Orleans).

158. See Jayne Chong-Soon Lee, *Review Essay: Navigating the Topology of Race*, 46 STAN. L. REV. 747, 759 (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, 1461 (2002) (discussing the theory that “race consciousness breeds a culture of inferiority, victimization, and helplessness among persons of color”); Ossorio & Duster, *supra* note 69, at 119 (stating that “people often interact with each other on the basis of their beliefs that race reflects physical, intellectual, moral, or spiritual superiority or inferiority”).

159. See AAA RESPONSE TO OMB DIRECTIVE 15, *supra* note 133 (referring to “the Holocaust, slavery, and the extirpation of American Indian populations” as examples of the “ultimate use of categorical notions of race [which] have occurred to achieve political ends . . .”).

160. See Condit & Bates, *supra* note 4, 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”).

161. RICHARD J. HERRNSTEIN & CHARLES MURRAY, *THE BELL CURVE: INTELLIGENCE AND CLASS STRUCTURE IN AMERICAN LIFE* 118-20 (The Free Press 1994).

162. *Id.* at 276.

163. See *THE BELL CURVE WARS: RACE, INTELLIGENCE, AND THE FUTURE OF AMERICA* 4-5 (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., *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, *Under the Skin: On the Impartial Treatment of Genetic and*

that this population simply was less intelligent than others.<sup>164</sup> 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.<sup>165</sup>

A second book, written by Michael Levin, *Why Race Matters*, went a step further, arguing that African-Americans are not only typically less intelligent than Whites, but also are more aggressive, assertive, and impulsive than Caucasians.<sup>166</sup> 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.<sup>167</sup>

It should be emphasized that I do not argue that individuals should stop thinking of themselves as African-American, White, Hispanic, Jewish, et cetera. 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.<sup>168</sup> Rather, in designing research and providing care, health professionals interested in a patient’s background should 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. Generally, however, no single aspect of a person’s identity should be the sole basis for research or therapeutic decisions.<sup>169</sup>

The term “race” obfuscates social discourse, policy-making, and medical

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*Environmental Hypotheses of Racial Differences*, 60 AM. PSYCH. 60, 60 (2005) (advocating the examination of both genetic and environmental hypotheses in studying differences in intelligence).

164. HERRNSTEIN & MURRAY, *supra* note 161, at 269.

165. *Id.* at 25-27, 63-64.

166. MICHAEL LEVIN, *WHY RACE MATTERS: RACE DIFFERENCES AND WHAT THEY MEAN* 213 (Praeger 1997).

167. *Id.* at 213, 322; *see also* J. Philippe Rushton, *Construct Validity, Censorship, and The Genetics of Race*, 50 AM. PSYCH. 40, 41 (1995) (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”).

168. *See* Charles Sullivan, *Racial Distinctions in Medicine*, 5 DEPAUL J. HEALTH CARE L. 249, 254 (2002) (arguing that in pursuing this medical inquiry, society runs the risk of breathing new life into the type of scientific racism prevalent at the turn of the twentieth century).

169. *See supra* notes 99-100 and accompanying text (contending that the unreliable concept of “race” should not serve as a method of categorizing individuals for purposes of medical treatment).

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.

### III. 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.<sup>170</sup> 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.<sup>171</sup> If cystic fibrosis is perceived as a disease that affects only people of Northern European descent, it will be under-diagnosed in Black patients.<sup>172</sup> Similarly, a recent study examined counseling concerning testing for BRCA1 and BRCA2, which are largely associated with Ashkenazi Jewish women.<sup>173</sup> 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.<sup>174</sup>

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170. See MARCIA M. BOUMIL & DAVID J. SHARPE, LIABILITY IN MEDICINE AND PUBLIC HEALTH 43 (2004) (explaining that 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); Crossley, *supra* note 89, at 244 (explaining that malpractice suits are often based on allegations that the physician “failed to conform to the standard of care” required for “treating patients with the plaintiff’s condition”).

171. See Kahn, *supra* note 7, at 38.

172. 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).

173. See 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 J. AM. MED. ASS’N 1729, 1734 (2005) (“Women with a first- or second-degree relative with breast or ovarian cancer, the predicted probability of a BRCA 1/2 mutation differed very little between African-American and White women.”); see also Karen H. Rothenberg, *Breast Cancer, The Genetic “Quick Fix,” and The Jewish Community*, 7 HEALTH MATRIX 97, 98 (1997) (estimating that roughly one percent of Eastern European Jews are predisposed to ovarian and breast cancer due to a specific gene mutation); Jacqueline Stevens, *Racial Meanings and Scientific Methods: Changing Policies for NIH-Sponsored Publications Reporting Human Variation*, 28 J. HEALTH POL. POL’Y & L. 1033, 1044 (2003) (providing background information concerning BRCA 1 and 2 testing).

174. Armstrong, *supra* note 173, at 1729; see Rita Nanda et al., *Genetic Testing in an Ethnically Diverse Cohort of High-Risk Women*, 294 JAMA 1925, 1925 (2005) (finding that “[i]rrespective of ancestry, early age at diagnosis and a family history of breast and ovarian cancer are the most powerful predictors of mutation status and should be used to guide

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.<sup>175</sup> On the other hand, physicians might automatically prescribe BiDil to all individuals who appear to be African-Americans, even though it might not be appropriate for some members of this population group. Therapies that are developed in the future could similarly be tested on only a limited population group and, therefore, be approved in a manner that is over-inclusive or under-inclusive or both.

Because genetic variations are shared by multiple populations, “race” is a crude and unreliable predictor of how an individual will respond to a particular therapy if genetic factors are involved.<sup>176</sup> To illustrate the complicated nature of “race-based” genetic susceptibility, one can turn to a recent report of the discovery of a genetic variation that is associated with a risk of heart attack.<sup>177</sup> The allele is common among Americans of European descent, but causes only a sixteen percent increase in risk within this population.<sup>178</sup> By contrast, it is found in only six percent of African-Americans, but increases the risk of heart attack by over 250% for American Blacks.<sup>179</sup> Furthermore, disease vulnerabilities and treatment responses are often explained by both genetic and environmental influences, including poor diet, poverty, and excessive stress, which cross population lines.<sup>180</sup> Consequently, it is inappropriate to make facile assumptions about medical treatment and prognosis based on “race.”

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-

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clinical decision making” concerning BRCA1 and BRCA2 testing).

175. See Saul, *supra* note 1, at C2 (indicating that some in the medical community believe BiDil could work for people of all “races,” not just Blacks).

176. See *supra* Part II.A; Jorde & Wooding, *supra* note 118, at S32.

177. Nicholas Wade, *Genetic Find Stirrs Debate on Race-Based Medicine*, N.Y. TIMES, Nov. 11, 2005, at A14.

178. *Id.*

179. *Id.*

180. See Nancy Krieger, *If “race” is the answer, what is the question?—on “race,” racism, and health: a social epidemiologist’s perspective*, <http://raceandgenomics.ssrc.org/Krieger/> (last visited Nov. 11, 2005) (stating that “[t]he evidence that health varies by socioeconomic position within all US racial/ethnic groups... is substantial and longstanding” (citing, among others, David R. Williams and Chiquita Collins, *US Socioeconomic and Racial Differences in Health: Patterns and Explanations*, 21 ANN. REV. SOCIOLOG. 349 (1995); G. Davey Smith, *Learning to Live with Complexity: Ethnicity, Socioeconomic Position, and Health in Britain and the United States*, 90 AM. J. PUB. HEALTH 1694, 1697 (2000); Nancy Krieger et al., *Painting a Truer Picture of US Socioeconomic and Racial/Ethnic Health Inequalities: The Public Health Disparities Geocoding Project*, 95 AM. J. PUB. HEALTH 312, 314 (2005))).

identification.<sup>181</sup> 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 have primarily European ancestry.<sup>182</sup> 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.<sup>183</sup> 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.<sup>184</sup> 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.<sup>185</sup>

### 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 most patients may reinforce negative "race-based" stereotypes and misconceptions.<sup>186</sup> Particular populations may be seen as diseased or incurable. This 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

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181. See Wang & Sue, *supra* note 119, at 43 (warning of the problems associated with "race-based" medicine). 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 patients to self-identify.

182. Ossorio & Duster, *supra* note 69, at 118 (citing Flavia C. Parra et al., *Color and genomic ancestry in Brazilians*, *FNAS*, 177-82 (2003); M.D. Shriver et al., *Skin Pigmentation, Biogeographical Ancestry and Admixture Mapping*, 112 *HUMAN GENETICS* 387-99 (2003)).

183. See Sharona Hoffman & Jessica W. Berg, *The Suitability of IRB Liability*, 67 *U. PITT. L. REV.* (forthcoming 2005) (discussing potential legal claims against Institutional Review Boards (IRBs) that improperly approve research studies).

184. Bowser, *supra* note 10, at 1113-14.

185. See Bloche, *supra* note 39, at 2035-37 (discussing the BiDil trial); Neil & Craigie, *supra* note 80, at 15; see also *supra* Part I.C (discussing the academic, commercial, and regulatory incentives for the pursuit of "racially-tailored" research).

186. Neil & Craigie, *supra* note 80, at 15.

would lead to stigmatization.<sup>187</sup> Commentators expressed anxiety that Jews would be generally considered to have defective or bad genes, and this possibility raised the specter of the Holocaust and Nazi claims about Jewish inferiority in some minds.<sup>188</sup>

Likewise, a study of lay people's attitudes towards "racially varied pharmacogenomics,"<sup>189</sup> revealed a significant amount of suspicion concerning "race-based prescription" and a preference for individualized genetic testing to determine the best course of treatment.<sup>190</sup> The practice of basing treatment decisions on "race" was viewed as unwelcome "racial profiling."<sup>191</sup>

Stigmatization, in turn, can lead to discrimination in the workplace and elsewhere.<sup>192</sup> 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.<sup>193</sup>

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

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187. See Gina Kolata, *Genetic Testing Falls Short of Public Embrace*, N.Y. TIMES, Mar. 27, 1998, at A16 (noting that patients have many concerns, including losing medical insurance if they test positive for genetic mutations associated with cancer).

188. Sheryl Gay Stolberg, *Concern Among Jews Is Heightened As Scientists Deepen Gene Studies*, N.Y. TIMES, Apr. 22, 1998, at A24; see Deborah J. Bowen et al., *Jewish Identity and Intentions to Obtain Breast Cancer Screening*, 9 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 79, 85 (2003) (mentioning "fear of genetic stigmatization" as a possible cause of a particular population group's failure to receive genetic testing for particular diseases); Lisa Soleymani Lehmann et al., *A population-based study of Ashkenazi Jewish women's attitudes toward genetic discrimination and BRCA 1/2 testing*, 4 GENETICS IN MED. 346-48 (2003) (reporting that thirteen percent of Jewish women surveyed believed "that BRCA 1/2 testing will lead to increased anti-Semitism"). There is no evidence that these fears have become justified thus far.

189. Jennifer L. Bevan et al., *Informed Lay Preferences For Delivery of Racially Varied Pharmacogenomics*, 5 GENETICS IN MED. 393 (2003).

190. See *id.* at 393, 398 (suggesting that minority groups may be especially suspicious of genetic testing).

191. *Id.* at 398; see Condit & Bates, *supra* note 4, at 100-01 (surveying studies regarding various attitudes concerning "racial profiling" in medicine).

192. Kahn, *supra* note 7, at 41.

193. 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 may, however, consider it worthwhile to violate Title VII and risk civil litigation in which plaintiffs bear a heavy burden of proof. See Sharona Hoffman, *Preplacement Examinations and Job-Relatedness: How to Enhance Privacy and Diminish Discrimination in the Workplace*, 49 KAN. L. REV. 517, 552-55 (2001) (discussing the reasons for employment discrimination against individuals with actual or potential disabilities).

misunderstanding of test results.<sup>194</sup> 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.<sup>195</sup> 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.<sup>196</sup>

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.<sup>197</sup> The Ninth Circuit 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 in part because African-Americans were treated differently from other employees.<sup>198</sup> Furthermore, according to a workplace testing survey conducted in 2001 by the American Management Association, 1.3% of employers acknowledged testing employees for sickle cell anemia.<sup>199</sup> 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<sup>200</sup> might

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194. 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).

195. See Kahn, *supra* note 7, at 38 (noting that those who carry the genetic variation for sickle cell anemia do not suffer from the illness, but 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). 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. *Id.*

196. See *id.* at 39 (noting that the Academy ended this policy only in 1981, after a lawsuit had been filed).

197. See *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1266-67 (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. *Id.*

198. *Id.* at 1275.

199. AM. MGMT. ASS'N, 2001 AMA SURVEY ON WORKPLACE TESTING: MEDICAL TESTING (2001), [http://www.amanet.org/research/pdfs/mt\\_2001.pdf](http://www.amanet.org/research/pdfs/mt_2001.pdf) (last visited Nov. 4, 2005).

200. 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. Lori B. Andrews, *A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models*, 79 WASH. U. L.Q. 221, 280 (2001). Such consumers might be subjected to discrimination in the form of exorbitant premium charges or complete denial of coverage. See *id.* Approximately ten to fifteen percent of insured individuals have individual policies.

use a person's "race" as a mechanism for risk assessment and price-setting despite its unreliability.<sup>201</sup> 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.<sup>202</sup> 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.<sup>203</sup>

### 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 we have experts today 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 hypothesize that an emphasis on differences among "racial" groups may encourage health care givers to provide inferior treatment to minorities, as some health care providers are already accused of doing.<sup>204</sup> 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.<sup>205</sup> "Race-based"

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Rothstein & Hoffman, *supra* note 112, at 869. *But see infra* Part IV.B.5 (discussing state insurance laws that prohibit "race" discrimination).

201. *See* Neil & Craigie, *supra* note 80, at 15 (mentioning the possibility of discrimination by insurers).

202. *Id.*

203. *See infra* Part V.B (discussing the difficulty of determining individual "racial" identity).

204. *See* Condit & Bates, *supra* note 4, at 98, 104 (warning that researchers and practitioners in the medical profession are at risk of having individual levels of "racism increased by the practice of race-based medicine" because individuals in the medical profession "are the persons most likely to receive repeated exposure to such messages").

205. *See* Kahn, *supra* note 7, at 6-7 (cautioning that BiDil and similar drugs may lead to significant "racial" disparities in treatment, as opposed to the intended result of developing innovative and beneficial therapies for underserved minorities). Many studies confirm that even without any recommended treatment differences, African-Americans are routinely under-treated for serious health conditions. *See* Viola Vaccarino et al., *Sex and Racial Differences in the Management of Acute Myocardial Infarction, 1994-2002*, 353 *NEW ENGL. J. MED.* 671, 671 (2005) (concluding that "[r]ates of reperfusion therapy, coronary angiography, and in-hospital death after myocardial infarction, but not the use of aspirin and beta-blockers, vary according to race and sex, with no evidence that the differences have



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.<sup>206</sup> 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.

#### IV. VIOLATION OF ANTI-DISCRIMINATION PROVISIONS

“Race-based” medicine may violate a variety of legal anti-discrimination mandates, including the Constitution, federal laws, state statutes, federal research regulations, and 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, they may run afoul of the law in a number of ways that are analyzed below.

##### A. 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.<sup>207</sup> 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.”<sup>208</sup> This prohibition would apply to actions by governmental agencies, public hospitals, and public research institutions.<sup>209</sup>

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narrowed in recent years”); Ashish K. Jha, *Racial Trends in the Use of Major Procedures among the Elderly*, 353 N. ENGL. J. MED. 683, 683 (2005) (finding that “[f]or the decade of the 1990s, [there was] . . . no evidence, either nationally or locally, that efforts to eliminate racial disparities in the use of high-cost surgical procedures were successful.”).

206. See Condit & Bates, *supra* note 4, at 98 (underscoring that medical treatment in the United States is characterized by a history of differential treatment that often leads to health disparities such as “substantially greater mortality and morbidity in non-dominant racialized groups”); see also Sharona Hoffman, *Continued Concern: Human Subject Protection, The Institutional Review Board, and Continuing Review*, 68 TENN. L. REV. 725, 729-31 (2001) (describing the Tuskegee syphilis trial and other medical research abuses). The Tuskegee syphilis trial began in 1932 and continued into the 1970s. *Id.* at 730. In the trial, Tuskegee researchers studied African-American males suffering from untreated syphilis. *Id.* The researchers did not give their subjects penicillin even after it became widely available and was known to be an effective cure for the disease. *Id.*

207. See Lillquist & Sullivan, *supra* note 10, at 442 (stating that “racial profiling” in medicine could implicate the Equal Protection Clause, 42 U.S.C. § 1981, Title VI of the Civil Rights Act of 1964 and Title II of the Civil Rights Act of 1964).

208. U.S. CONST. amends. V and XIV, § 1; see also *Adarand Constructors v. Peña*, 515 U.S. 200, 215-16 (1995) (explaining that while the Fourteenth Amendment applies to the states, the Fifth Amendment’s Due Process Clause imposes an identical equal protection mandate on the federal government).

209. See Lillquist & Sullivan, *supra* note 10, at 443 (noting that Equal Protection claims

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.<sup>210</sup> Eleventh Amendment immunity has been interpreted to extend to cases asserting constitutional claims in state court as well<sup>211</sup> and covers agencies and other arms of the state.<sup>212</sup> 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.<sup>213</sup> Likewise, the doctrine of federal sovereign immunity protects the United States from being sued without its consent.<sup>214</sup> Thus, state or federal institutions, such as hospitals or clinics, could not be sued by patients for constitutional violations.<sup>215</sup>

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."<sup>216</sup> Consequently, individual governmental actors can be held

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are enforced through actions brought under 42 U.S.C. § 1983 or as *Bivens* actions pursuant to *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971)).

210. U.S. CONST. amend. XI. The text of the Eleventh Amendment provides that "[t]he 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." See MARK R. BROWN & KIT KINPORTS, CONSTITUTIONAL LITIGATION UNDER § 1983 196 (LexisNexis 2003) (explaining that Congress can abrogate the states' sovereign immunity through legislation passed under Section V of the Fourteenth Amendment, which enables Congress to enforce the Amendment through appropriate legislation).

211. See *Alden v. Maine*, 527 U.S. 706, 712 (1999) (holding that the Eleventh Amendment deprives Congress of the authority to subject non-consenting States to private suits for damages in state courts).

212. See *Edelman v. Jordan*, 415 U.S. 651, 663 (1974) (holding that a suit against current and former directors of a state's department of public aid amounted to a suit against the state); *Ford Motor Co. v. Dep't of Treasury*, 323 U.S. 459, 463 (1945) (finding that a suit against a state's department of treasury and individuals on the treasury's board constituted an action against the state); see also RICHARD H. FALLON, JR. ET AL., HART AND WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 1056-57 (4th ed. 1996) (explaining that Supreme Court jurisprudence interprets statewide agencies as extensions of the state).

213. See *Alden*, 527 U.S. at 754 (holding that Congress cannot abrogate State sovereign immunity under Article I of the Constitution); JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW 49 (6th ed. 2000) (observing that even if the Eleventh Amendment applies, a federal court may hear the suit if the state consents).

214. FALLON ET AL., *supra* note 212, at 1001.

215. *Id.* at 1057 (emphasizing that Eleventh Amendment immunity does not extend to local government entities in most cases); *Monell v. New York Dep't of Soc. Servs.*, 436 U.S. 658, 690 (1978) (concluding that local government bodies are liable for damages under 42 U.S.C. § 1983 in some instances).

216. See *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982) (addressing whether senior presidential aides could assert a qualified immunity defense); see also *Davis v. Scherer*, 468 U.S. 183, 191 (1984) (stating that "[w]hether an official may prevail in his qualified

liable only if they could be expected to have known that their actions would result in a violation of constitutional rights.<sup>217</sup> Proving such knowledge is difficult, though not impossible.<sup>218</sup>

A second federal law provision that may apply to “racially-tailored” medicine, 42 U.S.C. § 1981, proscribes “race-based” discrimination with respect to contracts involving either public or private parties.<sup>219</sup> Section 1981, however, has rarely been successfully invoked in health care cases.<sup>220</sup> Furthermore, Section 1981 plaintiffs must prove that the alleged wrong occurred in association with a “contract,” a particularly challenging task in the research context.<sup>221</sup>

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.<sup>222</sup> Nevertheless, courts have held that Title VI does not apply to doctors receiving Medicare payments because they are not federally-funded “programs” as defined by the law,<sup>223</sup> even though Title VI covers hospitals and long-term care facilities receiving federal funds.<sup>224</sup>

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immunity defense depends upon the ‘objective reasonableness of [his] conduct as measured by reference to clearly established law.’” (citing *Harlow*, 457 U.S. at 818)).

217. See *Davis*, 468 U.S. at 191 (emphasizing that an official’s subjective state of mind is not relevant to the determination of a qualified immunity defense).

218. See *Harlow*, 457 U.S. at 818-19 (indicating that if the law is clearly established, an immunity defense will usually fail because a reasonably competent government official is presumed to know the law governing his conduct).

219. 42 U.S.C. § 1981(a) (2000). The statute provides that “[a]ll persons within the jurisdiction of the United States shall have the same right . . . to make and enforce contracts . . . as is enjoyed by white citizens . . .”; see also *Runyon v. McCrary*, 427 U.S. 160, 189 (1976) (holding that § 1981 applies to private conduct).

220. See *Daniels v. Murphy*, 528 F. Supp. 2, 5 (D.Okla. 1978) (holding that plaintiffs who filed a wrongful death action failed to state a claim under section 1981 because they did not allege “racial” discrimination by any defendant); *United States v. Med. Soc’y of S.C.*, 298 F. Supp. 145, 152 (D.S.C. 1969) (ruling that § 1981 protects African-American patients’ rights to be admitted to hospitals); *Sullivan*, *supra* note 168, at 254-55 (conceding that individuals rarely invoke § 1981, unless to challenge denials of medical staff privileges based on discrimination).

221. Courts rarely find the presence of a contract between a researcher and the human research subjects. 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). Only one court, *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001), has found that an informed consent agreement may constitute a contract between the researcher and subject. *Id.* at 243.

222. 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.”

223. See *Vuciecevic v. MacNeal Mem’l Hosp.*, 572 F. Supp. 1424, 1430 (N.D. Ill. 1983) (denying relief under Title VI because the plaintiff improperly relied on Medicare/Medicaid payments to defendant physician as the basis of plaintiff’s Title VI claim). The court determined that the defendant was not the intended beneficiary of such programs, making Title VI relief inappropriate. *Id.*; cf. *Lillquist & Sullivan*, *supra* note 10, at 445 (noting that these decisions severely restrict Title VI’s coverage in the medical context).

224. See *United States v. Harris Methodist Fort Worth*, 970 F.2d 94, 96 (5th Cir. 1992)

Finally, Title II of the Civil Rights Act of 1964<sup>225</sup> forbids discrimination and segregation in places of public accommodation.<sup>226</sup> However, the provision defining “a place of public accommodation” refers specifically to lodging, eating establishments, gasoline stations, and exhibition or entertainment facilities,<sup>227</sup> but not to medical facilities.<sup>228</sup> Thus, it remains unclear whether health care entities would constitute public accommodations under the law.<sup>229</sup>

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

### *B. State Laws Prohibiting Discrimination in the Medical Arena*

Many state laws prohibit discrimination by health care providers, some of which could apply to “race-based” medicine.<sup>230</sup>

#### *1. Civil rights statutes*

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

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(concluding that Title VI applies to physician staff privileges at hospitals receiving federal funds); *Bryan v. Koch*, 492 F. Supp. 212, 230 (S.D.N.Y. 1980) (stating that Congress intended Title VI to apply to federally funded health care programs).

225. 42 U.S.C. § 2000a (2000).

226. *Id.* § 2000a(a). 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.”

227. *Id.* § 2000a(b).

228. *Id.*; see *Bass v. Parkwood Hosp.*, 180 F.3d 234, 244-45 (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 from the hospital’s alleged discriminatory actions); *Verhagen v. Olarte*, No. 89 CIV. 0300, 1989 WL 146265, at \*4 (S.D.N.Y. Nov. 21, 1989) (finding that Title II does not cover hospitals). *But cf.* *United States v. Med. Soc’y of S.C.*, 298 F. Supp. 145, 147-48 (D.S.C. 1969) (holding that Title II covered a hospital, in part because the hospital had a cafeteria and snack bar that served food to interstate travelers).

229. See *Lillquist & Sullivan*, *supra* note 10, at 446 (noting that although case law in this area is contradictory and sparse, if section 2000(a) applies, “it is probably limited to disparate treatment discrimination”).

230. See OFF. OF MINORITY HEALTH, DEP’T OF HEALTH AND HUMAN SERVICES, EXECUTIVE SUMMARY: ASSESSMENT OF STATE LAWS, REGULATIONS AND PRACTICES AFFECTING THE COLLECTION AND REPORTING OF RACIAL AND ETHNIC DATA BY HEALTH INSURERS AND MANAGED CARE PLANS (2004), *available at* <http://omhrc.gov> (follow “Data/statistics” hyperlink; then follow “Assessment of State Laws, Regulations and Practices Affecting the Collection and Reporting of Racial and Ethnic Data by Health Insurers and Managed Care Plans” hyperlink) (describing state laws targeting discrimination by health care providers). The study concluded that most states provide protection against “racial” discrimination. *Id.*

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.<sup>231</sup>

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”<sup>232</sup> or some similar variation<sup>233</sup> to be places of public accommodation. 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, for example, forbids discrimination “in all business establishments of every kind whatsoever.”<sup>234</sup> Ten states include clinics and hospitals in their statutory definitions of “public accommodation” but exclude private health care providers or insurance providers.<sup>235</sup> Washington state covers any place “where medical service or care is made available,”<sup>236</sup> and Nevada specifies that an “office of a provider of health care” is a place of public accommodation.<sup>237</sup> Furthermore, the District of Columbia, Nevada, and Ohio include insurers and insurance offices in their definitions of places of public accommodation.<sup>238</sup> Other states direct laws specifically at HMOs. For example, Colorado's statute establishes that “[n]o HMO shall unfairly

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231. ARIZ. REV. STAT. ANN. § 41-1442 (2004).

232. *Id.* § 41-1441.

233. *E.g.*, ARK. CODE ANN. § 16-123-102 (Supp. 2005); CONN. GEN. STAT. ANN. § 46a-63 (West Supp. 2005); DEL. CODE ANN. tit. 6, § 4502 (1999); IDAHO CODE § 67-5902 (2001); IND. CODE ANN. § 35-46-2-1 (LexisNexis 2004); IOWA CODE § 216.2 (2000); KY. REV. STAT. ANN. § 344.130 (West 2003); LA. REV. STAT. ANN. § 51:2232 (2003); MICH. COMP. LAWS SERV. § 37.2302 (LexisNexis 2001); MINN. STAT. ANN. § 363A.03 (West Supp. 2005); N.M. STAT. ANN. § 28-1-2 (LexisNexis 2003); N.D. CENT. CODE § 14-02.4-02 (2004); OKLA. STAT. ANN. tit. 25, § 1401 (West 1987); OR. REV. STAT. § 659A.400 (2003); S.D. CODIFIED LAWS § 20-13-1 (2005); TENN. CODE ANN. § 4-21-102 (1998); UTAH CODE ANN. § 13-7-2 (2001); VT. STAT. ANN. tit. 9, § 4501 (1993); W. VA. CODE ANN. § 5-11-3 (LexisNexis 2002).

234. CAL. CIV. CODE § 51 (West Supp. 2005).

235. COLO. REV. STAT. § 24-34-601 (2004); HAW. REV. STAT. ANN. § 489-2 (LexisNexis 2002); MASS. GEN. LAWS ANN. ch. 272, § 92A (LexisNexis Supp. 2005); MONT. CODE ANN. § 49-2-101 (2003); N.J. STAT. ANN. § 10:5-5 (1) (West Supp. 2005); N.Y. CIV. RIGHTS LAW § 40 (McKinney 1992); 43 PA. STAT. ANN. § 954 (West Supp. 2005); R.I. GEN. LAWS § 11-24-3 (2002); S.C. CODE ANN. § 45-9-10 (Supp. 2004); WIS. STAT. ANN. § 106.52(1)(e)(1) (West Supp. 2004).

236. WASH. REV. CODE ANN. § 49.60.040 (West 2002).

237. NEV. REV. STAT. § 651.050 (2003); *see also* N.H. REV. STAT. ANN. § 354-A2 (XIV) (Supp. 2004) (providing that in New Hampshire, a “health care provider” is a place of public accommodation).

238. D.C. CODE § 2-1401.02 (24) (2005); NEV. REV. STAT. § 651.050 (2003); OHIO ADMIN. CODE § 4112-5-02 (I) (2004).

discriminate against any enrollee based on . . . race.”<sup>239</sup>

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 harm results from their actions. Under state law, 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.<sup>240</sup>

## 2. Hospital and medical facility licensing requirements

Massachusetts, Pennsylvania, Rhode Island, and Texas require that medical facilities licensed to operate in the state<sup>241</sup> agree to provide nondiscriminatory care. Pennsylvania’s statute, for example, mandates that “no provider shall discriminate in the operation of a health care facility on the basis of race . . . .”<sup>242</sup> Rhode Island establishes that health services providers must provide health services without regard to a person’s “race” and that violators will be denied certification.<sup>243</sup> Other states require

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239. 3 COLO. CODE REGS. § 4-7-2 (2003); *accord* 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. § 19-710 (h) (LexisNexis 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) (LexisNexis Supp. 2005) (“A health maintenance organization [“HMO”] contract . . . shall not discriminate on the basis of race . . . .”); N.M. CODE R. § 13.10.13.22(A) (2005) (“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: (1) gender, race . . . .”); N.Y. COMP. CODES R. & REGS. tit. 10, § 98-1.11 (2005) (requiring that each HMO shall not discriminate on the basis of “race” when providing services); 11 N.C. ADMIN. CODE 20.0202(13) (1997) (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 (2005) (prohibiting HMOs from unfairly discriminating against enrollees or applicants on the basis of “race”); S.C. CODE ANN. REGS. 69-22 (1989) (prohibiting HMOs from discriminating against any enrollee or applicant on the basis of “race”); 14 VA. ADMIN. CODE 5-210-80(C)(1) (2005) (prohibiting HMOs from discriminating against any enrollee on the basis of “race”); W. VA. CODE ANN. § 33-25D-15(e) (LexisNexis 2003) (prohibiting “prepaid limited health service organization[s]” from discriminating in the quality of services on the basis of “race”); *Id.* § 33-25A-14a(d) (prohibiting HMOs from discriminating in the quality of services on the basis of “race”).

240. 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 IV.B.5.

241. *See* 35 PA. STAT. ANN. § 448.801a (West 2003) (stating that 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.”).

242. *Id.* § 448.804(a); *see also* 105 MASS. CODE REGS. § 130.206 (2001) (providing that “[n]o hospital shall discriminate in the provision of service against any person on the basis of race . . . .”); 25 TEX. ADMIN. CODE § 157.16(d)(9) (2005) (applying exclusively to emergency medical services providers); 14-090-007 R.I. CODE R. § 18.2 (2004) (requiring only that hospitals do not deny admission based on a patient’s “race”).

243. R.I. GEN. LAWS § 42-62-11 (1998).

compliance with Patients’ Bill of Rights laws, which prohibit “racial” discrimination, as a condition of licensure.<sup>244</sup> These statutes bind the facilities at issue, even if they are not considered places of public accommodation for purposes of civil rights law.<sup>245</sup>

### 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,<sup>246</sup> while others placed patient rights provisions within more comprehensive laws.<sup>247</sup> The Florida Patient’s Bill of Rights and Responsibilities is 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.”<sup>248</sup> New Jersey’s law guarantees the right “[t]o treatment without discrimination as to race”<sup>249</sup> but applies only to patients in hospitals, while other state laws cover long term care, surgical centers, and home health agencies.<sup>250</sup>

Patients who receive different treatment because of “race-based” practices and are harmed as a result, may suffer a violation of their rights under the law. Some patients’ rights statutes expressly authorize a private cause of action.<sup>251</sup> The New York statute does not, but a court found that it

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244. *E.g.*, 175 NEB. ADMIN. CODE § 9-006.04 (2005); N.H. REV. STAT. ANN. § 151:21 (Supp. 2004); N.M. CODE R. § 7.7.2.19 (2005); *Id.* § 7.8.2.34; 14-090-007 R.I. CODE R. § 15 (2004).

245. *See* N.M. CODE R. § 7.7.2.19 (requiring hospitals to have written policies approved by the governing board that detail patients’ rights and responsibilities, including a provision stating that “patients may not be denied appropriate hospital care because of the patient’s race . . .”).

246. *E.g.*, FLA. STAT. ANN. § 381.026 (West Supp. 2005); KAN. ADMIN. REGS. § 28-34-3b (2005); MICH. COMP. LAWS SERV. § 333.20201 (LexisNexis Supp. 2005); N.J. STAT. ANN. § 26:2H-12.8 (West 2005); N.J. STAT. ANN. § 30:13-3 (West Supp. 2005); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.7 (2005); OHIO REV. CODE ANN. § 3721.13 (LexisNexis 2002).

247. *E.g.*, 40-700-014 DEL. CODE REGS. § 014 (Weil 2005); 16-4000-4405 DEL. CODE REGS. § 16.0 (Weil 2005); N.D. ADMIN. CODE § 33-03-10.1-10(6)(a)(5) (1998).

248. FLA. STAT. ANN. § 381.026 (West Supp. 2005).

249. N.J. STAT. ANN. § 26:2H-12.8(p) (West 2005).

250. *See, e.g.*, 40-700-014 DEL. CODE REGS. § 014 (Weil 2005) (long term care); 16-4000-4405 DEL. CODE REGS. § 1.0 (Weil 2005) (free standing surgical centers); KAN. ADMIN. REGS. § 28-34-3b (2005) (hospitals); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.7(c) (2005) (hospitals); N.D. ADMIN. CODE § 33-03-10.1 (1998) (home health agencies).

251. *See* N.J. STAT. ANN. § 30:13-4.2 (West 1997) (providing a cause of action against nursing homes for violation of N.J. STAT. ANN. §§ 30:13-1-30:13-4.1, which outlines nursing home responsibilities and rights of residents); OHIO REV. CODE ANN. § 3721.17(I) (LexisNexis 2002) (giving nursing home residents a private cause of action against “any person or home” committing a violation of nursing home patients’ bill of rights outlined in OHIO REV. CODE ANN. §§ 3721.10-3721.17 (LexisNexis 2002)); *Sprosty v. Pearlview, Inc.*, 666 N.E.2d 1180, 1184-84 (Ohio App. 8 Dist. 1995) (holding that OHIO REV. CODE ANN. 3721.17(I) permits an award of punitive damages for violation of the patients’ bill of rights);

nevertheless included an implied right of private action.<sup>252</sup>

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,<sup>253</sup> patients are entitled to reimbursement by the offending facility upon an administrative finding of a statutory violation.<sup>254</sup> Florida requires that copies of the patient's bill of rights be available to patients, imposes penalties for those who violate this requirement,<sup>255</sup> and enables patients to file grievances with the offending health care providers or the state licensing agency.<sup>256</sup> Similarly, hospitals in Kansas must inform patients of their rights during admission<sup>257</sup> and "establish a mechanism for responding to patient complaints."<sup>258</sup> Delaware patients in long-term care facilities can report mistreatment to the Patient Rights Unit<sup>259</sup> or other agencies,<sup>260</sup> and medical facilities must inform them in writing of their right to do so.<sup>261</sup> North Dakota's statute has a more limited scope. It applies only to home health agencies and requires government monitoring to ensure compliance with the anti-discrimination mandate.<sup>262</sup>

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see also Sharon Reece, *The Circuitous Journey to the Patients' Bill of Rights: Winners and Losers*, 65 ALB. L. REV. 17, 91-95 (2001) (listing state patient bills of rights).

252. See *McDonald v. N.Y. City Health & Hosps. Corp.*, 203 A.D.2d 6, 610 N.Y.S.2d 13 (1994) (finding that the state statute established an implied private right of action in a case in which the hospital failed to provide a licensed psychiatrist to supervise residents).

253. See MICH. COMP. LAWS SERV. § 333.20203 (LexisNexis 2001) ("The rights and responsibilities prescribed in sections 20201 and 20202 are guidelines for health facilities, facility staff, facility employees, patients, and residents. An individual shall not be civilly or criminally liable for failure to comply with those sections.").

254. See *id.* § 333.21799c(4) (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).

255. See FLA. STAT. ANN. § 381.026(6) (West Supp. 2005) (requiring health care providers to make a written copy of the Florida Patient's Bill of Rights and Responsibilities available to patients); *Id.* § 381.0261(4) (providing for an administrative fine if a health care facility does not make the patient's bill of rights available to a patient). For initial non-willful violations, the health care facility does not receive an administrative fine. *Id.* For subsequent violations, the Agency for Health Care Administration may fine the facility up to \$5,000 for non-willful violations and up to \$25,000 for intentional and willful violations. *Id.*

256. See *id.* § 381.026(6) (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).

257. KAN. ADMIN. REGS. 28-34-3b(10) (2005).

258. *Id.* § 28-34-3b(10)(b).

259. See 40-700-014 DEL. CODE REGS. § (V)(I) (Weil 2005) (listing the phone number and address for county Patient Rights Units).

260. See *id.* (listing the Division of Public Health, State Human Relations Commission, Dep't of Health and Social Services, and Office of Civil Rights addresses to which patients can send correspondence regarding discriminatory practices).

261. *Id.* § (III)(1), (2).

262. N.D. ADMIN. CODE § 33-03-10.1-10 (1998).



#### 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 by state staff at public facilities as well as by any private provider or contractor who receives state funds to provide medical services and any health care facilities enrolled as state Medicaid providers.<sup>263</sup>

To illustrate, Arizona mandates that “[a] contractor, provider, and nonprovider shall not discriminate against an eligible person or member because of race . . . .”<sup>264</sup> Other statutes’ wording differs to some extent, with different state laws addressing discrimination in enrollment, the provision of services, access to services, or separate treatment practices.<sup>265</sup> Therefore, 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.

263. See, e.g., 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 § 9-22-513 (2004) (“A contractor, provider, and nonprovider shall not discriminate against an eligible person or member because of race . . . .”); GA. COMP. R. & REGS. 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.”); 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.”).

264. ARIZ. ADMIN. CODE R9-22-513 (A) (2004).

265. ALA. ADMIN. CODE r. 56-X-1-.07(1) (Supp. 1997); ALASKA ADMIN. CODE tit. 7, § 78.130 (2004); *Id.* tit. 7, § 43.070; COLO. REV. STAT. § 26-19-110 (2004); CONN. AGENCIES REGS. § 17b-262-526(1) (2004); D.C. MUN. REGS. tit. 22, § 4405.2 (2004); *id.* tit. 22, § 5509.1; *id.* tit. 29, § 948.1; *id.* tit. 29, § 5319.1; *id.* tit. 29, § 5413.1; *id.* tit. 29, § 5618.1; FLA. ADMIN. CODE ANN. r. 59G-8.100(23) (2005); GA. COMP. R. & REGS. 350-1-.05 (1989); IDAHO ADMIN. CODE r. 16.03.09.026 (2003); 305 ILL. COMP. STAT. ANN. 5/11-1 (West Supp. 2005); 405 IND. ADMIN. CODE 5-1-2 (2005); IOWA ADMIN. CODE r. 441-88.2 (3)(e) (2005); *id.* § 441-152.2(10); KAN. ADMIN. REGS. § 30-2-1 (2005); KY. REV. STAT. ANN. § 205.640(7) (West 2001); LA. REV. STAT. ANN. § 46:437.11(A) (1999); MD. CODE REGS. 10.09.36.03(A)(7) (2005); *id.* § 10.09.64.07(C); *id.* § 10.09.65.02(C); 130 MASS. CODE REGS. 450.202(B) (2005); *id.* § 501.009(A) (2002); MICH. ADMIN. CODE r. 400.7172(2) (1999); MO. CODE REGS. ANN. tit. 19, § 10-2.010 (2002); MONT. CODE ANN. § 53-6-105 (2003); *id.* § 37.85.402(6); NEB. ADMIN. CODE § 2-001.04 (2005); N.J. ADMIN. CODE § 10:72-1.7 (1998); N.M. CODE R. § 8.302.1.14 (2004); N.Y. COMP. CODES R. & REGS. tit. 18, § 515.2(b)(13) (2001); 10A N.C. ADMIN. CODE 28B.0401 (2005); OHIO ADMIN. CODE 5101:3-26-12(C)(5)(h) (2004); OKLA. ADMIN. CODE § 317:25-7-25(e) (2004); OR. ADMIN. R. 410-120-1380(1)(c) (2005); *id.* § 461-105-0010; *Id.* 461-105-0190(8); 55 PA. CODE § 1101.51(b) (2000); 15-020-001 R.I. CODE R. § 0122 (Weil 2004); S.C. CODE ANN. § 126-125 (1992); S.D. ADMIN. R. 67:16:01:18 (2003); *id.* § 67:42:01:13; TENN. COMP. R. & REGS. 1200-13-1-.05(9) (2005); 25 TEX. ADMIN. CODE § 37.67 (2004); *id.* § 39.21; *id.* § 448.207 (2004); UTAH ADMIN. CODE r. 414-1-10 (2004); 13-170-001 VT. CODE R. §2000(3) (2004); 12 VA ADMIN. CODE § 30-10-970 (2005); WIS. ADMIN. CODE § HFS 104.01(1) (2002); WYO. STAT. ANN. § 42-4-107(b) (2005). *But cf.* OHIO ADMIN. CODE § 5101:3-26-02 (2004) (requiring nondiscrimination in admissions only).

### 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”<sup>266</sup>

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 . . . .”<sup>267</sup> The statute does not address denial of coverage for particular treatments based on a patient’s “race.” However, if an insurer issuing individual policies<sup>268</sup> attempted to

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266. N.J. STAT. ANN. § 17:29B-4(7)(c), (d) (West 2004); *accord* CAL. HEALTH & SAFETY CODE § 1365.5(b) (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(3) (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.”); 20 ILL. CODE R. 2051.55(c)(2)(L) (Weil 2005) (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) (LexisNexis 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 (LexisNexis 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. § 1751.18(A)(2) (LexisNexis 2004) (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) (2004) (prohibiting government insurers that discriminate on the basis of “race” from transacting insurance in the state).

267. NEV. REV. STAT. 686B.060(2) (2003); *accord* ARK. CODE ANN. § 23-67-209(b) (2001) (“Risks may be classified in any reasonable way . . . except that no risks may be grouped by classifications based in whole or in part on race, color, creed, or national origin of the risk.”); CAL. INS. CODE § 10140(a) (West 2005) (“Race, color, religion, national origin, ancestry, or sexual orientation shall not, of itself, constitute a condition or risk for which a higher rate, premium, or charge may be required of the insured for that insurance.”); WYO. STAT. ANN. § 26-14-105(b) (2005) (“Risks may be classified in any way except that no risk may be classified in whole or in part on the basis of race, color, creed or national origin.”).

268. *See supra* note 200 (explaining that the Health Insurance Portability and Accountability Act prevents insurers from discriminating in group plans based on “any health status-related factor” while offering no explicit protection for individual insurance plans); *see also* 42 U.S.C. § 300gg-1(b)(1) (2003).

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 state could find the insurer in violation of the law.

State mandates, however, will not protect patients enrolled in self-funded employee benefit plans.<sup>269</sup> The Employee Retirement Income Security Act ("ERISA"),<sup>270</sup> a federal law, preempts state laws regulating insurance with respect to self-funded plans, rendering them unenforceable.<sup>271</sup> This exception is quite consequential because a growing number of employers are self-insured.<sup>272</sup>

### C. Violation of Research Regulations and Guidelines

The best source of protection for the American public might be NIH guidelines<sup>273</sup> 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*.<sup>274</sup>

The Guidelines state the following:

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

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269. See 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). Self-insured employers directly assume responsibility for paying their employees' medical claims 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. *Id.*

270. 29 U.S.C. §§ 1001-1461 (2000).

271. See, e.g., *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) ("We read the . . . [statute] to exempt self-funded ERISA plans from state laws that 'regulat[e] insurance' . . . ." (citing 29 U.S.C. § 1144(b)(2)(A))); *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 735 n.14 (1985) (recognizing that ERISA preempts application of the Pennsylvania Motor Vehicle Financial Responsibility Law to self-insured health benefit plans).

272. See Rothstein, *supra* note 269, at 293 (observing that 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).

273. See NIH GUIDELINES, *supra* note 90 (providing guidance concerning the inclusion of minority populations in research studies and the reporting of research data).

274. *Id.*

exclusion except when the study would duplicate data from other sources.<sup>275</sup>

Researchers who seek to exclude particular minority groups from their clinical studies in an attempt to develop therapies for a different “racial” population (e.g. only African-Americans or only Hispanics), risk violation of these guidelines and denial of NIH funding.<sup>276</sup> Investigators would have to show 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,<sup>277</sup> the NIH should rarely, if ever, find a compelling justification for invoking the exception to the general rule of inclusion. The A-HeFT trial, for example, should be 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.<sup>278</sup>

While NIH’s rule of inclusion is laudable, its guidelines also feature a troubling mandate instructing researchers to report “race/ethnicity differences in the intervention effect” in appropriate circumstances.<sup>279</sup> The guidelines provide the following choices for “ethnic categories”: Hispanic or Latino and Not Hispanic or Latino.<sup>280</sup> The choices for “racial categories” are: American Indian or Alaska Native, Asian, Black or African-American, Native Hawaiian or other Pacific Islander, and White.<sup>281</sup> 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

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275. *Id.*

276. *See id.* (“The NIH Director may approve, on a case-by-case basis, the exclusion of subjects, as recommended by the Institute/Center Director, that may be inappropriate to include within the requirements of these guidelines on the basis of circumstances other than the health of the subjects, the purpose of the research, or costs.”).

277. *See supra* notes 99-106 and 128-131 and accompanying text.

278. *See supra* Part I.A (discussing the A-HeFT trial).

279. *See* NIH GUIDELINES, *supra* note 90 (describing the proper protocol for conducting sex/gender and ethnic/“racial” analyses and stating that publication submissions are strongly encouraged to include the results of “racial” and gender analyses).

280. *Id.* It is not clear why Hispanic or Latino are considered “ethnic” categories, while other classification are considered “racial.” *See supra* note 177 and accompanying text (discussing the ambiguities of the term “ethnicity”).

281. NIH GUIDELINES, *supra* note 90. The Guidelines further recognize that the changing “racial” and ethnic composition of the U.S. population reflects increasing diversity and changing demographics. *Id.* The terms “minority groups” and “minority subpopulations” are meant to include, rather than exclude, different “racial” and ethnic groups. *Id.* 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. OFF. OF MGT. AND BUDGET, STANDARDS FOR MAINTAINING, COLLECTING, AND PRESENTING FEDERAL DATA ON RACE AND ETHNICITY (1997), available at [www.whitehouse.gov/omb/fedreg/ombdir15.html](http://www.whitehouse.gov/omb/fedreg/ombdir15.html).

“racially-tailored” therapies. This approach has been criticized by other commentators and ought to be rejected.<sup>282</sup> It could constitute an incentive for sloppy science in which response differences are attributed to the subjects’ self-selected “racial” identity without deeper analysis of socio-economic conditions, genetic variations, and other factors.

A better alternative has been adopted by several prestigious publications, including *Nature Genetics* and the *Journal of the American Medical Association* (“JAMA”). Rather than encourage the use of “racial” categorization, these journals require authors who analyze data by sub-population to justify their doing so and to explain how they constructed their classifications.<sup>283</sup> 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.<sup>284</sup> In the words of the *Nature Genetics* editors, “this will raise awareness and inspire more rigorous design of genetic and epidemiological studies.”<sup>285</sup>

## 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.<sup>286</sup> While clinical trials involving treatments other than drugs and devices, such as surgery or bone marrow transplants, do not fall within the FDA’s jurisdiction, they are subject to U.S. Department of Health and Human Services (“HHS”) regulation if they are “conducted, supported or otherwise subject to regulation by any federal department or agency.”<sup>287</sup>

The federal regulations may serve as a further constraint upon “race-based” research as both FDA and HHS regulations instruct Institutional Review Boards (“IRBs”), which review and approve research projects,<sup>288</sup> to

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282. See, e.g., Stevens, *supra* note 173, at 1033-36; Lillquist & Sullivan, *supra* note 10, at 451-55; Bamshad, *supra* note 119, at 945.

283. See Editorial, *Census, Race and Science*, 24 NATURE GENETICS 97, 98 (2000) (encouraging reviewers of manuscripts to critically analyze research focusing on “race”); Winker, *supra* note 15, at 1614 (encouraging authors who analyze results by “race” to rely on self-designation but cautioning that such analysis, which has become a “knee jerk reflex,” must be thoroughly justified).

284. Winker, *supra* note 15, at 1614.

285. *Census, Race and Science*, *supra* note 283, at 98.

286. 21 C.F.R. § 50.1(a) (2005); see also U.S. Food and Drug Administration, <http://www.fda.gov/comments/regs.html> (describing items regulated by the FDA).

287. 45 C.F.R. § 46.101(a) (2005).

288. Federal regulations mandate that all research 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)

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.<sup>289</sup>

Investigators who design “racially-tailored” clinical trials subject to federal regulation risk violating this mandate by selecting enrollees in an inequitable fashion. If a high risk study includes members of only one minority, that minority group will disproportionately bear the burdens of the research. On the other hand, if the experimental treatment holds promise of significant benefits for participants, then all but the members of the selected minority will be deprived of the opportunity to enjoy those benefits during clinical trials.

Furthermore, if a study focusing on a particular minority includes 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. Thus, extra care must be taken to ensure that potential subjects fully understand the trial and its implications and are not coerced into enrolling.<sup>290</sup> 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 that deprives subjects of standard therapy,<sup>291</sup> or if enrollees are offered generous financial incentives, which some may feel unable to decline.<sup>292</sup>

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(2005). The IRB’s primary role is to safeguard the rights and welfare of human subjects. 21 C.F.R. § 56.108.

289. 45 C.F.R. § 46.111(a)(3); 21 C.F.R. § 56.111(a)(3).

290. See Sharona Hoffman, *The Use of Placebos in Clinical Trials: Responsible Research or Unethical Practice?*, 33 CONN. L. REV. 449, 484-90 (2001) (discussing the difficulties of obtaining meaningful informed consent from research participants and the flaws of the typical informed consent process).

291. See *id.* at 452-60 (discussing placebo controls and concerns about their use); see also *infra* text accompanying notes 311-319 (discussing safeguards that should be implemented for attribute-based research).

292. See NAT’L BIOETHICS ADVISORY COMM., DISCUSSION AND RECOMMENDATIONS ON UNDUE INDUCEMENT, reprinted in *Undue Influence and Coercion*, [http://alumni.imsa.edu/~jason/ethics\\_topics/undue.html](http://alumni.imsa.edu/~jason/ethics_topics/undue.html) (stating that monetary payments can induce subjects to participate in research); OFF. OF RES. SUPPORT COMMS., THE UNIV. OF TEX. HEALTH SCI. 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](http://www.uth.tmc.edu/ut_general/research_acad_aff/orsc/cphs/guidelines/pay.htm) (last visited Oct. 7, 2005) (prohibiting “monetary inducements to be utilized to recruit subjects for studies involving significant risk or excessive pain or discomfort”).

*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.<sup>293</sup> The Constitution’s Equal Protection Clause generally prohibits discrimination by governmental actors<sup>294</sup> but allows it when a compelling governmental interest justifies the conduct at issue, and when the government narrowly tailors its conduct to achieve the compelling goal.<sup>295</sup> Title VII of the Civil Rights Act of 1964 prohibits employment discrimination based on “race,” color, national origin, sex, and religion,<sup>296</sup> 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 enterprise.”<sup>297</sup> 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.<sup>298</sup> Similarly, the Americans with Disabilities Act (“ADA”)<sup>299</sup> prohibits employment discrimination based on disability, but authorizes

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293. See *supra* Part IV.C (analyzing NIH and regulatory research guidelines).

294. See *supra* Part IV.A (discussing the Equal Protection Clause and its applicability to “race-based” medicine).

295. See, e.g., *Shaw v. Hunt*, 517 U.S. 899, 899 (1996) (holding that North Carolina’s districting plan violated the Equal Protection Clause because it was not narrowly tailored to serve a compelling state interest); *Miller v. Johnson*, 515 U.S. 900, 900 (1995) (finding that Georgia’s districting plan violated the Equal Protection clause).

296. 42 U.S.C. § 2000e-2(a) (2000).

297. *Id.* § 2000e-2(e)(1). Note that “race” and color are not included in the list of allowable exceptions. However, in rare circumstances, the bona fide occupational qualification (BFOQ) defense has been applied to “race” and color discrimination as well. See JOEL WM. FRIEDMAN & GEORGE M. STRICKLER, JR., *THE LAW OF EMPLOYMENT DISCRIMINATION* 173-74 (5th ed. 2001) (discussing affirmative action programs, the hiring of actors for “race”-specific roles, and law enforcement positions that might require “racial” hiring). The authors argue that taking “race” into account is “common sense” in some situations. *Id.* For example, if a motion picture about Thurgood Marshall is being cast, auditioning a white actor would be senseless. *Id.*

298. See *id.* at 171-72 (discussing BFOQ defenses based on authenticity, privacy, and safety needs).

299. 42 U.S.C. §§ 12101-12213 (2000).

employers to exclude a candidate or employee if that employee cannot be reasonably accommodated by the employer<sup>300</sup> or will constitute a direct threat to the health or safety of himself or others in the workplace.<sup>301</sup>

In the research arena, the NIH Guidelines mandate inclusion of minorities in clinical studies unless concern about the subject's health or the research purpose militates against inclusive selection criteria.<sup>302</sup> 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.<sup>303</sup>

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 sound methodology because "race" lacks a coherent meaning.<sup>304</sup> 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 investigators may categorize these individuals into particular groups. The proper classifications might involve genetic variation, origin in a specific geographic area, socio-economic status, diet, exercise, or other factors,<sup>305</sup> 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.

## V. RECOMMENDATIONS

The advent of BiDil may well portend a future in which researchers enthusiastically pursue attribute-based medicine.<sup>306</sup> While this approach

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300. *Id.* § 12112(b)(5)(A).

301. *Id.* § 12113(b); *see also* *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 that applicant or employee did not pose a direct threat to anyone else in the workplace).

302. NIH GUIDELINES, *supra* note 90.

303. 45 C.F.R. § 46.111(a)(3) (2005); 21 C.F.R. § 56.111(a)(3) (2005).

304. *See supra* Part II (analyzing the meaning of "race" in medicine, genetics, the social sciences, and the law and arguing that it is an incoherent concept).

305. *See supra* Part III.A; *infra* Part V.B.

306. *See* Bowser, *supra* note 10, 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



could hold great promise for improving human health, 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.<sup>307</sup> The proposal then undergoes an extensive scientific review process in which groups with expertise in medicine, chemistry, and pharmacology/toxicology scrutinize the trial to ascertain its scientific integrity and safety.<sup>308</sup> 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.<sup>309</sup> Finally, most clinical trials must be approved by IRBs, institutional entities that are charged with the responsibility of safeguarding the welfare of research participants.<sup>310</sup> 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 A-HeFT study, for example, has been criticized for including only African-Americans and failing to examine whether the combination of BiDil and standard therapy would benefit non African-Americans.<sup>311</sup> 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

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overlooked differential racial response to drugs").

307. 21 C.F.R. § 312.22(c) (2005). In the IND application, the sponsor must detail the outcomes of animal studies, submit drug manufacturing data, and provide information concerning the study's design. *Id.* § 312.23; see also 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) (noting that the practical purpose of the IND application is to determine whether it is safe to proceed with clinical trials in humans, and the legal reason for submitting an IND is to receive an exemption from federal statutes that prohibit unapproved drugs from being shipped in interstate commerce).

308. CDER HANDBOOK, *supra* note 18, at 15-16.

309. See CYSTINOSIS RES. NETWORK, GRANT PROPOSAL GUIDELINES (2003), available at <http://www.cystinosis.org/grantguidelines.html> (discussing scientific review board review of research proposals submitted to the Cystinosis Research Network); Kennedy's Disease Ass'n, Sci. Rev. Bd., [http://www.kennedysdisease.org/aboutus\\_board.html](http://www.kennedysdisease.org/aboutus_board.html) (last visited Oct. 7, 2005) (detailing each board member's qualifications for serving on the scientific review board).

310. 21 C.F.R. § 56.111 (2005); 45 C.F.R. § 46.111 (2005).

311. See Kahn, *supra* note 64, at 481; Bloche, *supra* note 39, at 2036.

discussed below, if 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.<sup>312</sup> In the 2000 census, almost seven million Americans indicated that they belonged to two or more “races.”<sup>313</sup> In addition, many more individuals consider themselves to be of mixed origin and have genetic admixtures.<sup>314</sup> If a study that is designed to be population-exclusive has numerous subjects that self-identify as members of a particular “race” when forced to check a box but who have substantial ancestral mixing, its results might be skewed and inaccurate. As a recent study concluded, “significant population substructure differences exist that self-reported race alone does not capture.”<sup>315</sup> Researchers who believe that ancestry might be informative for research purposes should not only require self-identification, but also should ask subjects specific questions about their ancestries in order to gather more accurate information about potential genetic admixture or origin in a relevant sub-population.<sup>316</sup>

Furthermore, scientific review boards should require investigators to formulate careful hypotheses regarding factors that will influence treatment response.<sup>317</sup> If applicable, they should control for genetic, psychosocial, economic, environmental, cultural, educational and other elements that might provide a partial or complete explanation for treatment response rate differences.<sup>318</sup> These could include specific alleles, diet, exercise, stress,

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312. As noted in Part II.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.” See *supra* notes 121-124 and accompanying text. The components they analyzed, however, were microsatellites, non-functional DNA that are highly illuminating with respect to group differences but not relevant to health status and other medical information. *Id.* Furthermore, they did not focus on individuals of mixed “race” origins. *Id.*

313. U.S. CENSUS BUREAU, RACE, *supra* note 12.

314. See *supra* notes 156-157.

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

316. See Bamshad, *supra* note 119, at 945 (stating that if ancestry is relevant, “using race rather than geography or explicit genetic data to infer ancestry will be less useful for making decisions about disease risk or treatment response”); see also *supra* notes 55-60 and accompanying text (discussing studies that have found that origin in a specific country or geographic location and socioeconomic factors are relevant to health status).

317. See Bamshad, *supra* note 119, at 945 (stating that “[m]ost health-related traits, such as susceptibility to diabetes, obesity, infection, and cancer, are complex traits influenced by the combined effects of several or more gene variants, each with a modest effect, together with the environment”).

318. See Hacking, *supra* note 15, at 109 (stating that BiDiI might be particularly effective for African Americans because of social factors, such as diet); Shields et al., *supra* note 15, at 96 (recommending measurement of “specific social dimensions known to have

exposure to environmental toxins, or cultural and religious barriers to treatment compliance.<sup>319</sup>

A book by Anne Fadiman entitled *The Spirit Catches You and You Fall Down*<sup>320</sup> highlights potential social, religious, and cultural hurdles to the receipt of optimal health care.<sup>321</sup> It follows an immigrant Hmong family, whose young daughter suffers from severe epilepsy, through years of encounters with American medical and social service systems.<sup>322</sup> Despite everyone's best intentions, the daughter's medical treatment fails time and again.<sup>323</sup> 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 recommended treatments.<sup>324</sup> This experience surely is not unique.<sup>325</sup> Thus, while particular communities that are involved in clinical trials may demonstrate unusual therapeutic responses, these phenomena might be related to cultural elements or compliance difficulties.<sup>326</sup> 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.

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an impact on health and health outcomes”); Winker, *supra* note 15, at 1614 (encouraging investigators to measure a number of different variables, rather than to focus exclusively on “race,” in order to ensure the most accurate evaluation of the outcome at issue); Race, Ethnicity, and Genetics Working Group of the Nat'l Human Genome Research Inst., *The Use of Racial, Ethnic, and Ancestral Categories in Human Genetics Research*, 77 AM. J. HUM. GENETICS 519, 519 (2005) (“Investigations that fail to recognize and acknowledge the full range of mechanisms through which designations of race, ethnicity, and ancestry can correlate with personal traits and outcomes threaten to reinforce widely held stereotypes.”).

319. See *supra* Part III.A (discussing purported “race-based” outcome differentials and the “non-racial” factors to which they might in truth be attributed).

320. ANNE FADIMAN, *THE SPIRIT CATCHES YOU AND YOU FALL DOWN* (1997).

321. See *id.* at 83-84, 186-90 (discussing cultural and social impediments to medical care).

322. See *id.* at 110-13, 176-80, 219-24 (documenting the parents' increasing frustration with American medical care and their impression that American medical care was the cause of their child's health problems).

323. See *id.* (describing the extent to which the parents went to obtain traditional medical care for their daughter).

324. See *id.* at 83-84, 110-13, 176-80, 219-24.

325. See *id.* at 83 (discussing the manner in which Hmong attitudes toward parental responsibility conflict with American beliefs).

326. See Shankar Vedantam, *Racial Disparities Found in Pinpointing Mental Illness*, WASH. POST, June 28, 2005, at A16 (reporting that Blacks in the United States were more than four times as likely than Whites to be diagnosed with schizophrenia). The article noted one expert's warning that “there is a risk a psychiatrist with a different cultural experience than a patient can misinterpret the expression of a psychiatric symptom.” *Id.* It further described ““focus units”—inpatient psychiatric centers that focus on how culture and ethnicity influence psychiatric diagnosis and treatment.” *Id.*

## 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.<sup>327</sup> IRBs should be particularly vigilant when reviewing attribute-based protocols that are targeted at particular population groups.<sup>328</sup> The federal regulations mandate that the selection of participants be equitable.<sup>329</sup> IRBs, like scientific review boards, should scrutinize population-specific protocols to ensure that the selection criteria are justified by scientific data.<sup>330</sup> 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 the therapy.<sup>331</sup> 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.<sup>332</sup> If that is the case, the informed consent process should be designed to be comprehended by subjects with limited educations.<sup>333</sup> The informed consent process should include extensive verbal explanations, and the informed consent document should be kept as

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327. See 21 C.F.R. § 56.111 (2005); 45 C.F.R. § 46.111 (2005) (detailing “[c]riteria for IRB approval of research”).

328. See 21 C.F.R. § 56.111(a)(3) (2005) (recommending that IRBs take into account problems that arise in research involving “vulnerable populations”).

329. *Id.*; 45 C.F.R. § 46.111(a)(3) (2005).

330. Cf. Stuart L. Nightingale, *Challenges in Human Subject Protection*, 50 FOOD & DRUG L.J. 493, 500-01 (1995) (emphasizing that IRBs may adopt stricter approval criteria than federal regulations require and recommending that they do so if specific populations are excluded due to business concerns rather than medical or safety concerns).

331. See 21 C.F.R. § 56.111(a)(2) (2005); 45 C.F.R. § 46.111(a)(2) (2005) (instructing IRBs to consider whether the “[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”).

332. 45 C.F.R. § 46.111(a)(3) (2005) (directing IRBs to be “particularly cognizant of the special problems of research involving vulnerable populations, such as . . . economically or educationally disadvantaged persons”).

333. See 21 C.F.R. § 50.25 (2005); 45 C.F.R. § 46.116 (2005) (detailing requirements for informed consent and stating that the information conveyed “shall be in language understandable to the subject or the representative”); see also Hoffman, *supra* note 290, at 484-90 (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. CLINICAL ONCOLOGY 2211, 2212 (1994) (finding that the average person cannot read the typical consent form that describes a clinical oncology protocol because the consent form is often too complex and the average person reads at approximately an eighth grade reading level, and the mean grade level required for comprehension of the forms that were studied was between 11.1 and 14.1, depending on the index used).

short as possible, with language that is targeted at an adequately low reading comprehension level.<sup>334</sup> 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.<sup>335</sup>

Finally, the informed consent process should clearly disclose to subjects that the clinical study is limited to those with particular attributes. Some individuals may be concerned about potential stigmatization, discrimination, or other adverse consequences of attribute-based medical research and practice<sup>336</sup> 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.<sup>337</sup> 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 understand medical data. The informed consent process should include disclosure of the inclusion and exclusion criteria for the research project.<sup>338</sup> 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

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334. See 45 C.F.R. § 46.111(b) (instructing IRBs to examine safeguards implemented to protect economically disadvantaged subjects and other vulnerable populations).

335. See *id.* (recommending that IRBs examine safeguards that protect participants from coercion).

336. See *supra* Part III (discussing the risks and dangers of “racial profiling” in medicine).

337. See *supra* Part V.A.

338. See *supra* Part V.A.2 (detailing concerns that some subjects may have about participating in attribute-based medical research).

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% of babies categorized as Black at birth were deemed to be other than Black on their death certificates, and thirty-seven percent of those categorized as Native American on their birth certificates were classified differently on their death certificates.<sup>339</sup> The confusion is often due to the mixed ancestral origins of so many Americans.<sup>340</sup> Another study that asked respondents to identify "ambiguous race faces" found only a sixty-eight percent "correct" identification rate.<sup>341</sup>

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 non-Black or has a Jewish or non-Jewish sounding last name in deciding whether to discuss the topic. Instead, they should ask their patients specific questions about their ancestry.<sup>342</sup>

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

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339. Robert A. Hahn et al., *Inconsistencies in Coding Race and Ethnicity Between Birth and Death in US Infants*, 267 J. AM. MED. ASS'N 259, 260-61 (1992).

340. See *supra* notes 154-157 and accompanying text (emphasizing that seven million Americans chose two or more "races" by which to describe themselves in the 2000 census).

341. Otto H. MacLin & Roy S. Malpass, *Racial Categorization of Faces: The Ambiguous-Race Face Effect*, 7 PSYCHOL. PUB. POL'Y & L. 98, 105-06 (2001) (reporting that in their study, "sixty-eight percent of the Black faces (ambiguous race face + Afro hair feature) were classified as Black, seven percent as Hispanic, one percent Indian, three percent White, two percent Asian, and nineteen percent as other" while of "Hispanic faces (ambiguous race face + Hispanic hair feature), sixty-eight percent were classified as Hispanic, one percent as Black, seven percent Indian, three percent White, three percent Asian, and eighteen percent Other"). The faces that were shown to participants were created using a "facial composite construction kit." *Id.* at 105. See also Raymond Bruyer et al., *Ethnic Categorization of Faces is not Independent of Face Identity*, 33 PERCEPTION 169, 169 (2003) (finding that familiarity with particular facial features affected ethnic identification); Peter N. Shapiro & Steven Penrod, *Meta-Analysis of Facial Identification Studies*, 100 PSYCHOL. BULL. 139, 139, 151 (1986) (discussing the variables that influence facial identification).

342. See Feldman, *supra* note 126, 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").

responses will often depend on socio-economic factors, specific alleles that are shared by several populations, or other elements.<sup>343</sup> 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 promote their careers, enhance opportunities for further funding of their projects,<sup>344</sup> or please sponsors who are supporting their studies.<sup>345</sup> Investigators have been criticized for seeking publicity for "hot" research news prematurely,<sup>346</sup> either for personal gain or in order to promote the financial support that is necessary for the maintenance of research facilities.<sup>347</sup> 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.<sup>348</sup>

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343. See *supra* Part III.A (relating the dangers of "racial profiling" in medical diagnosis and research).

344. Dorothy Nelkin, *An Uneasy Relationship: The Tensions Between Medicine and The Media*, 347 THE LANCET 1600, 1601 (1996) (relating several examples of researchers who misrepresented information in an effort to attract venture capital or media attention for their research). Researchers at the University of Utah, for example, approached the media with news of cold fusion, hoping to attract venture capital to their research. *Id.* In another instance, behavioral psychologists at the University of Minnesota sought press coverage for studies that had been rejected by peer reviewed journals. *Id.*; see Douglas G. Altman et al., *Is There a Case for an International Medical Scientific Press Council?*, 272 J. AM. MED. ASS'N 166, 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).

345. See Celeste Condit, *Science Reporting to the Public: Does the Message Get Twisted?*, 170 CAN. MED. ASS'N J. 1415, 1416 (2004) (describing the financial, professional, and commercial pressures faced by medical researchers).

346. See *id.* (cautioning researchers against answering journalists' inquiries with an enthusiastic forecast of a drug's potential applications).

347. *Id.*

348. See *id.* (stating that "scientists and their institutions are increasingly seeking to

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*,<sup>349</sup> which require federal agencies to develop mechanisms to safeguard the “objectivity, utility, and integrity” of the information they release.<sup>350</sup> 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.<sup>351</sup>

At the same time, the media has been criticized for distortions in its reporting of scientific information.<sup>352</sup> 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.<sup>353</sup> The media has also been criticized for reporting scientific data before it has been published in peer reviewed journals and thus, prior to its validation by experts in the field.<sup>354</sup> Journalists may report results that they know to be preliminary, unclear, or dubious as definitive and groundbreaking.<sup>355</sup> For example, a trial that shows that fifty-four percent of

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define science news and to shape the content and style of science communication”); 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. ASS’N J. 1399, 1399 (2004) (describing how the research community may “sell” science to the public, the scientific community, and research sponsors); 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”).

349. 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. 49718-25 (Sept. 28, 2001).

350. *Id.* at 49723.

351. 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 (Aug. 13, 2001), [www.aau.edu/research/OMBLtr8.13.01.html](http://www.aau.edu/research/OMBLtr8.13.01.html).

352. See Nelkin, *supra* note 344, 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”).

353. *Id.*; see Sarah A. Wilcox, *Cultural Context and the Conventions of Science Journalism: Drama and Contradiction in Media Coverage of Biological Ideas About Sexuality*, 20 CRITICAL STUD. MEDIA COMM. 225, 236-38 (2003) (finding that journalists include sensationalistic, absolutist, and dramatic statements in their stories in order to gain newspaper space).

354. 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).

355. See Condit, *supra* note 345, at 1415 (highlighting that journalistic reporting is



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.<sup>356</sup>

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.<sup>357</sup> 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.<sup>358</sup> The authors also found many shortcomings in the way information was conveyed in both types of newspapers, including inconsistencies, data gaps, and confusing descriptions.<sup>359</sup> 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 or viewers to underestimate health risks or undervalue certain medical choices, including 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.<sup>360</sup> These include the principles that journalists "should apply

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frequently characterized by an "overly optimistic slant"). *But see* Bubela & Caulfield, *supra* note 348, at 1399 (2004) (examining 627 newspaper articles and finding that that most articles accurately report the results but nonetheless overemphasize the benefits and underrepresent risks); Caulfield, *supra* note 348, 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).

356. *See* 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 attract readers and noting the pressures placed on reporters by editors whose sole mission it is to maximize circulation).

357. *Id.* at 107.

358. *Id.* at 99. Jews were assumed to be more interested in genetic influences on cancer because of the BRCA 1/2 genetic abnormality, which is associated with Ashkenazi Jews. *See supra* notes 173-174 and accompanying text (discussing the BRCA1 and BRCA2 alleles).

359. *Id.* at 107-09; *see* 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, 336-37 (2005) (reporting that "[c]ancer coverage in ethnic and mainstream newspapers did not accurately reflect the leading causes of cancer death in Canada"). The authors suggest that cancer data should be collected by minority populations in Canada so that at-risk populations can be better served and educated. *Id.*

360. AM. MED. WRITERS ASS'N, CODE OF ETHICS OF THE AMERICAN MEDICAL WRITERS

objectivity, scientific accuracy and rigor, and fair balance,”<sup>361</sup> that journalists “[t]est the accuracy of information from all sources,”<sup>362</sup> and that they “[a]void stereotyping by race” or other classifications.<sup>363</sup> 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.<sup>364</sup> 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.<sup>365</sup> Furthermore, some may feel justified in discriminating against particular population groups in the workplace or elsewhere based on allegedly hard data.<sup>366</sup> 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.<sup>367</sup>

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.<sup>368</sup> A robust body of literature is emerging concerning DTC advertising,<sup>369</sup> and an

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ASSOCIATION (1994) [hereinafter AMWA CODE], [http://www.presscouncils.org/librar y/USA\\_medical\\_writers.doc](http://www.presscouncils.org/librar y/USA_medical_writers.doc); SOC’Y OF PROF. JOURNALISTS, CODE OF ETHICS (1996) [hereinafter SPJ CODE], [http://www.spj.org/ethics\\_code.asp](http://www.spj.org/ethics_code.asp); see CODES OF PROFESSIONAL RESPONSIBILITY: ETHICS STANDARDS IN BUSINESS, HEALTH, AND LAW 187-90, 194-95, 199-201, 266-69 (Rena A. Gorlin ed., 4th ed. 1999) (reproducing codes of ethics promulgated by the American Society of Journalists and Authors, the American Society of Newspaper Editors, the Society of Professional Journalists, and the American Hospital Association, all of which address truth and accuracy requirements).

361. AMWA CODE, *supra* note 360.

362. SPJ CODE, *supra* note 360.

363. *See id.*

364. *See* Tim Radford, *Influence and Power of the Media*, 347 THE LANCET 1533, 1533, 1535 (1996) (discussing the role of the media as a source of information for the public).

365. *See* Condit & Bates, *supra* note 4, at 102 (underscoring the concern that research linking “race,” genetics, and health can have the inadvertent and unfortunate consequence of increasing racism).

366. *See supra* Part III.B.

367. *See* Condit, *supra* note 345, at 1416 (proposing guidance for researchers who communicate with the media). Condit advises researchers that they “must prepare for such interviews as carefully as they would prepare for a talk at a scientific conference.” *Id.*; *see also* Eliza Mountcastle-Shah et al., *Assessing Mass Media Reporting of Disease-Related Genetic Discoveries*, 24 SCI. COMM. 458, 458 (2003) (developing an instrument to assess the “content and balance of mass media stories about genetic discoveries . . .”).

368. *See* Saul, *supra* note 1 (announcing the approval of BiDil as a drug to treat African-American heart failure patients).

369. *E.g.*, Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct to Consumer Pharmaceutical Advertising on the Learned Intermediary*

extensive analysis of this phenomenon is beyond the scope 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.

#### CONCLUSION

The medical community is demonstrating a growing interest in “racially-tailored” medical practice and research.<sup>370</sup> “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.<sup>371</sup> “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.<sup>372</sup> 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.<sup>373</sup>

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.<sup>374</sup> 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.”<sup>375</sup>

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.<sup>376</sup> Health care professionals should avoid making

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*Doctrine*, 20 CAMPBELL L. REV. 113 (1997); 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 NEW ENG. J. MED. 325 (2005).

370. Condit & Bates, *supra* note 4.

371. *See supra* Parts V.A and V.B (delineating recommendations for reviewers and health care professionals).

372. *See supra* Part II (examining the meaning of the concept of “race”).

373. *See supra* Parts V.A and V.B (delineating recommendations for scientific reviewers, IRBs, and health care professionals).

374. *See supra* Parts III, IV (describing medical and legal problems associated with “race-based” medicine).

375. Richard S. Cooper, *Race and IQ: Molecular Genetics as Deus ex Machina*, 60 AM. PSYCHOL. 71, 75 (2005).

376. *See supra* Part V.A.

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.<sup>377</sup> 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 link health disparities such as differences in hypertension rates with non-biological factors, including diet, environment, exercise, and stress.<sup>378</sup> 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 limited resources, prudent decisions need to be made concerning funding allocation between medical research endeavors and other initiatives that could do as much or more to improve the health status of disadvantaged minorities. These include work in the areas of education, nutrition, environment, and job training.<sup>379</sup> 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.<sup>380</sup>

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.

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377. *See supra* Part V.B.

378. Kahn, *supra* note 64, at 481.

379. *Cf.* Kahn, *supra* note 64, at 481 (lamenting the "longstanding division between the professions of medicine and public health" that often prevents professionals in both fields from reaching the best solutions to particular problems).

380. *See id.* (observing that "environmental, psychosocial, and economic factors" may be more likely than biological factors to adequately explain "racial" disparities in health).