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## Funding Race as Biology: The Relevance of “Race” in Medical Research

Taunya Lovell Banks\*

### I. INTRODUCTION: ‘DEM BONES, ‘DEM BONES, ‘DEM “BLACK” BONES

In 1940 the State of North Carolina classified my friend as “colored” despite her “white skin, blue eyes, [and] curling blond hair.”<sup>1</sup> She—like her parents, grandparents, and many other black Americans—is often mistaken for white.<sup>2</sup> Sixty years later when she went for a bone densitometry test—a must for postmenopausal women—the technician asked her to fill out a form that asked her race. Surprised, she asked why. The technician explained that “since the bones of black people are different than the bones of white people, the doctor needed this information to interpret the scan correctly.”<sup>3</sup>

The radiologist who analyzed my friend’s bone scan acknowledged that there is a debate within the radiology

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1. Judy Scales-Trent, Bones Essay 1 (Nov. 7, 2008) (unpublished manuscript) (on file with author). In 1940 under the North Carolina State Constitution and the state anti-miscegenation statute a “negro” or “person of negro descent” was someone “of negro descent to the third generation, inclusive,” in other words, a “person who has one-eighth [or more] negro blood in his veins.” *State v. Miller*, 29 S.E.2d 751, 752 (N.C. 1944). *See also* N.C. CONST. art. XIV, § 8 (unenforceable in 1967); N.C. GEN. STAT. § 51-3 (1943).

2. *See generally* JUDY SCALES-TRENT, NOTES OF A WHITE BLACK WOMAN: RACE, COLOR, COMMUNITY 2 (1995); GREGORY HOWARD WILLIAMS, LIFE ON THE COLOR LINE: THE TRUE STORY OF A WHITE BOY WHO DISCOVERED HE WAS BLACK (1996).

3. Scales-Trent, *supra* note 1, at 1.

community about the scientific validity of interpreting an X-ray through the lens of race.<sup>4</sup> But, he claimed, it is impossible to interpret the bone scan without factoring in race because the machines that analyze the bone scan can only produce an analysis if the race of the person being analyzed is included.<sup>5</sup> The doctor could not explain how the x-ray machine defined “race,” replying that the definitions “were created by the companies that built the machines.”<sup>6</sup>

My friend asked if there was any way she could get more helpful advice about the condition of her bones.<sup>7</sup> The radiologist thought for a moment, then suggested that perhaps my friend should have her bone densitometry test performed twice, once as “white,” then as “black.”<sup>8</sup> The condition of her bones, he told her, would lie somewhere between the two results.<sup>9</sup> However, my friend concluded that “one-half of a fantasy definition of ‘white’ plus one-half of a fantasy definition of ‘black’ will only yield one whole fantasy: it will not provide a sound medical diagnosis.”<sup>10</sup> Thus she marked “black” or “African American” because that had always been her legal and social identity.<sup>11</sup> So what did the results really tell her doctor?

For years my friend taught and wrote about the social construction of race and knew that her doctor’s explanation about the use of race as a biological term by the radiology community was flawed.<sup>12</sup> She found it reminiscent of the World War II era when the Nazis kept “separate blood banks for ‘Jewish blood’ and ‘Aryan blood,’ [and] American blood banks were separating ‘white blood’ and ‘black blood.’”<sup>13</sup> The United States has a long and continuing history of “unconscionable medical research” involving black Americans.<sup>14</sup>

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4. *Id.* at 2. For further discussion regarding this debate see Anne Fausto-Sterling, *The Bare Bones of Race*, 38 SOC. STUD. SCI. 657, 659 (2008).

5. Scales-Trent, *supra* note 1, at 2.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.* at 3.

11. Telephone conversation with Professor Judy Scales-Trent, Professor Emerita at The University at Buffalo Law School (Sept. 20, 2010).

12. Scales-Trent, *supra* note 1, at 1–3.

13. *Id.* at 2.

14. HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES*

In 1950 the United Nations Educational, Scientific and Cultural Organization (UNESCO), mindful of race-science's dark and not so distant history,<sup>15</sup> drafted a statement on the use of race in modern science.<sup>16</sup> This statement, developed by an esteemed group of anthropologists, psychologists, and sociologists, concludes: “[f]or all practical social purposes ‘race’ is not so much a biological phenomenon as a [damaging] social myth.”<sup>17</sup> Today most scientists agree that race and ethnicity (ethno-race) classifications are the result of social and political conditions, as opposed to biological differences.<sup>18</sup> There is, however, disagreement about the scientific validity of these categories.<sup>19</sup>

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TO THE PRESENT 2 (2006).

15. Raj Bhopal, *Is Research into Ethnicity and Health Racist, Unsound, or Important Science?*, 314 BRIT. MED. J. 1751 (1997); Lundy Braun et al., *Racial Categories in Medical Practice: How Useful Are They?*, 4 PLOS MED. 1423 (2007); Charis Thompson, *Race Science*, THEORY, CULTURE & SOC'Y, May 2006, at 547; WASHINGTON, *supra* note 14.

16. *The Race Question in Modern Science: The Race Concept Result of an Inquiry*, UNITED NATIONS EDUC., SCIENTIFIC AND CULTURAL ORG. (1952), available at <http://unesdoc.unesco.org/images/0007/000733/073351eo.pdf>. UNESCO acted in response to “a resolution . . . adopted by the United Nations Economic and Social Council . . . asking UNESCO . . . to consider the desirability of initiating and recommending the general adoption of a programme of disseminating scientific facts designed to remove what is generally known as racial prejudice.” *Id.* at 6 (punctuation omitted).

17. *Id.* at 101. A half of century later the Human Genome Project seemed to confirm the scientific irrelevance of race, finding “high levels of genetic similarity within the human species.” Dorothy E. Roberts, *Legal Constraints on the Use of Race in Biomedical Research: Toward a Social Justice Framework*, 34 J.L. MED. & ETHICS 526, 526 (2006). For a discussion of the Human Genome Project see *All About the Human Genome Project*, NAT'L HUMAN GENOME RESEARCH PROJECT, <http://www.genome.gov/10001772> (last visited Dec. 7, 2010). As a result, some scholars speculated that genetic differences “would replace race as the preeminent means of grouping people for scientific purposes.” Roberts, *supra*, at 526. But genetic differences did not replace racial categories, instead, debates about the scientific validity of race reemerged in connection with genomic, biomedical and biotechnology research. *Id.*

18. See, e.g., Timothy Caulfield et al., *Race and Ancestry in Biomedical Research: Exploring the Challenges*, 1 GENOME MED 8.1, 8.2 (2009); Roberts, *supra* note 17, at 526.

19. See generally JENNY REARDON, RACE TO THE FINISH: IDENTITY AND GOVERNANCE IN AN AGE OF GENOMICS 4 (2005); S.O.Y. Keita & Rick A. Kittles, *The Persistence of Racial Thinking and the Myth of Racial Divergence*, 99 AM. ANTHROPOLOGIST 534 (1997); Dorothy Roberts, *What's Wrong with Race-Based Medicine?: Genes, Drugs, and Health Disparities*, 12 MINN. J.L. SCI. & TECH. 1, 2–7 (2011). Because self-identified ethno-race often serves as a “poor proxy for underlying genetic relatedness,” many researchers have begun

Even though an increasing number of scientists believe that too often ethno-race is used as a surrogate for various socioeconomic and environmental factors,<sup>20</sup> for most of the late twentieth century social science and medical researchers continued to use ethno-race in a biological context.<sup>21</sup>

Nevertheless, there are times when ethno-racial designations have value in medical research. As one scholar writes, “using race as a *social* category” to study the impact of racism on health and access to medical care is critical to eliminating health inequities based on race.<sup>22</sup> But, she cautions that using race as a *biological* category can reflect and reinforce racial stratification as well as racist notions of inherent human difference.<sup>23</sup> Several commentators call this phenomenon the reification of race, where the social concept of race is transformed “into a specific, definite, concrete, and now presumably genetic category which can feed back into preexisting lay understandings of racial difference.”<sup>24</sup>

Congress regulates a great deal of medical research with the promise of federal monies. The relevance of ethno-race in medical research has been heightened by two decades of federal legislation, most notably the U.S. National Institutes of Health Revitalization Act of 1993 (Revitalization Act), which contains initiatives on minority health.<sup>25</sup> The Revitalization Act requires that, among other things, women and “minority

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using DNA estimates of ancestry (ancestral DNA) in genetic-association research. Caulfield et al., *supra* note 18, at 8.2. The major genetic variations, however, correspond to the major continents, giving rise to the same racial distinctions the use of ancestry seeks to avoid. *Id.* at 8.2.

20. Otis W. Brawley & Harold P. Freeman, *Race and Outcomes: Is This the End of the Beginning for Minority Health Research?*, 91 J. NAT'L CANCER INST. 1908, 1908 (1999).

21. See Braun, *supra* note 15, at 1424.

22. Roberts, *supra* note 17, at 527.

23. *Id.*

24. OSAGIE K. OBASOGIE, CENTER FOR GENETICS & SOC'Y, PLAYING THE GENE CARD? A REPORT ON RACE AND HUMAN BIOTECHNOLOGY 5 (2009), available at [http://geneticsandsociety.org/downloads/complete\\_PTGC.pdf](http://geneticsandsociety.org/downloads/complete_PTGC.pdf). Jonathan Kahn argues that the approval of BiDil signals that “powerful federal agencies have acknowledged the legitimacy of using race as a marker for biological difference.” Jonathan Kahn, *How a Drug Becomes “Ethnic”: Law, Commerce, and the Production of Racial Categories in Medicine*, 4 YALE J. HEALTH POL'Y & ETHICS 1, 33 (2004). Anthropologist Alan Goodman characterizes this type of research as a “comeback” in “racialized notions of biology.” *Id.*

25. See 42 U.S.C. § 201 (1993); see also Roberts, *supra* note 17, at 527.

groups” be included in all intramural and extramural National Institutes of Health (NIH) funded biomedical and behavioral research.<sup>26</sup> Since most biomedical research is funding driven, minority health initiatives may, by promoting greater racial diversity among clinical subjects, generate a medical research market that unintentionally promotes the misuse of ethno-race.<sup>27</sup>

Some commentators express concern about the resulting re-emergence of race in biomedical studies, but most concede that legal challenges to the current medical research practices may not be the most effective means of quickly minimizing or remedying the problem.<sup>28</sup> Further, litigation may actually discourage needed and valid race related studies.<sup>29</sup> Courts, searching for ethno-racial medical biases, may become overzealous and act in ways that actually thwart positive race-related medical research, such as inquiries into access to care and equal treatment.<sup>30</sup> In addition, federally funded biomedical research that uses race inappropriately is socially harmful because, as I will discuss throughout this article, the practice tends to perpetuate the disputed notion that race is biological, and it evokes the historical baggage associated with race-science. Thus, due to the probable ineffectiveness of legal challenges, some government regulation or oversight is warranted where public funds are involved.

Only a handful of legal scholars have addressed the dangers inherent in the uncritical use of ethno-race in medical studies and the debates within the biomedical research community about the use of ethno-race in research.<sup>31</sup> None, I

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26. Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women's Health Care*, 32 HOUS. L. REV. 1201, 1231 (1996).

27. See Roberts, *supra* note 17, at 529.

28. For a discussion of this point see Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J.L. MED. & ETHICS 491, 494–95 (2008) (discussing the strengths and weaknesses of applying a constitutional law based “strict scrutiny” approach to the use of race-specific labels in the pharmaceutical field).

29. Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391, 466–68 (2004) (noting the potential loss of certain beneficial race-based medical research).

30. *Id.* at 466.

31. See Kahn, *supra* note 24 (arguing for tighter Food and Drug Administration (FDA) regulation of race specific drugs); Lillquist & Sullivan, *supra* note 29 (exploring the constitutionality of using race in scientific research); Obasogie, *supra* note 28 (focusing on the role of the FDA in determining whether to approve race specific medicine); Roberts, *supra* note

contend, provide a comprehensive overview of the issue nor propose an effective remedy. While there is a general consensus that race and other social classifications influence health, “there is little agreement about why or how [ethno-] race matters, how best to study its effects and how to translate and communicate research results from racially stratified studies.”<sup>32</sup>

Legal scholar Dorothy Roberts posits that “[f]ederal funding agencies’ control over the funding for biomedical research is a powerful basis for restricting the use of race” in medical studies.<sup>33</sup> She also offers a few general suggestions for how funding restrictions might operate.<sup>34</sup> In this article I build on Roberts’ initial suggestions by offering more specific recommendations for federal funding restrictions on biomedical research that uses ethno-racial categories.

This article proceeds from the assumption that there are few clear instances, other than perhaps access to health care or measuring equality in medical treatment, where the use of ethno-race in medical research is appropriate. Even in those limited situations the justification for using ethno-race, how the ethno-racial categories are defined, and the method for assigning ethno-race warrant close scrutiny and oversight, especially when these studies are funded with federal money. In the next section, this article explains the scientific basis for that assertion. First, it explores the debates within the medical community about the connection between race and biology in biomedicine. Then it examines literature on race-related stress to determine whether this might be an instance where ethno-racial labels help explain health outcomes, and argues that

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17 (proposing a “social justice framework” designed to encourage the appropriate use of race in medical research); Michael D. Ruel, *Using Race in Clinical Research to Develop Tailored Medications Is the FDA Encouraging Discrimination or Eliminating Traditional Disparities in Health Care for African Americans?*, 27 J. LEGAL MED. 225 (2006) (arguing that while using race in medical trials is acceptable, the government needs to develop rules on this based on scientific evidence to make sure discrimination does not occur).

32. Caulfield et al., *supra* note 18, at 8.2 (concluding that “[r]esearch that simultaneously assesses both genetic and environmental contributions to disease risk, drug response and other health-related variation, and that deliberately puts such findings in the context of self-identified race, is urgently needed,” or else race will continue to be used, problematically, in biomedical research).

33. Roberts, *supra* note 17, at 529.

34. *Id.* at 530–33.

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guidelines or regulation are needed.

The third section of this article examines two sets of guidelines on the use of ethno-race in biomedical research: guidelines adopted by high impact medical journals, and federal guidelines on the use of ethno-race in federally funded biomedical research. Finding these measures inadequate, this article argues that the only way to quickly change research behavior in this area is through greater regulation and oversight of federal medical research grants. More stringent government regulation and oversight of federally funded biomedical research grants that use ethno-race may trigger changes in the medical culture faster than litigation.

In the fourth section this article proposes a regulatory scheme that offers a standard to measure the appropriateness of ethno-race in applications for federally funded biomedical research that will cause both researchers and grant reviewers to give more thought to how and why ethno-race is used in research protocols. This article concedes that this proposal is only a first step, and acknowledges that meaningful progress also requires strong and effective measures designed to change how biology is taught in undergraduate, graduate, and professional schools. But without a change in the medical culture, another generation of researchers and health care providers will be trained to think about ethno-racial differences inappropriately.

Before effective remedies for the problem described can be discussed, it is important to clarify both the meaning and use of the term “race” in scientific discussions. The next section of this paper looks at debates within the scientific community about the meaning of ethno-racial labels.



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## II. "IF RACE IS THE ANSWER, WHAT IS THE QUESTION?"<sup>35</sup> DEBATES ON THE USE OF RACE IN RESEARCH

### A. LINKS BETWEEN RACE AND BIOLOGY

#### 1. Contemporary Debates

In the late nineteenth century "scientists [named and] ranked races on their biological and social worth."<sup>36</sup> Much of the resulting research from this era is "racist, unethical, and ineffective."<sup>37</sup> Even more troubling, race-science was used to justify slavery, anti-immigration policies, and imperialism.<sup>38</sup> Although race-science was abandoned by the mid-twentieth century, a few researchers in the 1990s expressed concerns that ethno-race was still being misused in contemporary biomedical research.<sup>39</sup> This section looks at the debates within research communities about the use of racial categories in biomedical research.

Most contemporary scientists concede that nineteenth century stereotypes of race and racial variations probably reflect the superficial understanding of the relationship between ethno-race and biological difference or lack of

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35. Taken from the title of an article about the misuse of "race" as explaining persistent health outcome disparities among racial and ethnic groups in the United States. Nancy Krieger, *If "Race" is the Answer, What is the Question?—On "Race," Racism, and Health: A Social Epidemiologist's Perspective*, IS RACE REAL?, SOC. SCI. RES. COUNCIL (June 7, 2006), <http://raceandgenomics.ssrc.org/Krieger/>.

36. Bhopal, *supra* note 15, at 1751.

37. *Id.*

38. *Id.*

39. See Trevor A. Sheldon & Hilda Parker, *Race and Ethnicity in Health Research*, 14 J. PUB. HEALTH MED. 104, 104 (1992). The authors write that "[h]ealth research appears to be reflecting the process of 'racialization' . . . whereby the idea of race or ethnicity is increasingly being introduced to help define or give meaning to the population [being studied]" and argue for more thought and care in the use of race and ethnicity as health research variables. Their article was part of a debate within the United Kingdom about the use and misuse of race and ethnicity. See, e.g., R.S. Bhopal et al., *Inappropriate Use of the Term 'Asian': An Obstacle to Ethnicity and Health Research*, 13 J. PUB. HEALTH MED. 244 (1991); Jenny L. Donovan, *Ethnicity and Health: A Research Review*, 19 SOC. SCI. MED. 663, 668 (1984) (concluding that studying particular diseases or illnesses affecting ethnic groups tends to place blame on subalterns rather than attributing these health problems to economic and social structures).

difference held by scientists in that era.<sup>40</sup> The debate continues, however, over whether race has *any* legitimacy as a scientific concept, and more fundamentally, whether and how to study human biological diversity. Biologist Marcus Feldman and his co-authors write: “[t]he issue of whether race is a biologically useful or even meaningful concept when applied to humans in a medical context is controversial.”<sup>41</sup> But the authors claim that there really is “no contradiction” between the bodies of evidence on each side of the debate. This is because the issue conflates two different questions: whether distinguishable DNA sequences related to “major geographical origin” exist and whether “most genetic diversity occurs within groups.”<sup>42</sup> The answer to both questions, according to the authors, is yes.<sup>43</sup> Therefore, those who argue that race is relevant present evidence linking race to geographic origin, and those who argue that race is irrelevant present evidence of genetic diversity within racial groups.

This debate does not contest the use of socially constructed ethno-racial categories to measure differences in access to health care, delivery of health care, and equal medical treatment. Studies such as these measure *social* attitudes of health care providers. Therefore, they are distinguishable from studies that use ethno-race to explain *biological* differences in disease or medical outcomes unrelated to social disparities in health care.<sup>44</sup> Nevertheless, as my friend’s bone density test experience illustrates, the undifferentiated connection between race and biology persists in America.

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40. See, e.g., Bhopal *supra* note 15, at 1752; Braun, *supra* note 15, at 1724; Thompson, *supra* note 15, at 547.

41. Marcus W. Feldman et al., *A Genetic Melting-Pot*, 424 NATURE 374, 374 (2003). The authors explain:

Race as a biological concept has had a variety of meanings. In the taxonomic literature, a race is any distinguishable type within a species . . . . In 1937, Theodosius Dobzhansky introduced the idea of geographical races—populations of species that differ in the frequencies of one or more genetic variants . . . . The classical definition of race . . . is based on phenotypes such as skin colour, facial features and hair . . . . An underlying assumption is that all of these defining features . . . are characteristic of the genome in general.

*Id.*

42. *Id.*

43. *Id.*

44. See *supra* notes 1–13 and accompanying text.

## 2. SICKLE CELL DISEASE AND RACE

Discussing the connection between race and genetics, Feldman and his co-authors argue that ancestral geographical origin can be useful in diagnosis and treatment, but that a person's racial classification, whether self-identified or assigned, "is both too broad and too narrow a definition of ancestry to be biologically useful."<sup>45</sup> They specifically cite sickle-cell disease, widely thought by Americans to be a trait connected to African ancestry, but which in reality is "characteristic of ancient ancestry in a geographic region where malaria was endemic."<sup>46</sup> Since individuals with the sickle cell trait do not get malaria, researchers now believe that the trait is a genetic mutation that developed as a protective measure in areas around the world where malaria is common.<sup>47</sup>

Malaria most often found in Africa, once was common around the Mediterranean as well.<sup>48</sup> Thus, the trait also is found in "Portuguese, Spaniards, French Corsicans, Sardinians, Sicilians, mainland Italians, Greeks, Turks and Cypriots."<sup>49</sup> Today, sickle-cell disease is most common in Middle Eastern countries like Lebanon, Israel, Saudi Arabia, Kuwait and Yemen and Near Eastern countries like India and

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45. Feldman et al., *supra* note 41, at 374.

46. *Id.*; see also Anthony C. Allison, *Two Lessons From the Interface of Genetics and Medicine*, 166 GENETICS SOC'Y AM. 1591, 1592 (2004) (finding, when testing his hypothesis that sickle cell was related to malaria, that the "distribution, involving diverse populations, supported the belief that an environmental factor, malaria transmission, was the principle determinant of high sickle-cell frequencies"); Donovan, *supra* note 39, at 665 ("Sickle-cell anemia first occurred in Britain when immigrants arrived from Africa and the Caribbean where the disease had developed to give partial immunity to endemic malaria.").

47. See, e.g., Allison, *supra* note 46, at 1592-93; *Blood Diseases*, U. MD. MED. CENTER, <http://www.umm.edu/blood/sickle.htm> (last updated Jan. 30, 2008).

48. *Blood Diseases*, *supra* note 47.

49. McKinley Health Center, *Sickle Cell Disease*, U. OF ILL. AT URBANA-CHAMPAIGN (Mar. 7, 2007), [http://www.mckinley.illinois.edu/handouts/sickle\\_cell\\_disease.html](http://www.mckinley.illinois.edu/handouts/sickle_cell_disease.html). According to the National Heart Lung and Blood Institute, sickle cell anemia is "most common in people whose families come from Africa, South or Central America (especially Panama), Caribbean islands, Mediterranean countries (such as Turkey, Greece, and Italy), India, and Saudi Arabia." See also *Who Is at Risk for Sickle Cell Anemia?*, NAT'L HEART LUNG AND BLOOD INST., [http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA\\_WhoIsAtRisk.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA_WhoIsAtRisk.html) (last visited Dec. 7, 2010).

Sri Lanka.<sup>50</sup>

The tendency in the United States to link sickle-cell disease to black Americans stems from the fact that black Americans are more likely than any other ethno-racial group in the country to have the sickle-cell trait.<sup>51</sup> A closer examination of the evidence indicates, however, that geography, rather than race, factors into the trait's prevalence.<sup>52</sup> Most black Americans are descendants of enslaved Africans from West and Central Africa where the disease is most common.<sup>53</sup> It follows, therefore, that in the United States, African ancestry is a factor in the prevalence of sickle-cell among black Americans. Although most states routinely test all newborns for the trait,<sup>54</sup> public health officials may continue to link sickle-cell to race and target only black Americans for outreach.<sup>55</sup> This results from an incorrect assumption that the prevalence of sickle cell among black Americans is due to a connection between biology and race.<sup>56</sup>

As Feldman and his co-authors caution, other variables like migration and mating may result in new populations, thus, “[a] person classified as ‘black’ or ‘Hispanic’ by social convention could have any mixture of ancestries, as defined by

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50. *Who Is at Risk for Sickle Cell Anemia?*, *supra* note 49.

51. Eight percent of African Americans have the sickle cell trait. DIV. OF BLOOD DISEASES AND RESOURCES, NAT'L INST. OF HEALTH, THE MANAGEMENT OF SICKLE CELL DISEASE 15 (4th ed. 2002), *available at* [http://www.nhlbi.nih.gov/health/prof/blood/sickle/sc\\_mngt.pdf](http://www.nhlbi.nih.gov/health/prof/blood/sickle/sc_mngt.pdf); *Learning About Sickle Cell Disease*, NAT'L HUMAN GENOME RESEARCH INSTITUTE, *available at* <http://www.genome.gov/page.cfm?pageID=10001219> (last visited Dec. 16, 2010) (“In the United States, sickle cell disease is most prevalent among African Americans. About one in 12 African Americans and about one in 100 Hispanic Americans carry the sickle cell trait . . .”).

52. *See generally* Allison, *supra* note 46.

53. *Who Is at Risk for Sickle Cell Anemia?*, *supra* note 49. According to the University of Maryland Medical Center, “[s]ickle cell disease primarily affects those of African descent and Hispanics of Caribbean ancestry, but the trait has also been found in those with Middle Eastern, Indian, Latin American, Native American, and Mediterranean heritage.” U. MD. MED. CTR., *supra* note 47.

54. U. MD. MED. CTR., *supra* note 47.

55. *See* Braun et al., *supra* note 15, at 1425–26 (arguing that “[i]n the case of sickle cell disease, it would be best to work from symptoms rather than racial assumptions, and to enquire about geographic ancestry since sickle cell is more prevalent in populations from the Mediterranean region, sub-Saharan Africa, and the Indian subcontinent”).

56. *Id.* at 1426.

continent of origin.”<sup>57</sup> Physicians might fail to test individuals for sickle cell disease because they are not classified as black. If the disease remains undiagnosed and untreated, severe medical consequences, or even death, may result. Thus, it may be more important to know a patient’s family medical history than race, since a person who identifies as black *or* white may have grandparents or great grandparents whose ancestral geographical origins include areas where the trait or disease is common.<sup>58</sup>

### 3. BONE DENSITY AND RACE

Similarly, some researchers continue to argue that there is a correlation between race and biology in bone density. According to the first sentence of an article in a 2008 issue of the *Journal of Nutrition*: “Diet and race are important predictors of areal bone mineral density (aBMD) and fracture risk.”<sup>59</sup> The introductory sentence reads like a general fact; it is not footnoted.<sup>60</sup> Under the subheading, *Racial differences in bone density*, the authors write:

African American men and women have higher aBMD than other racial groups, including American white, Asian, Hispanic, and Native Americans. Such differences are attenuated but still generally persist when aBMD data are adjusted for weight, bone size, and other

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57. Feldman et al., *supra* note 41, at 374 (arguing that social race “provides information about the social circumstances and lifestyle of patients”). However, even this description ignores the heterogeneity and class differences within populations raced as black in America.

58. “A ‘black’ person walking into a Boston, Massachusetts clinic could easily be the child of a recent immigrant from Ethiopia or Brazil who has a genetic makeup as well as cultural and environmental exposures that differ significantly from the descendants of 19th century US [sic] slaves from the western coast of Africa.” Braun et al., *supra* note 15, at 1426. Another researcher wrote: “In the case of sickle cell disease, it would be best to work from symptoms rather than racial assumptions, and to enquire about geographic ancestry.” *Id.* Thus Feldman et al. conclude that a better approach is to identify “all contributions to a patient’s ancestry” when “diagnosing and treating disease with genetic influences.” Feldman et al., *supra* note 41, at 374.

59. Marcella D. Walker et al., *Race and Diet Interactions in the Acquisition, Maintenance, and Loss of Bone*, 138 J. NUTRITION 1256S, 1256S (2008).

60. There is, however, reason to doubt these “important predictors.” See Marc C. Hochberg, *Racial Differences in Bone Strength*, 118 TRANSACTIONS AM. CLIN. & CLIMATOLOGICAL ASS’N 305, 308–10 (2007) (discussing several studies that support the claim that whites have lower bone mineral density than blacks).

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covariates, such as physical activity, calcium intake, smoking, and alcohol use.<sup>61</sup>

The authors base these statements on earlier studies of fracture risk and bone density among various ethnic groups.<sup>62</sup> These earlier studies are the basis for the different measurement standards for determining bone density that were applied to my friend.

The same year as the aforementioned study, biologist and feminist scholar Anne Fausto-Sterling asked whether accepted studies on bone density that report notable differences based on race *really* reflect racial differences and if so, what this means “biologically and socially.”<sup>63</sup> Fausto-Sterling looked at a sample of published research to determine how researchers defined race in studies examining claims about the relationship between race and bones. She notes that many early papers discussing bone density cite to Mildred Trotter’s work in the 1960s and 1970s,<sup>64</sup> but that new technology prompted a shift away from Trotter’s methods to large-scale studies.<sup>65</sup> The change in methodology, however, was not accompanied by a shift in thought about the use of race as a factor. Fausto-Sterling takes issue with these modern studies, arguing they reveal “profound inconsistencies in the definitions and modes of ascertainment of racial categories, a lack of theory about why race might be an important study variable, and no clear rationale about how race might exert effects on bone biology.”<sup>66</sup>

Yet papers addressing bone density into the early twenty-first century still began with the presumption that race-based differences in bone density are “incontrovertibly established.”<sup>67</sup>

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61. Walker et al., *supra* note 59, at 1256S–57S.

62. *Id.*

63. Fausto-Sterling, *supra* note 4, at 659. Fausto-Sterling’s question applies to biomedical, biotechnological, and genomic research generally, but this article only focuses on biomedical or medical research.

64. Trotter was a well-known anatomist and anthropologist whose professional career spanned from 1922 until 1984. “Her research led to discoveries about the structure and distribution of hair, and the growth, racial and sexual differences, and aging of the human skeleton. Additionally, her work in skeletal biology led to the creation of formulas to estimate stature based on the lengths of long leg bones.” *Missouri Women in the Health Sciences: Mildred Trotter*, WASH. U. ST. LOUIS SCH. OF MEDICINE, <http://beckerexhibits.wustl.edu/mowihsp/bios/trotter.htm> (last visited Dec. 7, 2010).

65. Fausto-Sterling, *supra* note 4, at 661.

66. *Id.* at 662.

67. *Id.*

As such, Fausto-Sterling argues based on her research, these studies are suspect because the scientists used race uncritically.<sup>68</sup> She is not alone in her criticism, which applies equally to other medical research studies.

#### B. DEBUNKING THE LINK BETWEEN RACE AND BIOLOGY

In the late 1990s, American social scientists spoke out strongly against connecting race with biology. After studying the issue, the Executive Committee of the American Anthropological Association (AAA) concluded: “present-day inequalities between so-called ‘racial’ groups are not consequences of their biological inheritance but products of historical and contemporary social, economic, educational, and political circumstances.”<sup>69</sup> The AAA’s statement reflects the concerns expressed two years earlier by British social researchers attempting to fashion a framework for the

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68. She writes that “the social [notion of racial distinction] *produces* the biological in a system of constant feedback between body and social experience.” *Id.* at 658 (emphasis in original). The accepted scientific assumption for bone disease in adults is that white and Asian women are at highest risk, followed by Hispanic women, then by white and Asian men, then Hispanic men, then black men. Black women have rates similar to white men. *Id.* Further, as my colleague Amanda Pustilnik commented to me, even if these findings were real, their significance is open to question. If what matters is fracture risk, and fracture risk results from current bone density—not percentage of bone loss from baseline—then a starting point would seem irrelevant. But if a starting point mattered, then it seems that the doctor would want to compare that patient’s current results to her own, individual scan taken at Time 1. There must be all kinds of starting point bone density differences, depending on childhood nutrition, individual genetics, childhood sports, etc. So not only is the “racial” dimension of this claim questionable, the whole starting point position seems to be a pure nonsense dimension.

69. *Statement on “Race”*, AM. ANTHROPOLOGICAL ASS’N (May 17, 1998), <http://www.aaanet.org/stmts/racepp.htm>. A few years earlier the AAA adopted a resolution that read in part: “differentiating species into biologically defined ‘races’ has proven meaningless and unscientific as a way of explaining variation.” *Statement on “Race” and Intelligence*, AM. ANTHROPOLOGICAL ASS’N (Dec. 1994), <http://www.aaanet.org/stmts/race.htm>. Almost a decade later, social scientist Troy Duster repeated this concern about the “current understandings of the relationship between race and disease . . . [and the increasing reliance on] genetically oriented biomedical scientists . . . to define and identify causes for a wide-ranging set of problems—from alcoholism to gender and racial health disparities.” Fausto-Sterling, *supra* note 4, at 657 (citing the 2005 inaugural address of Troy Duster, *Comparative Perspectives and Competing Explanations: Taking on the Newly Configured Reductionist Challenge to Sociology*, AM. SOC. REV 1 (2006)).

“classification of ethnic or cultural groups.”<sup>70</sup> They argued that when medical researchers use ethno-racial categories, under the belief that ethno-race explains the differences in disease patterns, the onus should be on the researchers to clearly establish the biological correlation.<sup>71</sup> Unlike the British model, the later AAA statement contains no qualifiers; no circumstances when the use of ethno-racial classifications is warranted. This absolutist approach is a sticking point with some researchers who believe that there are instances where ethno-racial categories can function as both an *ascriptive* factor (“to identify the causal mechanisms involved and to select clinical interventions”)<sup>72</sup> and as a *descriptive* factor (“to document progress in the health status of populations”).<sup>73</sup> Other researchers argue that ethno-race is only relevant in biomedical research as a descriptor. But even in this instance researchers have yet to agree on how to define ethno-racial categories.

Two articles that appeared in the September 2007 issue of *PLoS Medicine*, a peer-reviewed journal published by the Public Library of Science, illustrate the ongoing debate in the medical research community about the use of ethno-race. The first, written by Lundy Braun (with Fausto-Sterling and other co-authors), begins by drawing the distinction between the importance of the *descriptive* use of racial and ethnic categories, as negative health outcomes differ among racial and ethnic groups, and the widespread *ascriptive* use of U.S. census ethno-racial categories in biomedical research.<sup>74</sup> The misuse of ethno-racial categories in the latter instance, Braun et al. argue, is reinforced by the National Institutes of Health’s (NIH) funding regulations designed to ensure greater inclusion of

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70. Kwame McKenzie, *Describing Race, Ethnicity, and Culture in Medical Research*, 312 BRIT. MED. J. 1054, 1054 (1996) (also noting that the U.K. adopted categories used by the Office of Population Censuses and Surveys for use in the 1991 census). See also Mike Pringle & Ian Rothera, *Practicality of Recording Patient Ethnicity in General Practice: Descriptive Intervention Study and Attitude Survey*, 312 BRIT. MED. J. 1080, 1082 (1996) (ethnicity should be self-defined and is of questionable value in general practice).

71. See McKenzie, *supra* note 70.

72. George T.H. Ellison et al., *Racial Categories in Medicine: A Failure of Evidence-Based Practice?*, 4 PLOS MED. 1434, 1434 (2007).

73. Braun et al., *supra* note 15, at 1427. See also Ellison et al., *supra* note 72, at 1424 (defining the descriptive use as “to identify differences in health and health care that warrant further investigation and intervention”).

74. Braun et al., *supra* note 15, at 1423.



racial/ethnic minorities in clinical research.<sup>75</sup> These regulations use the racial and ethnic categories as defined by the U.S. Office of Management and Budget (OMB)'s Directive No. 15<sup>76</sup> to measure inclusion rates. The result is "poorly defined racial categories [that become] reified in biomedical research practices."<sup>77</sup>

Consider, for example, the classification problem that might arise if a clinical protocol calls for the physician to identify the race of a man who immigrated to the United States at a young age and self-identifies as Cape Verdean.<sup>78</sup> "The large Cape Verdean population in New England resists any simple categorization. The inhabitants are the descendents of Portuguese colonists, former slaves, explorers, and sailors of

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75. *Id.* at 1424 (noting that the Institute of Medicine's (IOM) definition of race, is an example of how "granting agencies' regulations do little to clarify the extent to which racial and ethnic categories are intended to capture biological, cultural, or social dimensions of human diversity").

76. *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, U.S. DEP'T HEALTH & HUM. SERVS. (Oct. 2001), [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). For a discussion of this point, see Braun et al., *supra* note 15, at 1424. The American Anthropological Association describes OMB Directive 15 as follows:

The Statistical Policy Division, Office of Information and Regulatory Affairs, of the Office of Management and Budget (OMB) determines federal standards for the reporting of "racial" and "ethnic" statistics. In this capacity, OMB promulgated Directive 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting in May, 1977, to standardize the collection of racial and ethnic information among federal agencies and to include data on persons of Hispanic origins, as required by Congress. Directive 15 is used in the collection of information on "racial" and "ethnic" populations not only by federal agencies, but also, to be consistent with national information, by researchers, business, and industry as well.

Directive 15 described four races (i.e., American Indian or Alaskan Native, Asian or Pacific Islander, Black, and White) and two ethnic backgrounds (of Hispanic origin and not of Hispanic origin). The Directive's categories allowed collection of more detailed information as long as it could be aggregated to the specified categories.

*American Anthropological Association Response to OMB Directive 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting*, AM. ANTHROPOLOGICAL ASS'N (Sept. 1997), <http://www.aaanet.org/gvt/ombdraft.htm> [hereinafter *Response to OMB Directive 15*].

77. Braun et al., *supra* note 15, at 1423-24.

78. *Id.* at 1424.

various nationalities.”<sup>79</sup> Given this reality, is the subject black? Is the subject “now African American or should [the physician] consider [the subject’s] health needs from the perspective of his immigrant status? The data on response to therapy seem to suggest that hypertension in blacks is somehow special, implying a separate genetic factor for blacks.”<sup>80</sup>

Given the historical misuse of ethno-racial categories in ways that perpetuate notions about racial inferiority, Braun et al. ask whether ethno-race is a useful factor to consider in determining medical care.<sup>81</sup> Their concern is that physicians, relying on race-based biomedical research, will make diagnoses or risk assessments and treatment decisions based on a person’s race rather than using a procedure that considers factors like environment, family history, stress, and other socioeconomic contributors to health disparities.<sup>82</sup> Braun et al. argue that because racial categories are deceptively simple they conceal diverse internal populations. For example, a person with black, white, and Native American ancestors may self-identify as black, as would a recent immigrant from Ethiopia. Rather than work from racial assumptions, some grounded in geographic ancestry, Braun et al., like Feldman and his co-authors, argue that researchers should focus on individual symptoms.<sup>83</sup> Otherwise, “[o]nce race is presumed . . . [c]linical clues can become invisible.”<sup>84</sup>

To counter this troubling trend, Braun et al. recommend educating medical researchers and practitioners about cultural competency, historical misuse of racial categories, current debates about the validity of ethno-race in medicine, limits of racial categorization in the medical context, population race

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79. *Id.*

80. *Id.* (explaining that “African Americans suffer at rates 3.5 times those of Nigerians living in Africa, although African Americans experience only 0.75 the rates of Germans in Germany. Which category matters more for [a] patient, country of origin or social status in the adopted nation?”) (internal citations omitted).

81. *Id.* at 1424–25.

82. *Id.*

83. *Id.* at 1426. Braun et al. also discuss the idea of cultural competency, espoused in some quarters, which encourages clinicians to “familiarize themselves with the history of the particular communities they serve.” Conceding that the approach may have some benefits (“[it] brings greater attention to the attitudes and behaviors that patients may bring to the clinical encounter”), they also believe it brings the danger that the clinician may see patients as “types” rather than individuals. *Id.*

84. *Id.* at 1425–26.

versus individual race, and geographical genetic variation.<sup>85</sup> While they acknowledge the need for “an international consensus” on the use of ethno-racial categories in science, they argue for more immediate action by the NIH in reevaluating its policies on racial categorization and by medical schools in improving their instruction on race in medicine.<sup>86</sup>

Medical anthropologist George T.H. Ellison and his co-authors recognize the challenges to instituting more precise attributive factors as well as the need to distinguish between the *descriptive* use of ethno-racial categories, and the *ascriptive* use of such categories.<sup>87</sup> Ellison and his co-authors, however, find Braun and her co-authors’ proposals problematic. First, they point to a “lack of consensus about what race and ethnicity mean and how these [categories] should be operationalised.”<sup>88</sup> Second, while researchers know that ethno-racial categories are inaccurate, Ellison et al. adopt a “pragmatic” approach to NIH requirements designed to insure greater representation of ethno-racial groups in research studies.<sup>89</sup> Ellison et al., like Braun et al., worry that the crude ethno-racial categories that NIH uses to monitor inclusion of racial and ethnic minorities in clinical trials and to describe differences in health care and health outcomes actually may be harmful. They warn that NIH policies that use OMB-like ethno-racial categories for these purposes may undermine efforts to ascertain “more precise

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85. *Id.* at 1426–27.

86. *Id.* at 1427. Braun et al. ends by restating the distinction drawn by anthropologist Michael Montoya between using ethno-race descriptively and ascriptively. *Id.*

87. Ellison et al., *supra* note 72, at 1435.

88. *Id.* at 1434. Ellison et al. concede this lack of consensus means that “researchers and practitioners may conflate the utility of racial and ethnic categories for sampling diverse study populations with their ability to identify and address aetiological variation therein.” *Id.* (internal citations omitted). Ellison et al. argue that Braun’s proposal “would require unprecedented agreement amongst a comprehensive international consortium of funders and providers” about the use of ethno-racial categories. *Id.* at 1436.

89. *Id.* Ellison et al. concede that “[t]he use of crude socio-political categories of race and ethnicity to describe variation in health risks and health needs, and to attribute these differences to innate genotypic and socio-cultural factors, has a long and discredited history.” *Id.* at 1435. In an effort to avoid stigmatizing particular racial or ethnic groups, some researchers “adopt the more socially acceptable term ‘ethnicity’ in preference to ‘race,’” while other researchers adopt “crude socio-political classifications” such as the OMB categories. *Id.*

*attributive* evidence.”<sup>90</sup> Ellison and his co-authors propose that ethno-racial categories be used only as “*descriptive* variables in different scientific, clinical, and social contexts.”<sup>91</sup> They argue that other genetic, cultural, or structural markers need to be identified and developed to provide a more precise causal connection of the disparities in health and health care.<sup>92</sup>

### C. STRESS AND BLACK AMERICANS: DOES SOCIAL RACE HAVE A BIOLOGICAL COMPONENT?

The foregoing discussion does not squarely address another question, whether there is validity in doing research on different race-based outcomes that flow from social and environmental factors. Arguably, there could be a biological yet socially created reality to race differences in health. This section explores what might be required to make such research useful.

Medical experts agree that stress can affect the onset, progression, and severity of illness, and that racism and race-related stress have an impact on health.<sup>93</sup> Stress literature

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90. *Id.* While racial and ethnic categories are helpful for descriptive purposes, Ellison et al. argue that “researchers and clinicians do need to be encouraged to use more specific attributive markers of genotype, culture, and structural disadvantage wherever appropriate.” They argue that the use of racial and ethnic categories in describing differences in health risks and outcomes might result in the same crude categories being misattributed as the cause of health differences. *Id.*

91. *Id.*

92. *Id.*

93. David R. Williams & Selina A. Mohammed, *Discrimination and Racial Disparities in Health: Evidence and Needed Research*, 32 J. BEHAV. MED. 20, 27 (2009) (explaining how, according to stress literature, stress affects the onset, progression, and severity of illness, and describing several health conditions that may be affected by stress, including five physiological categories where stress has been shown to affect symptoms (neuroendocrine system, cardiovascular system, gastrointestinal system, pain sensitivity and chronic pain, and immune function)). Williams and Mohammed also encourage future research that “focus[es] its attention on those outcomes where prior research has documented that stress in general is linked to health.” *Id.* at 38. See also Elizabeth Brondolo et al., *Race, Racism and Health: Disparities, Mechanisms, and Interventions*, 32 J. BEHAV. MED. 1, 3 (2009) (noting that exposure to racism, in any form, may initiate a series of “acute and enduring changes in cognition, affect, behavior, and psychophysiological responses”); Yin Paradies, *A Systematic Review of Empirical Research on Self-Reported Racism and Health*, 35 INT’L J. EPIDEMIOLOGY 888, 893 (2006) (reporting that a group of twenty-six studies revealed a significant association between self-reported racism and 44% of certain health outcomes, including blood pressure,

suggests that acute and chronic experiences with racism have different effects on illness and disease.<sup>94</sup> The strongest association has been found between racism and negative mental health outcomes.<sup>95</sup> Some studies have also found a relationship between racism and certain physical health risks, conditions, or behaviors.<sup>96</sup>

Overall, the associations between racism and health vary among different ethno-racial groups, with black Americans experiencing the strongest associations and white Americans experiencing the weakest associations, even when socioeconomic factors are taken into account.<sup>97</sup> It is important to note, however, that whites generally experience less racism than non-whites, which may explain the different race-related

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birth weight, BMI/obesity, and mortality; 36% of all negative health outcomes were significantly associated with racism).

94. Williams & Mohammed, *supra* note 93, at 33.

95. *Id.* at 22; Paradies, *supra* note 93, at 892.

96. See Paradies, *supra* note 93, at 893 (finding that 44% of negative physical health outcomes were “significantly associated with self-reported racism” based on measured physical health outcomes including blood pressure, birth weight, BMI/obesity, and mortality); Shawn O. Utsey et al., *Effect of Ethnic Group Membership on Ethnic Identity, Race-Related Stress and Quality of Life*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 366, 368 (2002) [hereinafter *Effect of Ethnic Group Membership*] (discussing the effects of race-related stress response on the immune, neuroendocrine, and cardiovascular systems); Shawn O. Utsey et al., *Race-Related Stress, Quality of Life Indicators, and Life Satisfaction Among Elderly African Americans*, 8 CULTURAL DIVERSITY & ETHNIC MINORITY PSYCHOL. 224, 225 (2002) [hereinafter *Race-Related Stress*] (explaining that racism has been associated with stress-related diseases such as hypertension, coronary heart disease, and cancer, as well as psychological ailments including depression).

97. See Deidre Franklin-Jackson & Robert T. Carter, *The Relationships Between Race-Related Stress, Racial Identity, and Mental Health for Black Americans*, 33 J. BLACK PSYCHOL. 5, 6 (2007) (noting studies that linked racism to various psychological symptoms and the hypothesis among scholars and researchers that Blacks may experience racism as a chronic or life event stressor); Hope Landrine et al., *Conceptualizing and Measuring Ethnic Discrimination in Health Research*, 29 J. BEHAV. MED. 79, 79 (2006) (stating that “[m]inorities who perceive and report individual-level ethnic discrimination have more physical and psychiatric symptoms and problematic health behaviors than their White and than their no-discrimination minority cohorts”); Chalsa M. Loo et al., *Measuring Exposure to Racism: Development and Validation of a Race-Related Stressor Scale (RRSS) for Asian American Vietnam Veterans*, 13 PSYCHOL. ASSESSMENT 503, 525 (2001); Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 96, at 366–67 (noting that African Americans have higher measures of race-related stress than Whites and Asians); .

stress levels.<sup>98</sup> Nevertheless, several comparative studies “found that self-reported racism was related to ill-health for African Americans and Latinos/as, but not [w]hites.”<sup>99</sup> Other studies found inverse associations, leading one researcher to conclude that “the association between self-reported racism and health-related outcomes for studies that included [w]hite participants is comparable with the findings of studies involving other ethnic/racial groups.”<sup>100</sup>

While factors like intensity, frequency, and duration of the stressor can affect negative outcomes,<sup>101</sup> further research is needed to determine whether racism is analogous to other stressors,<sup>102</sup> whether there is an association between mature stages of racial identity and less race-related stress,<sup>103</sup> and whether racial identity may modify the association between self-reported racism and ill health.<sup>104</sup> Research also is needed to determine the additional long-term effects of race-related stress.<sup>105</sup> Further illustrating the complexity of race in biomedicine, researchers acknowledge problems in conceptualizing and measuring racism.<sup>106</sup>

While early stress studies focused on health disparities between different ethno-racial groups, new research suggests that there are also differences *within* each racial group.<sup>107</sup> Thus, some commentators suggest that future research should consider both the differences *between* and *within* groups to determine whether ethnicity is “a moderating factor in the

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98. Paradies, *supra* note 93, at 891.

99. *Id.*

100. *Id.* at 893.

101. Williams & Mohammed, *supra* note 93, at 35–38.

102. *Id.* at 33.

103. Franklin-Jackson & Carter, *supra* note 97, at 18–19.

104. Paradies, *supra* note 93, at 893.

105. Utsey et al., *Race-Related Stress*, *supra* note 96, at 231 (stressing that professionals need to understand how racism as a chronic stressor affects quality of life). While coping strategies and socialization are specified by Utsey et al. as potential mediating factors, in another article, Utsey mentions a positive association between ethnic identity and quality of life. See Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 96, at 374.

106. See Brondolo et al., *supra* note 93, at 3 (“One of the most challenging issues in the study of racism has been its conceptualization and measurement . . . . Therefore, studies contrasting the prevalence and health effects of different categories of racism/ethnic discrimination are also needed, and this will require alterations in approaches to conceptualizing and measuring racism.”).

107. *Id.*

relationship of psychosocial stressors, such as racism, to health outcomes.”<sup>108</sup> These commentators also suggest that future studies focus on different categories of racism (cultural, institutional, individual) and the varying contexts in which racism occurs.<sup>109</sup>

The stress studies literature suggests that under some circumstances self-identified ethno-race, even though socially constructed, may be valid as a measure in scientific research. But even here, simplistic ethno-racial categories are inadequate measures. Following early studies that found “perceived racial discrimination contributed significantly to psychiatric symptoms among African Americans,” some researchers looked for a reliable way to measure perceived racial discrimination.<sup>110</sup> Each of these measures acknowledges that stress resulting in physical and mental illness is not triggered by social race alone, but is heavily linked to individual perceptions of race, the extent of racial and cultural self-identification, and how individuals experience and process racist or discriminatory behavior. Further, the stress response to racism and discrimination is associated with psychological and physiological reactions such as anxiety and paranoia, and the physiological responses primarily involve the immune,

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108. *Id.* Examples of psychophysiological reactivity cited were cortisol, blood pressure, and heart rate responses. *Id.* at 4.

109. *Id.* at 4. For additional commentary on the need for future research in this area, see David R. Williams et al., *The Concept of Race and Health Status in America*, 109 PUB. HEALTH REP. 26 (1994) (discussing the potential effects of racism and racial discrimination on health outcomes, particularly stress and hypertension, and the need for further research).

110. Loo et al., *supra* note 97, at 503–04. A proposed Race-Related Stressor Scale (RRSS) created three categories of race-related stressors: (1) racial prejudice and stigmatization (direct experiences of perceived discrimination or exclusion), (2) bicultural identification and conflict (identifying with a racial or ethnic minority and culture), and (3) racist environment (witnessing racist or discriminatory behavior). *Id.* at 504–05. The study applied this measure to Asian American Vietnam veterans finding that exposure to one, or a combination of, the three categories above contribute to Post Traumatic Stress Disorder (PTSD) and general psychiatric symptoms. *Id.* at 514–15. Another research group, concerned about the failure of early stress studies to measure the frequency and appraisal of stressful events offered another measure, the General Ethnic Discrimination Scale (GEDS) that looks at both frequency and appraisal of discriminatory events across all ethnic groups based on the stress coping model. Landrine et al., *supra* note 97, at 80–81. Still another research group used the Index of Race-Related Stress (IRRS) that in its “brief version” measures cultural, institutional, and individual racism. Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 96, at 370.

neuroendocrine, and cardiovascular systems.<sup>111</sup>

Ethnic group membership was found to have a statistically significant effect on race-related stress, ethnic identity score, and quality of life scores. African Americans had higher scores for race-related stress, ethnic identity, and the psychological well-being subscale of the quality of life measure. The results further indicated that racial identity and cultural racism stress both significantly predicted qualities of life. As might be expected, cultural racism was inversely related to quality of life. Notably, one study indicated that ethnic identity was the best predictor of quality of life, which implies that ethnic identity is related to psychological and physical health.<sup>112</sup> Thus, studies on race-related stress that only take race into account would be, according to these articles, fatally flawed. Future studies need to account for a range of other factors that can affect how race-related stress impacts individuals. Such factors should include socialization, coping strategies, cultural identity, individual perception, types of racism, environmental factors, and traditional stressors.

As the race-related stress studies suggest, descriptive race in its crudest form may overlook important differences within categories. Even if stress is a circumstance where ascriptive ethno-race may contribute to a medical outcome, it is important to look at other contributing factors. Thus, more thoughtful use of ethno-race as either a descriptor or ascriptor should be the goal of any biomedical research-related guideline or regulation.

In their critiques of race's relevance in biomedical research, Braun, Ellison, and their co-authors acknowledge the potential influence that biomedical journals have on the use of ethno-racial categories. They point out that journals approach this question from one of three perspectives. Some journals accept self-identified race or ethnicity as an acceptable proxy for genetic makeup, others state that race should not be used in genetic research because of the genetic variation within self-identified populations, and still others adopt a middle position whereby race can be used to ensure diversity in studies, but not as a proxy for genetic variation.<sup>113</sup> Braun et al. cite a recent

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111. Utsey et al., *Effect of Ethnic Group Membership*, *supra* note 96, at 368. Previous studies found that the psychological effects of stress include anxiety and paranoia, and the physiological responses primarily involve the immune, neuroendocrine, and cardiovascular system. *Id.*

112. *Id.* at 372–75.

113. Braun et al., *supra* note 15, at 1424.



study finding that “commonly used ethnic labels are both insufficient and inaccurate representations of the inferred genetic clusters, and that drug-metabolizing profiles . . . differ significantly among the clusters.”<sup>114</sup> Ellison et al. advocate advancing their proposal through biomedical journals, noting, however, that some journals are resistant to guidelines, and that the guidelines have not significantly affected the content of the journals that do have them.<sup>115</sup> Recently a few high-impact medical journals stepped into this debate. The next section examines and critiques both medical journal and federal guidelines on the use of ethno-race in biomedical research.

### III. GUIDELINES ON RACE AND ETHNICITY

#### A. JOURNAL GUIDELINES

Some experts agree with Braun and Ellison about the role high impact scientific journals can play in discouraging the misuse of race in medical research, but they disagree about the goal and focus of journal guidelines. Stacie Geller et al., for example, argue that these journals need to adapt their editorial guidelines to reinforce the importance of greater compliance with federal guidelines aimed at promoting more diversity among clinical study participants.<sup>116</sup> Fausto-Sterling, on the other hand, advocates even stronger measures. She argues that

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114. *Id.* at 1424 (internal citations omitted).

115. Ellison et al., *supra* note 72, at 1436. According to the authors, “648 journals signed up to the [sic] International Committee of Medical Journal Editors’ *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, which recommend that ‘When [sic] authors use variables such as race or ethnicity, they should define how they measured the variables and justify their relevance.’” *Id.* Ellison et al. call for an international consensus in the biomedical community to support guidelines that (1) improve racial and ethnic categories as descriptive factors; (2) advocate for the inclusion of specific genotypical, cultural, and structural attributive factors; and (3) “generat[e] evidence from population studies of racial and ethnic groups that can be used to improve the care of individual patients from these groups across different social and clinical contexts.” *Id.*

116. See Stacie E. Geller et al., *Adherence to Federal Guidelines for Reporting of Sex and Race/Ethnicity in Clinical Trials*, 15 J. WOMEN’S HEALTH 1123, 1130–31 (2006). The authors also argue that funding agencies must engage in greater scrutiny of the clinical trials they support to ensure equitable enrollment among gender and race/ethnicity. *Id.*

editors of scientific journals and those who review articles for these journals should require that researchers define and justify their use of racial categories, especially since other factors like socioeconomic status, geography, and individual life cycle may be better predictors of specific disease patterns.<sup>117</sup>

To date, three major English language scientific academic publications, the *British Medical Journal*, *Nature Genetics* and the *Journal of the American Medical Association*, have announced guidelines on the use of race and ethnicity in medical research. With the exception of *Nature Genetics*, these journal guidelines are aspirational, not mandatory. A fourth journal, the *New England Journal of Medicine*, entertained a debate on the subject but adopted no guidelines. Most guidelines advocate for increased clarity in why ethno-race is being considered, the rationale behind the ethno-racial groupings, and the method of subject assignment. This section critiques these guidelines to determine whether any contain useful restrictions Congress might adopt to discourage the inappropriate use of ethno-race in federally funded bio-medical research.

The *Journal of the American Medical Association (JAMA)* is the only journal to expressly advocate the use of self-identified race in biomedical research.<sup>118</sup> According to Margaret Winkler, Deputy Editor of *JAMA*, the guidelines elaborate on and clarify the published guidelines of the International Committee of Medical Journal Editors (CMJE) that advise authors who use ethno-racial variables to “define how they measured the variables and justify their relevance.”<sup>119</sup> The *JAMA* guidelines add that “authors should describe who designated race and/or ethnicity for an individual” and also note that “*self-designation generally is preferred.*”<sup>120</sup> Rather than discourage the use of ethno-racial labels in research, the *JAMA* guidelines support subject self-identification of ethno-racial identity that, as mentioned previously and discussed

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117. Fausto-Sterling, *supra* note 4, at 670.

118. Margaret A. Winkler, Editorial, *Measuring Race and Ethnicity: Why and How?*, 292 J. AM. MED. ASS'N 1612, 1614 (2004).

119. *Id.* (citing INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS: WRITING AND EDITING FOR BIOMEDICAL PUBLICATION, sec. IV.A.6.a (updated Nov. 2003), <http://www.icmje.org/#prepare>). The CMJE guideline statement emphasizes the need for clarity in racial categorization. *Id.*

120. *Id.* (emphasis added).

below, is a poor proxy for genetic variation.<sup>121</sup>

One example of why self-identification of ethno-racial identity is a poor proxy for genetic variation lies in the fact that a subject's self-identified ethno-racial status may be different from that individual's bio-geographic ancestry based "on a range of historical, cultural and sociopolitical factors."<sup>122</sup> My friend, for example, self-identifies as black (remote African ancestry), while her bio-geographic ancestry may more strongly correspond to her remote European ancestry. Thus, self-identification as a method to assign ethno-racial categories (and sometimes inappropriately infer genetic makeup) is limited because it may only provide a partial view of the individual's geographic genetic ancestry.<sup>123</sup> Nevertheless, self-identified race and bio-geographic ancestry are important in studying health disparities.<sup>124</sup>

Second, the *JAMA* guidelines state that "[a]uthors should indicate whether the options for [racial and ethnic] designation were closed or open."<sup>125</sup> Winkler notes that while open-ended options potentially provide a more accurate description of individual ethno-racial identity, open-ended self-reported ethno-race is difficult to categorize for research purposes.<sup>126</sup> Knowing, for example, that a clinical subject self-identifies as having Hawaiian, Chinese, English, and Korean ancestry helps establish the diversity of enrollees, but outside of a study of populations in Hawaii this level of self-identification will result in too small a sample group to provide researchers with useful information. Unfortunately, Winkler offers no solutions for dealing with problematic open-ended options.

The *JAMA* guidelines further suggest that researchers should make ethno-racial coding in studies more "transparent" by disclosing the options for racial categories used by researchers, how these options were established, and what

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121. See Caulfield et al., *supra* note 18, at 8.2. For a discussion of this point, see *supra* footnotes 17, 28, 84 and accompanying text.

122. Sandra Soo-Jin Lee et al., *The Ethics of Characterizing Difference: Guiding Principles on Using Racial Categories in Human Genetics*, 9 *GENOME BIOLOGY* 404, 404.2 (2008) (Statement 3).

123. *Id.* at 404.2.

124. *Id.*

125. Winkler, *supra* note 118, at 1614. The guideline continues: "If the options were closed, authors are asked to provide what the options were, whether categories were combined, and, if so, how." *Id.*

126. *Id.*

subcategories are included in the study.<sup>127</sup> Thus, this guideline, which seems to favor closed option ethno-racial designations for coding purposes, undercuts the first and supposed primary guideline goal, clarity in racial categorization.

Clarity in ethno-racial designations is also relevant in monitoring who has access to clinical studies, a point addressed in part by the last *JAMA* guideline, which states that authors should justify why they believe ethno-race is “relevant to the particular study.”<sup>128</sup> The goal of this guideline is to encourage researchers to more critically consider the relevance of ethno-race as factors in their study<sup>129</sup> or, in other words, to analyze whether the ascriptive use of ethno-race is appropriate. Thus, *JAMA* encourages researchers to directly measure other social and environmental factors as causes.<sup>130</sup>

By not renouncing the use of race as a proxy for genetic similarity, the *JAMA* guidelines, while an improvement, only hint at the potential for misuse of ethno-racial labels in research. Under the guideline, race is a permissible proxy for other difficult to measure variables, so long as the rationale for doing so is clearly stated.<sup>131</sup> Yet Winkler cites no examples of situations where race would be an acceptable substitute for these difficult to measure and unspecified variables, a troublesome omission.

Further, Winkler’s reasoning seems circular. She concedes that race is a social construct with little or no scientific value but argues that ethno-racial self-identification may have some unspecified value in biomedical research. Because the *JAMA* guidelines provide little real guidance researchers are likely to continue following old familiar patterns, relying on older studies that used race inappropriately.

As mentioned earlier, the *British Medical Journal (BMJ)* was the first high impact medical journal to publish guidelines

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127. *Id.*

128. *Id.* (noting that the authors should state their rationale if they use race or ethnicity as proxies for unknown, or hard to measure variables and providing the following examples of social and environmental factors that should be measured directly: “socioeconomic status, education, urban vs. rural location, or income region by zip code”).

129. *Id.*

130. *Id.* (instructing the researcher to “determine whether an outcome is truly related to ethno-race (as defined by the study) or to other factors with a closer relationship to the causal pathway”).

131. *Id.* (identifying variables such as socioeconomic status, education, urban versus rural locations, or income region by ZIP code).

on the use of ethno-race in biomedical research. The journal offers three major guidelines with the first two meant to encourage authors to explain “the logic behind their ‘ethnic’ groupings.”<sup>132</sup> First, the journal urges authors “to use accurate descriptions” when employing ethno-racial terminology.<sup>133</sup> In explaining the need for these guidelines, *BMJ* discusses how ethno-race terminology is subject to culture, political debates and imperatives.<sup>134</sup> Since ethno-race terms are forever changing, the journal reasons, authors should provide descriptions with racial terminology so that future researchers will be able to more reliably compare past results to future ones.<sup>135</sup>

Secondly, *BMJ* announced that, henceforth, racial or ethnic descriptions should reference the method behind these groupings.<sup>136</sup> Thus, *BMJ* encourages specific descriptions of ethno-racial categories, as well as a notation of how the groupings were assigned. As an example of the first two guidelines, *BMJ* used the ethno-racial self-identified label “black Caribbean” instead of “black.”<sup>137</sup>

The third guideline provides that any ethno-racial “[c]ategorisation . . . should relate to the type of hypothesis under investigation.”<sup>138</sup> *BMJ* notes that “race has limited biological validity,”<sup>139</sup> thus categories based on genetic make-up, for example, should be used ascriptively in studies assessing health risks, whereas ethno-racial categories may be more helpful descriptively in studies assessing health services. If researchers do not know which, among race, ethnicity, or culture, will be the most powerful determinant of the outcome, *BMJ* advises them to measure each factor.<sup>140</sup> Thus, *BMJ* encourages researchers to collect a range of information, including genetic differences, self-assigned ethnicity, observer-assigned ethnicity, country or area of birth, years in country of

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132. Editorial, *Ethnicity, Race, and Culture: Guidelines for Research, Audit, and Publications*, 312 BRIT. MED. J. 1094 (1996).

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.*

140. *Id.*

residence, and religion.<sup>141</sup> These guidelines aim at ensuring that biomedical research is more comparable in the future.<sup>142</sup>

Whereas *JAMA* and *BMJ* published their guidelines hoping that authors would try to follow them, only one journal, *Nature Genetics*, stated that their guidelines are mandatory.<sup>143</sup> In an editorial describing the new guidelines, *Nature Genetics* discussed how the 2000 U.S. Census, in an effort to address the nation's increasing diversity, included an option for "Other Race."<sup>144</sup> The editorial explains that this option allows individuals to self-select more than one ethno-racial category and will create "63 possible permutations."<sup>145</sup> The editorial goes on to acknowledge that in most scientific communities, "race" is not a scientific term.<sup>146</sup> *Nature Genetics* then states, however, that ethno-race may be a valid variable in scientific studies as a proxy for discriminatory experiences, diet, or other environmental factors, but it should not be used as a substitute for measurable parameters such as genetic variation or differences in metabolism.<sup>147</sup>

*Nature Genetics*' goal in mandating journal guidelines is to "raise awareness and inspire more rigorous design of genetic and epidemiological studies."<sup>148</sup> Going forward, *Nature Genetics* will *require* authors to explain the reason for their use of specific ethno-racial groups and how that classification was achieved.<sup>149</sup> The hope is that these guidelines will encourage researchers to find ways to improve the health of populations

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141. *Id.* (explaining that, to determine genetic differences, research should use "relevant genetically determined polymorphism," that "nationally agreed guidelines" should be used to determine self-assigned ethnicity" thereby "enabling comparability with census data," that "observer-assigned ethnicity" should use "OPCS or other national census categorisation or the researchers' own logically argued categories," and "country or area of birth" should be determined by using "the subject's own, or parents' and grandparents' if applicable").

142. *Id.*

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

144. *Id.* at 97.

145. *Id.* at 97.

146. *Id.* at 97-98 (referencing the AAA's 1997 recommendation that the U.S. government stop using race in collection of data because race is a social not a scientific concept).

147. *Id.* at 98.

148. *Id.*

149. *Id.*

without using ethno-race as a “pseudo-biological” variable.<sup>150</sup>

In 2001, the *New England Journal of Medicine (NEJM)* entertained a debate about the use of ethno-race in biomedical research, but stopped short of imposing guidelines. Instead, it published a powerful editorial by Dr. Robert S. Schwartz, a deputy editor of *NEJM*, criticizing the uncritical use of race in research.<sup>151</sup> He also encourages all journals to adopt the *Nature Genetics* guidelines on the use of racial and ethnic categories in medical research.<sup>152</sup>

In his editorial, Dr. Schwartz cites two articles published in the same issue that use race inappropriately.<sup>153</sup> Like others, he believes that any study using ethno-racial categories “should begin with a plausible, clearly defined, and testable hypothesis” which considers the relevance of these categories.<sup>154</sup> A better approach, according to Dr. Schwartz, is to focus on genetic variations, rather than ethno-racial differences.<sup>155</sup> He reasons that the genetic similarities across ethno-race categories reported by the human genome project “should force an end to medical research that is arbitrarily based on race.”<sup>156</sup>

Reflecting the ongoing debate about the use of race in biomedical research, Dr. Schwartz’s editorial was countered by another editorial “praising” the use of race in medical research.<sup>157</sup> The debate in *NEJM* continued in 2003 when the journal published another pair of articles for and against the

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150. *Id.*

151. Robert S. Schwartz, *Racial Profiling in Medical Research*, 344 *NEW ENG. J. MED.* 1392, 1392–93 (2001).

152. *Id.* at 1393.

153. *Id.* at 1392 (citing Clyde W. Yancy et al., *Race and the Response to Adrenergic Blockade with Carvedilol in Patients with Chronic Heart Failure*, 344 *NEW ENG. J. MED.* 1358–65 (2001) (reporting that carvedilol, a beta blocker, has a similar benefit in blacks and nonblacks with chronic heart failure) and Derek V. Exner et al., *Lesser Response to Angiotensin-Converting-Enzyme Inhibitor Therapy in Black as Compared with White Patients with Left Ventricular Dysfunction*, 344 *N. ENGL. J. MED.* 1351, 1351–57 (2001) (claiming that enalapril, an angiotension-converting-enzyme inhibitor, is more effective when used in whites with left ventricular dysfunction than in blacks)).

154. *Id.* at 1393.

155. *Id.* at 1393.

156. *Id.* at 1393. *See* sources cited *supra* note 17.

157. Lillquist & Sullivan, *supra* note 29, at 394 (citing Alastair J.J. Wood, *Racial Differences in the Response to Drugs—Pointers to Genetic Differences*, 344 *NEW ENG. J. MED.* 1393 (2001) (favoring the use of race)).

uncritical use of race in research.<sup>158</sup> The question of *NEJM* guidelines in this area remains unresolved to this day.

The journal guidelines discussed above are generally similar to the recommended guidelines announced in 2008 by a multi-disciplinary group from Stanford University (the Stanford Group<sup>159</sup>).<sup>160</sup> Although the Stanford Group's guidelines regarding the use of ethno-racial categories were developed for use in research exploring "human genetic variation,"<sup>161</sup> they seem equally applicable to biomedical research. In some respects, the *Nature Genetics* guidelines are almost identical to provisions of the Stanford Group guidelines. *Nature Genetics*, for example, requires authors to "explain why they make use of particular ethnic groups or populations, and how classification was achieved."<sup>162</sup> Similarly, the Stanford Group encourages researchers to "describe how individual samples are assigned category labels, [and] to explain why samples with such labels were included in the study."<sup>163</sup> Unfortunately, however, the *Nature Genetics* guidelines, like the guidelines proposed by *JAMA* and *BMJ*, fail to address the myriad of other issues surrounding racial categorization presented in the Stanford Group model.

More specifically, the Stanford Group recommends that researchers, when considering whether to use ethno-race as a factor in a study, ask themselves three questions: (1) why race or ethnicity is relevant to the study, (2) how race or ethnicity is to be determined, and (3) whether the ethno-racial categories are variables in the research.<sup>164</sup> Thus rather than construct a

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158. *Id.* (referencing Esteban González Burchard et al., *The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice*, 348 *NEW ENG. J. MED.* 1170 (2003) (favoring the use of race) and Richard S. Copper et al., *Race and Genomics*, 348 *NEW ENG. J. MED.* 1166 (2003) (opposing the use of race)).

159. The Stanford Group consists of "faculty from the humanities, social sciences, life sciences, law, and medicine." Lee et al., *supra* note 122, at 404.1.

160. *Compare, e.g., Census, Race and Science, supra* note 143, at 98 (requiring authors to "explain why they make use of particular ethnic groups or populations, and how classification was achieved") with Lee et al., *supra* note 122, at 404.2 (encouraging researchers to "describe how individual samples are assigned category labels, [and] to explain why samples with such labels were included in the study").

161. Lee et al., *supra* note 122, at 404.1.

162. Editorial, *supra* note 143, at 98.

163. Lee et al., *supra* note 122, at 404.2.

164. *Id.* (suggesting that in order to design a research protocol that minimizes the "use of science for racial stereotyping," researchers can "assess



study of cancer rates among ethno-racial groups, the Stanford Group argues that it might be more appropriate to construct a study of cancer rates based on age or gender that also records the ethno-race of subjects. Other researchers also agree with the Stanford Group about the importance of education in remedying the problem.<sup>165</sup> Dr. Schwartz, for example, writes that educating academics and researchers about “the fallacy of race as a scientific concept”, is an especially important component in preventing misuse of race in medical research.<sup>166</sup>

*BMJ's* guidelines have had mixed results. *BMJ* published sixteen post-guideline studies between 2000 and 2009 that considered race or ethnicity.<sup>167</sup> Four studies clearly meet the

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the purpose and impact of using racial and ethnic categories in their research and investigate whether alternative approaches would be appropriate”). *But see* Dale E. Hammerschmidt, *It's as Simple as Black and White! Race and Ethnicity as Categorical Variables*, 133 J. LABORATORY & CLINICAL MED. 10, 11 (1999) (suggesting that race should be treated the same as other categorical variables by: identifying what about race may be important to the study [which often leads to a more appropriate socioeconomic variable]; establishing criteria for subject assignment, and applying such criteria consistently, in an organized manner; and emphasizing clarity in the method of subject assignment and awareness of the potential misuse of study findings).

165. Schwartz, *supra* note 151, at 1393; *see also* Lee et al., *supra* note 122, at 404.3 (arguing for the genetics curriculum to include a history of the use of science to further racist theories and policies).

166. Schwartz, *supra* note 151, at 1392.

167. Imelda Balchin et al., *Racial Variation in the Association Between Gestational Age and Perinatal Mortality: Prospective Study*, 334 BRIT. MED. J. 833 (2007); J. Boydell et al., *Incidence of Schizophrenia in Ethnic Minorities in London: Ecological Study into Interactions with Environment*, 323 BRIT. MED. J. 1336 (2001); Annie Britton et al., *Does Access To Cardiac Investigation and Treatment Contribute to Social and Ethnic Differences in Coronary Heart Disease? Whitehall II Prospective Cohort Study*, 329 BRIT. MED. J. 318 (2004); Francesco P. Cappuccio et al., *Application of Framingham Risk Estimates to Ethnic Minorities in United Kingdom and Implications for Primary Prevention of Heart Disease in General Practice: Cross Sectional Population Based Study*, 325 BRIT. MED. J. 1271 (2002); Desiree M.A. Choi et al., *Ethnicity and Prescription of Analgesia in an Accident and Emergency Department: Cross Sectional Study*, 320 BRIT. MED. J. 980 (2000); Gene Feder et al., *Ethnic Differences in Invasive Management of Coronary Disease: Prospective Cohort Study of Patients Undergoing Angiography*, 324 BRIT. MED. J. 511 (2002); Nick Freemantle et al., *What Factors Predict Differences in Infant and Perinatal Mortality in Primary Care Trusts in England? A Prognostic Model*, 339 BRIT. MED. J. 2892 (2009); Julia Hippisley-Cox et al., *Association of Deprivation, Ethnicity, and Sex with Quality Indicators for Diabetes: Population Based Survey of 53,000 Patients in Primary Care*, 329 BRIT. MED. J. 1267 (2004) [hereinafter Hippisley-Cox et al. I]; Julia Hippisley-Cox et al., *Predicting Risk of Type 2 Diabetes in England and Wales: Prospective Derivation and*

*BMJ* guidelines,<sup>168</sup> if the census categories provide adequate description of the ethno-racial categories.<sup>169</sup> In five other studies, it is unclear whether the first guideline recommending the use of accurate ethno-racial descriptions is actually met. Some articles provide no description whatsoever of the ethno-racial categories beyond the names of the categories themselves.<sup>170</sup> Thus, while we know what is included in the ethno-racial category (i.e., black includes black African, black Caribbean, and mixed), the categories in the studies still use the broad, non-descriptive terms (i.e., black, white, non-white, and Asian) that the guidelines attempted to discourage.

The most difficult part of the *BMJ* guidelines is to discern whether the ethno-racial categorization in these studies relates

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*Validation of QDScore*, 338 BRIT. MED. J. b880 (2009) [hereinafter Hippisley-Cox et al. II]; Marian Knight et al., *Inequalities in Maternal Health: National Cohort Study of Ethnic Variation in Severe Maternal Morbidities*, 338 BRIT. MED. J. b542 (2009); Trevor W. Lambert et al., *Characteristics of Consultants Who Hold Distinction Awards in England and Wales: Database Analysis with Particular Reference to Sex and Ethnicity*, 328 BRIT. MED. J. 1347 (2004); Kath Moser et al., *Inequalities in Reported Use of Breast and Cervical Screening in Great Britain: Analysis of Cross Sectional Survey Data*, 338 BRIT. MED. J. b2025 (2009); Sonia Saxena et al., *Socioeconomic and Ethnic Group Differences in Self Reported Health Status and Use of Health Services by Children and Young People in England: Cross Sectional Study*, 325 BRIT. MED. J. 520 (2002); Jane Wardle et al., *Development of Adiposity in Adolescence: Five Year Longitudinal Study of an Ethnically and Socioeconomically Diverse Sample of Young People in Britain*, 332 BRIT. MED. J. 1130 (2006); Peter H. Whincup et al., *Early Evidence of Ethnic Differences in Cardiovascular Risk: Cross Sectional Comparison of British South Asian and White Children*, 324 BRIT. MED. J. 635 (2002); Katherine Woolf et al., *Ethnic Stereotypes and the Underachievement of UK Medical Students from Ethnic Minorities: Qualitative Study*, 337 BRIT. MED. J. a1220 (2008).

168. Hippisley-Cox et al. II, *supra* note 167; Knight et al., *supra* note 167; Saxena et al., *supra* note 167; Woolf et al., *supra* note 167.

169. U.K. census categories are as follows: White (includes options for British, Irish, or any other white background), mixed (includes options of White and Black Caribbean, White and Black African, White and Asian, or any other mixed background), Asian or Asian British (includes options for Indian, Pakistani, Bangladeshi, any other Asian background), Black or Black British (includes options for Caribbean, African, any other black background), Chinese or other ethnic group (includes options for Chinese, or write-in for other ethnic group). OFFICE FOR NAT'L STATISTICS, EXEC. OFFICE OF THE UK STATISTICS AUTHORITY, CENSUS 2001 FORM: ENGLAND HOUSEHOLD FORM (2001), available at <http://www.statistics.gov.uk/census2001/pdfs/engh1.pdf>.

170. Balchin et al., *supra* note 167; Boydell et al., *supra* note 167; Britton et al., *supra* note 167; Cappuccio et al., *supra* note 167; Choi et al., *supra* note 167; Feder et al., *supra* note 167; Freemantle et al., *supra* note 167; Hippisley-Cox et al. I, *supra* note 167; Lambert et al., *supra* note 167; Moser et al., *supra* note 167; Wardle et al., *supra* note 167; Whincup et al., *supra* note 167.

to the type of hypothesis under investigation. According to the guidelines, “race has little biological validity”;<sup>171</sup> therefore, if the studies were looking for biological differences, they should have used categories based on genetic variation, not race. If the studies were merely looking for racial disparities in quality and access to health care, or the impact of social and environmental factors on health outcomes, then ethno-racial categories may be appropriate. Several articles seemed to use race this way,<sup>172</sup> but a few articles seem to be looking for biological difference and, therefore, used ethno-racial categories inappropriately.<sup>173</sup>

Only one of four identified studies published in *Nature Genetics* from 2000 to 2009 seems to meet the criteria established by that journal.<sup>174</sup> Two of the three remaining studies meet one of the two guidelines, but differ as to which guideline was met.<sup>175</sup> The last study does not seem to meet either guideline.<sup>176</sup> Thus, there is no real pattern as to how authors use or disregard the *Nature Genetics* guidelines.<sup>177</sup>

While all of the journal guideline statements mentioned above are promising developments, without stringent oversight, there is little incentive for researchers to change their methodologies or thinking about ethno-race. Even mandatory

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171. *Ethnicity, Race, and Culture*, *supra* note 132.

172. Boydell et al., *supra* note 167; Britton et al., *supra* note 167; Choi et al., *supra* note 167; Feder et al., *supra* note 167; Freemantle et al., *supra* note 167; Hippisley-Cox et al. I, *supra* note 167; Hippisley-Cox et al. II, *supra* note 167; Knight et al., *supra* note 167; Lambert et al., *supra* note 167; Moser et al., *supra* note 167; Saxena et al., *supra* note 167; Woolf et al., *supra* note 167.

173. These studies seem to use ethno-race inappropriately: Cappuccio et al., *supra* note 167; Whincup et al., *supra* note 167. It is unclear whether the following studies use race inappropriately: Balchin et al., *supra* note 167; Wardle et al., *supra* note 167.

174. John P.A. Ioannidis et al., ‘Racial’ Differences in Genetic Effects for Complex Diseases, 36 NATURE GENETICS 1312 (2004).

175. Anna Helgadottir et al., A Variant of the Gene Encoding Leukotriene A4 Hydrolase Confers Ethnicity-Specific Risk of Myocardial Infarction, 38 NATURE GENETICS 68 (2006); Richard S. Spielman et al., Common Genetic Variants Account for Differences in Gene Expression Among Ethnic Groups, 39 NATURE GENETICS 226 (2007).

176. E.J. Parra et al., Implications of Correlations Between Skin Color and Genetic Ancestry for Biomedical Research, 36 NATURE GENETICS S54 (2004).

177. Although the journal guidelines are intended for clinical studies, two commentaries published in *Nature Genetics* seem to partially meet the guidelines. See David B. Goldstein & Joel N. Hirschhorn, *In Genetic Control of Disease, Does ‘Race’ Matter?*, 36 NATURE GENETICS 1243 (2004); Hua Tang, *Confronting Ethnicity-Specific Disease Risk*, 38 NATURE GENETICS 13 (2006).

guidelines, like those established by *Nature Genetics*, are not always enforced. The federal guidelines on ethno-racial categories are equally problematic, but for different reasons, a point explored in next section.

#### B. FEDERAL GUIDELINES ON ETHNO-RACE IN BIOMEDICAL RESEARCH

Although life expectancy and overall health for all Americans improved substantially in the twentieth century, significant health disparities remained, especially among racial and ethnic minority communities.<sup>178</sup> As a result, in 1998 President Clinton proposed a twelve-year plan to end health disparities in six areas.<sup>179</sup> The Clinton effort was one of many national attempts to address health disparities among Americans.<sup>180</sup> Similar efforts continue to this day, as the National Institute on Minority Health and Health Disparities (NIMHD) “leads, coordinates, supports and assesses the NIH

178. David Satcher, *Our Commitment to Eliminate Racial and Ethnic Health Disparities*, 1 YALE J. HEALTH POL’Y L. & ETHICS 1, 1 (2001).

179. *Id.* at 2 (“President Clinton committed . . . to eliminate the disparities experienced by racial and ethnic minority populations in six health-related areas, including cancer screening and management, cardiovascular disease, diabetes, HIV/AIDS, immunization rates, and infant mortality.”).

180. *Id.* (“Clinton’s goal parallel[ed] the focus of *Healthy People 2010*—the nation’s health objectives for the twenty-first century—which Donna Shalala, former Secretary of the U.S. Department of Health and Human Services (DHHS) . . . released in January 2000.”). In 1986, the Office of Minority Health (OMH) was created to “improve health and healthcare outcomes for racial and ethnic minority communities by developing or advancing policies, programs, and practices that address health, social, economic, environmental and other factors which impact health.” *About OMH*, THE OFFICE OF MINORITY HEALTH, <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=1&lvlID=7> (last visited Mar. 2, 2011); see also Jeffrey Brainard, *Debate Over Improving Minority Health Pits NIH Director Against Black Leaders*, CHRON. HIGHER EDUC., Sept. 10, 1999, at A41. In 1992 the Office of Research on Minority Health (ORMH) unveiled the *Minority Health Initiative* (MHI), consisting of a multi-year biomedical and behavioral research and research training program designed to “improve prenatal health and reduce infant mortality,” fund “studies of childhood and adolescent lead poisoning, HIV infection and AIDS, and alcohol and drug abuse,” conduct “research in adult populations focused on cancer, diabetes, obesity, hypertension, cardiovascular diseases, mental disorders, asthma, visual impairments, and alcohol abuse,” and train “faculty and . . . students at all stages of the educational pipeline.” Press Release, Nat’l Insts. of Health, Office of Research on Minority Health (Apr. 14, 2000), available at <http://www.nih.gov/news/pr/apr2000/od-14.htm>; *The NIH Almanac*, NAT’L INSTS. OF HEALTH, <http://www.nih.gov/about/almanac/organization/NIMHD.htm> (last visited Dec. 17, 2010).

research effort to reduce and ultimately eliminate health disparities” as they affect racial and ethnic communities and medically underserved individuals.<sup>181</sup>

Unfortunately, these well-intended legislative attempts to encourage greater study of minority health send confusing signals to researchers. As Dorothy Roberts points out, the federal funding guidelines create a paradox: guideline measures designed to remedy past discrimination and exclusion in biomedical research based on ethno-racial labels actually require race consciousness.<sup>182</sup> This form of race-consciousness, however, risks “reinforcing biological definitions of race that have historically legitimized racial inequalities.”<sup>183</sup> Thus, then-U.S. Surgeon General Dr. David Satcher, a black physician, had to remind readers in the supplement to a comprehensive 1999 federal report on mental health that the term “race” as used in that report referred to “social characteristics held in common, such as general societal treatment and access to resources,” and not purported

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181. *The NIH Almanac*, *supra* note 180. The Institute was, until recently, the National Center on Minority Health and Health Disparities. See Press Release, Nat'l Insts. of Health, NIH Announces Institute on Minority Health and Health Disparities (Sept. 27, 2010), available at <http://www.nih.gov/news/health/sep2010/nimhd-27.htm>. The NIH has several programs engaged in “medical research concerning racial and ethnic minorities” including: the NCMHD which “leads, coordinates, supports and assesses the NIH effort to reduce and ultimately eliminate health disparities”; Centers for Population Health and Health Disparities, “designed to support research to understand and reduce differences in health outcomes, access and care”; NIH’s National Health Lung and Blood Institute (NHLBI), which “partners with African American communities through Enhanced Dissemination and Utilization Centers to implement education and intervention programs to cut the rates of CVD risk factors and to promote healthy lifestyles.” NHLBI is also conducting the Jackson Heart Study C the first large-scale cardiovascular disease study among African Americans to examine the factors that influence the diseases development in this population. The National Institute of Environmental Health Sciences (NIEHS) which is “a leader in the area of understanding how poverty, environmental pollution, and health interrelate.” Press Release, U.S. Dep’t of Health & Human Servs., Protecting the Health of Minority Communities (Jan. 13, 2006), available at <http://www.hhs.gov/news/factsheet/minorityhealth.html>. For further information on these and other environmental health programs of NIEHS and NIMH, visit <http://www.niehs.nih.gov/> and <http://www.nimhd.nih.gov/>.

182. Roberts, *supra* note 17, at 528.

183. *Id.*

biological differences.<sup>184</sup>

Federal grant application regulations establish guidelines and provide incentives for the inclusion of different racial and ethnic groups in clinical trials.<sup>185</sup> But these guidelines also create confusion. Section 5.8 of the Application Guide for NIH and Other Public Health Services (PHS) Agencies, for example, explains the inclusion guidelines for federally funded studies.<sup>186</sup> Under this provision, studies funded by these federal agencies are required to “identify research subjects by race and ethnicity, to include minorities in clinical trials, and . . . report their findings according to the racial and ethnic identity of research subjects”<sup>187</sup> using OMB’s concededly socially constructed standards, which contain five racial and two ethnic categories.<sup>188</sup>

These guidelines, however, seem to ignore OMB’s own caveat that “the racial and ethnic categories set forth in the standards should not be interpreted as being primarily biological or genetic in reference.”<sup>189</sup> Moreover, federal databases confuse racial and ethnic categories in genetic research because samples are organized into categories that overlap and/or conflate notions of race, ethnicity, nationality, continental geography, and religion.<sup>190</sup> Mindful that OMB’s categories are overly broad, NIH encourages reporting on

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184. Matt Boucher, *Turning a Blind (White) Eye in Legislating Mental Health Parity: The Unmet, Overlooked Needs of the Working Poor in Racial and Ethnic Minority Communities*, 19 J. CONTEMP. HEALTH L. & POL’Y 465, 466 n.5 (2003) (citing U.S. DEP’T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: CULTURE, RACE, AND ETHNICITY: A SUPPLEMENT TO MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 9 (2001) [hereinafter MHCRE] (defining ethnicity as “a common heritage shared by a particular group”)). Boucher’s report “uses the term ‘minority’ to ‘signify [a] group[s] limited political power and social resources, as well as their unequal access to opportunities, social rewards, and social status.” Boucher, *supra*, at 471 n.31 (citing MHCRE, *supra*, at 5).

185. Jonathan Kahn, *Genes, Race, and Population: Avoiding a Collision of Categories*, 96 AM. J. PUB. HEALTH 1965, 1966 (2006).

186. See U.S. DEP’T OF HEALTH & HUM. SERVS., PUBLIC HEALTH SERVICE GRANT APPLICATION INSTRUCTIONS § 5.8 (June 2009), available at <http://grants.nih.gov/grants/funding/phs398/phs398.pdf>.

187. Roberts, *supra* note 17, at 529. Roberts also argues that state laws are another potential source of regulation. *Id.* at 530.

188. For a critique of the OMB’s standards for reporting race and ethnic statistics, see *Response to OMB Directive 15*, *supra* note 76.

189. Kahn, *Genes, Race, and Population*, *supra* note 185, at 1968.

190. *Id.* at 1966–67.

ethno-racial categories in greater detail.<sup>191</sup> In determining ethno-race, NIH also advises researchers to use subject self-identification,<sup>192</sup> which, as this article previously argued, is problematic.<sup>193</sup>

In addition to the inadequate descriptive racial categories, NIH's enforcement mechanisms are not particularly helpful because they focus on problems that arise after the research project has received funding.<sup>194</sup> Continuation of the grant and disbursement of the award depend on the submission of periodic reports that must disclose the race and ethnicity of human subjects.<sup>195</sup> This system of oversight seems to give NIH the ability to impose funding restrictions on studies that are not following the inclusion guidelines as mandated by federal law.

But the inappropriate use of ethno-race usually appears at the grant application stage in the research protocol. Further, the follow-up to determine whether researchers complied with

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191. U.S. DEPT OF HEALTH & HUM. SERVS., GRANT APPLICATION INSTRUCTIONS, *supra* note 186, at II-20 ("Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self identify with more than one race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study.").

192. *Id.* The OMB also encourages self-reporting: "respondent self-identification should be facilitated to the greatest extent possible, recognizing that in some data collection systems observer identification is more practical." Recommendations From the Interagency Committee for the Review of the Racial and Ethnic Standards to the Office of Management and Budget Concerning Changes to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 Fed. Reg. 36,873, 36,881 (Jul. 9, 1997), *available at* <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/ombdir15.pdf>.

193. *See supra* notes 83, 122–123, and accompanying text.

194. *See* NIH GRANTS POLICY STATEMENT (2003), *available at* [http://grants1.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part5.htm#\\_Toc54600106](http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600106) (noting that "NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget periods.").

195. *See Final Progress Report*, NIH GRANTS POLICY STATEMENT (2003), [http://grants1.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600141](http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600141).

their plan is not with the researchers, but with the institutes reviewing the proposals, who are required to prepare reports “describing the manner in which the institute has complied” with the Revitalization Act.<sup>196</sup> While the NIH *Policy on Reporting Race and Ethnicity Data* suggests that researchers have to complete annual reports of the total enrollment by race, ethnicity, and gender, it does not address the consequences if researchers fail to comply with this requirement or identify race inappropriately.<sup>197</sup>

A 2006 study of adherence to federal guidelines for reporting race, ethnicity, and sex in federally funded clinical trials published in high impact journals in 2004 found that 67% of the trials reported the number of black subjects and 48% reported the number of Hispanic subjects, while only 18% of studies reported nothing with respect to the race/ethnicity of their subjects.<sup>198</sup> These studies generally did not report results by race (which seems appropriate), and the vast majority did not acknowledge any limitations on generalizability due to the race or ethnicity of the subjects.<sup>199</sup> Further, none of the four phase III trials provided race-specific results or addressed any statistically significant racial/ethnic differences.<sup>200</sup> Despite the lack of compliance with the guidelines, and resulting lack of diversity among trial subjects, the vast majority of studies generalized the results to all populations.<sup>201</sup> Thus, requiring researchers to be race conscious in the selection of clinical subjects does not necessarily translate into a reification of race in most federally funded studies.

Another study looked at the use of racial and ethnic terminology in genetic research, and whether the use of such

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196. See NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14,508, 14,510 (Mar. 28, 1994).

197. *NIH Policy on Reporting Race and Ethnicity Data*, NIH (Aug. 8, 2001), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

198. Geller et al., *supra* note 116, at 1126. The authors excluded studies that identified no federal support. In evaluating the articles, researchers noted whether race/ethnicity specific results were reported, whether race/ethnicity was considered in analyzing the outcomes, and whether the trials recognized any limitations on generalizability to broader populations based on race or ethnicity. Follow up papers were also examined for any information relating to race or ethnicity. *Id.* at 1124–25.

199. *Id.* at 1127.

200. *Id.* at 1128. The sex-specific OB-GYN studies similarly did not report results by race or ethnicity. *Id.* at 1127.

201. *Id.* at 1130.



terms is justified or explained when the research is published.<sup>202</sup> The researchers' concern was that using ethno-racial terms without providing definitions allows the reader to infer definitions that may be based on negative stereotypes that, in the context of genetic research, reinforce biological notions of race.<sup>203</sup> The results indicated that race or ethnicity terminology was used as a variable in a little more than half (51.5%) of the 330 articles reviewed.<sup>204</sup> Of the remaining articles, approximately half did not include race or ethnicity terms at all, while the other half used racial or ethnic terminology, but only to identify the study sample, not as a variable.<sup>205</sup>

Most articles neither explained nor justified the use of the particular populations studied.<sup>206</sup> Significantly, only 9.1% of articles explained how a label was given to a particular population, a basic procedure in some journal guidelines, and arguably "a basic, easily fulfilled requirement."<sup>207</sup> The authors note that the failure to adequately explain the basis for ethno-racial assignment "impedes constructive use of study findings."<sup>208</sup> However, as recent studies of race-related stress discussed earlier illustrate, a more thoughtful use of ethno-race as descriptor and ascriptor can lead researchers to look more

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202. Pamela Sankar et al., *Race and Ethnicity in Genetic Research* 143A AM. J. MED. GENETICS 961 (2007). The articles examined in this study show that the issue of ensuring clarity and precision in the use of racial and ethnic terminology still warrants attention, and "inadequate explanation of the meaning and purpose of race and ethnicity is widespread across journals." *Id.* at 968.

203. *Id.* at 962.

204. *Id.* at 966.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.* at 968. Unlike the NIH guidelines, the FDA guidelines do "not address the level of participation of racial and ethnic groups in clinical trials" nor "establish legally enforceable responsibilities." U.S. DEPT OF HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS 2 (2005), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf>. Rather, the FDA guidelines on the collection of race and ethnicity data are actually a series of recommendations to help applicants meet the requirements of new drug applications that require subjects to be reported by race, among other factors. Logically then, the consequence of failing to follow FDA guidelines, or at least failing to collect racial and ethnic data, would be the inability to complete a new drug application process.

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critically at these categories. Nevertheless, researchers still need effective guidelines about the use of ethno-race in biomedical research that are imposed at the beginning of the process.

The next section of this article offers a tentative two-step process for regulating the use of race and ethnicity in biomedical research that addresses concerns relating to ethno-racial inclusion in clinical studies, access to health care, and discrimination in treatment, as well as ethno-race related disease. The proposed two-step process for a single regulatory scheme in federal minority health initiatives would minimize researcher confusion and trigger re-education about the use of ethno-race in biomedical research.

#### IV. PROPOSAL FOR REGULATING BIOMEDICAL RESEARCH USING RACE/ETHNICITY

As my friend's bone density test story illustrates, racial identity is ambiguous, even in biomedicine. This section first proposes a two-step regulatory scheme that addresses the concerns raised in this article about the inappropriate use of ethno-race in biomedical research. This proposal is then applied to a hypothetical race-related biomedical research proposal.

##### A. A PROPOSED REGULATORY SCHEME

One suggestion Dorothy Roberts makes about using funding restrictions to regulate the use of ethno-race in biomedical research is that researchers ask themselves questions like whether race is being defined biologically or socially and whether membership in the racialized group "continue[s] to affect health status, access to health care and medical treatment" and would thus require "race-conscious scientific investigation and legal remedies."<sup>209</sup> While the focus of these questions is sound, they do not provide enough guidance for reviewers and researchers. Rather, the three questions recommended by the Stanford Group are sharper, and better suited for incorporation into NIH and other PHS funding guidelines.<sup>210</sup>

As mentioned previously, the Stanford Group advises

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209. Roberts, *supra* note 17, at 531.

210. See *supra* notes 160–166 and accompanying text.

researchers when considering ethno-racial categories to ask themselves first why race or ethnicity is relevant to the study and whether alternative approaches are more appropriate.<sup>211</sup> Addressing this question helps researchers focus on the real objective of their study: whether there are differences in bone metabolism based on lifestyle.

Ethno-racial categories, for example, may be perfectly acceptable if researchers are assessing health services, but even in that situation, given the varied circumstances of black, Latino and Asian American subgroups, broad non-descriptive terms like black, white, non-white and Asian should be avoided. Further, ethno-racial categories may be totally inappropriate if studying the correlation between diet and high blood pressure. Other factors like socio-economic status, geographical location, gender, and family medical history may be more accurate and helpful.

A second question is how race or ethnicity will be determined.<sup>212</sup> As my foregoing discussion points out, subject self-identification as opposed to researcher identification may be appropriate if studying access to health care or physician bias, but unhelpful when studying the prevalence of certain diseases or conditions like sickle cell that are more prevalent in certain areas of the world. In that case, looking at subjects' biogeographic ancestry might provide a more useful measure.

The third question is whether the ethno-racial categories are variables in the research.<sup>213</sup> Given that ethno-race has little if any biological basis, researchers should avoid research protocols that use only ethno-racial categories. Thus, ethno-race should not be used as a variable outside of access to health care and treatment.

These three questions should be threshold inquiries that applicants *must* address in their request for federal funding. High impact journals also should ask these same questions when researchers submit their findings for publication. As a result, there would be a check at both ends of the process with funding and publication tied to compliance with these guidelines.

However, the existence of funding guidelines in and of

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211. *Id.*

212. *Id.*

213. Lee et al., *supra* note 122, at 404.2.

themselves is not enough. As the experience with the *Nature Genetics* publishing guidelines indicates, mandatory guidelines may be no more effective than aspirational ones. Thus, additional checks are needed.

One such additional check that should be used is a review by a health impact assessment group (HIAG) that would be triggered any time a grant applicant's answers to any of the three threshold questions raise the possibility that ethno-race will be used as an ascriptive factor.<sup>214</sup> In that instance a multi-disciplinary HIAG would be convened and charged with drafting a health impact assessment (HIA) to "clarify the expected health implications of a given action, and of any alternatives being considered, for the population groups affected by the proposal."<sup>215</sup>

An HIA is a valuable tool to protect against the misuse of race in scientific research because it is designed "to clarify health implications by disaggregating the determinants of health and well-being."<sup>216</sup> In addition, an HIA focuses on informed decision-making, and as such, "attempts to identify health inequalities that may arise from a proposal."<sup>217</sup>

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214. Information about health impact assessments (HIAs) can be found on the World Health Organization website. *Health Impact Assessments*, WORLD HEALTH ORG., <http://www.who.int/hia/en/> (last visited Dec. 17, 2010); see also R. Quigley et al., *Health Impact Assessment: International Best Principles*, INT'L ASS'N FOR IMPACT ASSESSMENT (2006), <http://www.iaia.org/publicdocuments/special-publications/SP5.pdf> (summarizing health impact assessments).

215. Nancy Krieger et al., *Assessing Health Impact Assessment: Multidisciplinary and International Perspectives*, 57 J. EPIDEMIOLOGY & CMTY. HEALTH 659, 660 (2003) (citing the WORLD HEALTH ORGANISATION, REGIONAL OFFICE FOR EUROPE, TECHNICAL BRIEFING: HEALTH IMPACT ASSESSMENT—A TOOL TO INCLUDE HEALTH ON THE AGENDA OF OTHER SECTORS (2002)).

216. Quigley et al., *supra* note 214, at 2. The determinants of health include individual factors, social, environmental, and institutional factors. INT'L FINANCE CORP., WORLD BANK GROUP, INTRODUCTION TO HEALTH IMPACT ASSESSMENT 7 (2009), available at [http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/p\\_HealthImpactAssessment/\\$FILE/HealthImpact.pdf](http://www.ifc.org/ifcext/sustainability.nsf/AttachmentsByTitle/p_HealthImpactAssessment/$FILE/HealthImpact.pdf).

217. Quigley et al., *supra* note 214, at 2. The World Health Organization identifies several guiding principles of HIAs, including equity, defined as "emphasizing the desire to reduce inequity that results from avoidable differences in the health determinants and/or health status within and between different population groups." *Id.* at 3. Another guiding principle, the ethical use of evidence, focuses on ensuring that "the best available evidence from different disciplines and methodologies is utilized, that all evidence is valued, and that recommendations are developed impartially." *Id.*

Legal scholar Osagie K. Obasogie proposed a similar impact assessment mechanism that he calls a racial impact assessment, as a regulatory tool to prevent new biotechnologies from advancing unsubstantiated notions of biological race.<sup>218</sup> Although he uses the FDA approval process as an example of when race impact assessments would be appropriate, Obasogie notes that this process may still be useful in other contexts.<sup>219</sup> The value of race impact assessments, according to Obasogie, is the shared responsibility between “regulators, researchers, internal review boards, and affected communities and their representatives.”<sup>220</sup> My proposal expands on Obasogie’s idea, applying it to biomedical research in general and providing a more detailed example below of how the assessment impact would work.

#### B. APPLYING THE PROPOSED STANDARD: BONE DENSITY STUDIES REVISITED

This section explains how the two-step process I outlined in the prior section might work in real life. Suppose researchers submitted a grant proposal seeking federal funding for a study examining whether racial differences in bone density between blacks and whites can be explained by differences in bone metabolism and lifestyle.<sup>221</sup> The researchers propose to study a cohort of roughly equal numbers of women and men, black and

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218. Obasogie, *supra* note 28, at 496. As an example, Obasogie proposes an FDA advisory committee ‘as part of its review process to evaluate whether medicines like BiDil might reinforce biological understandings of race when no biological or genetic mechanism has been identified. OBASOGIE, GENE CARD, *supra* note 24, at 47. Obasogie’s recommendation is equally workable for biomedical research. The ultimate goal in both instances is to “increase the dialogue between stakeholders and policymakers so as to balance competing interests through strategic planning that promotes public good.” *Id.*

219. Obasogie also suggests race impact assessments in evaluating marketing of ancestry tests and the effects of DNA forensics on certain communities. OBASOGIE, GENE CARD, *supra* note 24, at 47.

<sup>220</sup> *Id.* at 46.

221. For just such a study see Bruce Ettinger et al., *Racial Differences in Bone Density Between Young Adult Black and White Subjects Persist after Adjustment for Anthropometric, Lifestyle, and Biochemical Differences*, 82 J. CLIN. ENDOCRINOLOGY & METABOLISM 429 (1997). This study was supported in part by the National Institute of Health & Human Services. *Id.* The researchers conclude that “the appearance of . . . large racial difference in young adults cannot be attributed to persistent differences in metabolic or lifestyle factors and supports the view that bone density differences result from influences operating during childhood and adolescence.” *Id.* at 434.

white, between the ages of 25-36 years.<sup>222</sup>

Other than reporting ethno-race to comply with federal regulations designed to ensure greater access to clinical trials by ethno-racial minorities, other use of ethno-race automatically would be suspect.<sup>223</sup> If ethno-racial categories are to be used for other purposes, researchers must explain why these categories are relevant. Thus the researchers in the hypothetical would need to explain why race is relevant in their study. They might justify the use of ethno-racial categories to examine the validity of earlier studies that found differences in bone density between whites and blacks saying that they are trying to determine whether these differences reflect lifestyle rather than racial differences.

As my foregoing discussion indicates, this justification suggests that race would be used ascriptively and thus inappropriately. At this stage, the second step of my proposal, an HIA, would likely be triggered. HIAG members might discuss whether the proposed use of ethno-race in the study tends to reinforce biological understandings of race when no biological or genetic mechanism has been identified. If so, the HIAG members might require that the researchers reconsider the proposed use of ethno-race or they will withhold funding until the researchers modify their protocol so that ethno-racial categories are eliminated or used appropriately.

Assuming the researchers can satisfactorily explain the relevance of race in their proposed study, the next inquiry would be how the subjects' race would be determined for biomedical research as opposed to federal reporting purposes. Consider again the problem with determining the racial classification of the clinical subject mentioned earlier who self-identifies as Cape Verdean. This is a question Braun and her co-authors address.<sup>224</sup> Their response is that this individual defies conventional census-related racial classification for

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222. *Id.* at 430. The researchers also excluded “for certain laboratory abnormalities and pregnancy-related criteria . . . breast-feeding women” and women currently using oral contraceptives. *Id.*

223. As mentioned previously, federal regulations require that researchers use a universal standard, the OMB ethno-racial categories, in reporting the diversity of the research study subject population. The use of OMB ethno-racial categories is used in the regulations as a way of guarding against past exclusionary practices, but these categories are insufficiently precise for biomedical purposes, even in access to health care studies. *See* Braun et al., *supra* note 15, at 1424.

224. *Id.*

biomedical purposes.<sup>225</sup> If the researchers' proposed method for identifying the race of clinical subjects in this case seems inappropriate, an HIA could again be triggered at this point.

HIAG members might suggest other approaches. One possible approach in determining the ethno-race of a clinical subject might be to supplement the detailed subject self-identification collected for reporting purposes with a questionnaire to ascertain a subject's bio-geographical ancestry. Thus if my friend, for example, was a subject, she might self-identify as black or African American (as opposed to black Caribbean or black South African or Afro-Cuban or bi/multi-racial). The supplemental questionnaire would ask more detailed information about bio-geographic ancestry, where she was raised and currently resides.

This additional information would help separate recent immigrants from native-born Americans, perhaps an important variable in some studies and would naturally lead to an examination of the answer to the third question, whether ethno-race is used as a variable in the research. Under the Stanford Group standard, ethno-race should not be used as a variable outside of studies of access to health care and treatment.<sup>226</sup> Thus if the research protocol indicates that research would be used in another context, this as well would trigger an HIA.

Concededly an HIA inquiry can be a costly and labor-intensive mechanism to protect against the inappropriate use of ethno-race in biomedical research. But without rigorous guidelines like the ones I propose, researchers will continue "to use these same variables in the subsequent analysis and theoretical framing of the research."<sup>227</sup> Hopefully, HIA inquiries will be temporary measures that can be useful in helping federal funding agencies develop more substantial guidelines as they gain more experience reviewing individual protocols.

It must again be noted, however, that better federal guidelines alone will be insufficient to remedy the problem I

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225. "In clinical research projects or in the clinic, the assignment of race assumes an equivalence between census categories and genetics embodied by patients. . . . We suggest that, as with Cape Verdeans, census race cannot be assumed to reflect a particular genetic make-up." *Id.*

226. Lee et al. *supra* note 122, at 404.2.

227. Braun et al., *supra* note 15, at 1424.

have described. My suggestions are just a first step in changing the way the medical community thinks about ethno-race. The importance of better biology education, starting in high school, is also essential in addressing the tendency to misuse ethno-race in biomedical research.<sup>228</sup>

## V. CONCLUSION

It is clear that changing how medical research communities think about race will be difficult. Researchers, many of whom are affiliated with medical schools, continue to use outdated and inaccurate notions about the validity of racial and ethnic differences in medical research unrelated to healthcare access and provider treatment bias. These researchers transmit their biases to their students replicating the problematic use of ethno-race in medical research and practice.

As my friend's experience with her bone density test illustrates, health care providers, like biomedical researchers, also continue to rely, often unthinkingly, on socially constructed racial categories in treatment and diagnosis, often to the detriment of ethnic and racial minorities.<sup>229</sup> I know this from personal experience. In 1983 my daughter's pediatrician suspected she had Crohn's Disease and required hospitalization. But upon her admission to Texas Children's Hospital in Houston the pediatric gastroenterologist, one of the best in the nation, resisted this diagnosis, telling me that Crohn's Disease was found in "middle-class Jewish children," not black children. It took ten days of testing before the gastroenterologist agreed with the pediatrician's initial diagnosis.

It is important to determine the validity of ethno-racial

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228. Braun and her co-authors write:

Improved medical training about race can sharpen diagnostic skills. Cultural competency instruction should be modified to include information on the history of racial categories, current controversies about their biological significance, and the limits of their utility. A teaching unit on race would also contrast the differences between race as a population concept with its meaning when applied to the lives of individuals. In this context it would be appropriate to teach about geographical variations in specific allele frequencies for genes linked to particular disease processes, as well as the cultural practices, historical trends, and environmental conditions that favor their prevalence or not.

Braun et al., *supra* note 15, at 1426–27.

229. Roberts, *supra* note 17, at 531.



classifications in each setting. In medicine, as in other areas, ethno-race is so powerful that it tends to shout, drowning out other explanations for adverse health outcomes. As Troy Duster explains “[t]he task is to determine how the social meaning of race can affect biological outcomes.”<sup>230</sup> Mandatory funding guidelines that require researchers to think more critically about any proposed use of ethno-race in biomedical research is one important mechanism government should use to discourage inappropriate use of ethno-racial categories in biomedical research and ultimately the medical treatment of all Americans.

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230. Troy Duster, *Buried Alive: The Concept of Race in Science*, CHRON. HIGHER EDUC., Sept. 14, 2001 at B12. See also Pilar Ossorio & Troy Duster, *Race and Genetics: Controversies in Biomedical, Behavioral, and Forensic Sciences*, 60 AM. PSYCHOLOGIST 115, 116 (2005).