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Race-Based Medicine: Remediating Health Care Disparities in a Distrustful Race

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Race-Based Medicine: Remediating Health Care Disparities in a Distrustful Race

By: Martavis Clarke

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I. Introduction

Racial and ethnic minorities persistently classify as low performance with respect to health indicators.¹ Specifically, infants born to black women are 1.5 to 3 times more likely to die before their first birthday than those born to women of other races/ethnicities and cancer is the second leading cause of death for most racial and ethnic minorities.² Even more, African Americans, American Indians, and Alaska Natives are twice as likely to have diabetes as white individuals.³ Health disparities, as defined by the National Conference of State Legislatures [hereinafter the NCSL], “refers to population specific differences in the presence of disease, health outcomes, quality of health care and access to health care services that exist across racial and ethnic groups.”⁴ Because of these low health indicators it would seem that minorities, particularly African Americans, would take measures to improve their health. However, the opposite holds true. African Americans are regarded as distrustful of clinical research which in turn impacts health outcomes and quality of life. This paper will address African American perceptions of clinical research and how those perceptions in turn negatively impact the health decisions of this minority group. A public health and community based health approach that educates minorities on the legal and ethical protections available should be explored to alter minority perceptions.

Supporters of efforts to improve African American health defend the notion that the pharmaceutical industry can assist in debunking African American perceptions of clinical

1. National Conference of State Legislature [hereinafter NCSL], *Disparities in Health*, available at <http://www.ncsl.org/issues-research/health/health-disparities-overview.aspx>, (Jan. 2012).

2. *Id.* See also Joon-Ho Yu, Sara Goering, Stephanie M. Fullerton, *Race-Based Medicine and Justice as Recognition: Exploring the Phenomenon of BiDil*, 18 Cambridge Quarterly of Healthcare Ethics (UK), 57, (2009) also stating that racial health disparities have been documented for cardiovascular disease, cancer, diabetes, HIV/AIDS, and numerous other diseases; Department of Health & Human Services, *Fact Sheet: Preventing Infant Mortality*, press release at <http://www.hhs.gov/news/factsheet/infant.html> (2006) last accessed Apr. 20, 2013 defining infant mortality as an infant dying before his/her first birthday.

3. *Id.*

4. *Id.*

research.⁵ Yu and his co-authors “believe that African American community leaders capitalized on an opportunity to bring attention to African American health issues” with respect to the drug BiDil a heart failure drug.⁶ BiDil is linked to remedying health care disparities because it specifically targets the African American population who disproportionately suffer from heart disease.⁷ The link between improving health care disparities and pharmaceutical drug marketing research is one mechanism to further decrease the disparities between minorities and other racial populations. Marketing is a powerful tool to not only advance the pharmaceutical drug’s profit margin but to also educate the minority population on the advantages of seeking treatment.

Part I of this paper will introduce the issues surrounding public perceptions of clinical research and the access issues in the African American community. Part II will explore historical clinical practices and outline early historical events, the current paradigm implemented in current drug development and clinical trials, and minority perspectives on recent developments. Part III will explore health indicators specifically access to pharmaceutical drugs as a health indicator. Part IV will then discuss the drug BiDil and how it has improved minority perceptions in clinical research; it will also set forth several of the criticisms of the development and approval history of the drug. Part V will address methods of improving addressing minority perceptions of clinical research through public health and community based education programs that specifically target African American populations. Part VI will conclude with recommendations.

5. Yu et. al, supra note 2.

6. *Id.*

7. *Id.*

II. Historical “Clinical” Practices

Historically, African Americans were discriminated against not only in social and cultural contexts, but were also discriminated against in health care clinical research practices.⁸ Unfortunately, “the deeply ingrained habits, customs, and practices of racism are not easily uprooted.”⁹ Before civil rights legislation was passed, hospitals prevented African American patients and physicians from using their facilities.¹⁰ Despite legislative efforts to equalize treatment between whites and minorities, separate but equal legislation only perpetuated discrimination and inferior treatment of minorities by providing federal funds to health care entities who maintained racially segregated facilities.¹¹ “Until 1964, the nation infused either slavery, legal subordination, or overt cultural subordination into its health care system.”¹² Title VI of the Civil Rights Act of 1964 made it illegal for health care entities receiving federal funding to discriminate on the basis of race.¹³

African American attitudes of health care research are linked to racism towards minorities by the medical community.¹⁴ Looming doubts about “the true intentions” of health care providers furthers the divide in the provision and advancement of health care between

8. Patricia A. King, *The Law-Medicine Center 50th Anniversary Symposium: The Field of Health Law: Its Past and Future: Reflections on Race and Bioethics in the United States*, 14 HEALTH MATRIX 149 (2004). Stating that differential and negative treatment of African Americans was pervasive in the health care system in the early 20th century with studies such as Tuskegee.

9. *Id.* at 151.

10. Brian D. Smedley, et. al., *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Institute of Medicine. Washington D.C.: National Academic Press (2002).

11. *See Simkins v. Moses Cone Memorial Hosp.*, 323 F.2d 959 (5th Cir. 1963), *cert. denied*, 376 U.S. 938 (1964).

12. King *supra* note 1 at 151.

13. Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 240 (codified as amended at 42 U.S.C. §§ 2000d-2000d-1 (2000)).

14. Harriet A. Washington, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* (Doubleday) (2007).

African Americans and Caucasians.¹⁵ The Tuskegee Syphilis Study is the most notorious historical event that is often attributed to minority distrust of clinical research;¹⁶ however, distrust of clinical research among blacks began prior to public awareness of what actually occurred.¹⁷ In the antebellum south, African Americans were often used on “dissecting tables, operating amphitheaters, classroom or bedside demonstrations, and experimental facilities.”¹⁸ Blacks were a particularly vulnerable population as they were easily identified because of their skin color and lack of protection in the eyes of the law.¹⁹

During this time antebellum period many medical institutions requested black patients for their facilities.²⁰ This was particularly attractive for slave owners who could send their slaves for low-cost treatments and beneficial for these medical institutions that needed test subjects.²¹ Even though whites were also used as subjects during this time, blacks were used in far greater proportion.²²

Two notable events occurred prior to the turn of the 20th century. The first involved John “Fed” Brown, a slave who was subjected to experiments at the hands of a Georgia physician, Dr. Hamilton.²³ Dr. Hamilton was performing experiments to determine how to

15. Isabel Wilkerson, *Medical Experiments Still Haunt Blacks*, N.Y. TIMES, June 3, 1991, available at query.nytimes.com/gst/fullpage.html?res=9D0CEEDD1E38F930A35755C0A967958260 [hereinafter *Wilkerson*]; Vanessa Northington Gamble, *Under the Shadow of Tuskegee: African-Americans and Health Care*, 87 AM. J. PUB. HEALTH 1773, 1776 (1997) [hereinafter *Under the Shadow*]. See also Ronald Roach, *History's Burden: After Decades of Neglect, an Academic Research Agenda is Being Built Around Health Disparities*, 20 BLACK ISSUES HIGHER EDUC. 1, 18 (May 8, 2003), available at findarticles.com/p/articles/mi_m0DXK/is_6_20/ai_101939864 [hereinafter *History's Burden*].

16. Discussed in II.A, *infra* page 6.

17. *Under the Shadow* at 1773.

18. Todd L. Savitt, “*The Use of Blacks for Medical Experimentation and Demonstration in the Old South*,” JOURNAL OF SOUTHERN HISTORY 331 (1982).

19. *Id.* at 332.

20. *Id.* at 333.

21. *Id.*

22. *Under the Shadow* at 1774.

23. Louis Alexis Chamerovzow, *Slave Life in Georgia: A Narrative of the Life, Sufferings, and Escape of John Brown, A Fugitive Slave Now in England*, electronic edition, 45 available at <http://docsouth.unc.edu/neh/jbrown/jbrown.html>.

remedy sun-stroke.²⁴ In Brown's recount of the events he described how Dr. Hamilton asked permission of his owner, Stevens, who "never inquired what was going to be done" and even if Brown had known what was going to be done he could not himself refuse participation.²⁵ Dr. Hamilton had a hole dug into the ground filled with wood and set a fire.²⁶ Dr. Hamilton then forced Brown into the pit naked to sit with various mechanisms maintaining the heat inside.²⁷ Brown was provided with various medications; however, the experiments did not conclude until after Brown passed out.²⁸ Between the series of experiments Brown was placed on a diet and bled every other day; after he became weak from this experiment Dr. Hamilton began an experiment to ascertain how deep Brown's skin went.²⁹ In an effort to ascertain how deep Brown's skin went Dr. Hamilton he applied blisters to Brown's hands, legs, and feet and continued to create blisters until a layer of dark skin formed.³⁰

In a second event, a study conducted in Alabama slaves were used for gynecological experiments. Dr. J Marion Sims, now known as the founder of modern surgical gynaecology, developed an operation for the cure of vesicovaginal fistula.³¹ Dr. Sims was able to develop this cure by using slave subjects that he housed in hospital behind his home in Montgomery, Alabama.³² One slave in particular underwent thirty operations by Dr. Sims, who was able to repair holes in her bladder and rectum.³³ In total, Dr. Sims had seven subjects who involuntarily

24. *Id.*

25. *Id.*

26. *Id.* at 46.

27. *Id.*

28. *Id.*

29. Chamerovzow, *supra* note 23 at 47-48.

30. *Id.* at 48; *see also* Alondra Nelson, *Unequal Treatment*, Washington Post, Jan. 7, 2007 at <http://www.washingtonpost.com/wp-dyn/content/article/2007/01/05/AR2007010500180.html> last accessed Apr. 20, 2013 stating that the study to determine how deep Brown's skin went was without therapeutic value.

31. LL Wall, *The Medical Ethics of Dr. J Marion Sims: A Fresh Look at the Historical Record*, 32 (6) J. MED. ETHICS 346 (2006).

32. *Id.*

33. *Id.*

underwent experimentation.³⁴ Procedures were performed without anesthetics, and one subject almost died.³⁵ Experiments such as this and the one involving John Brown were only the beginning of unethical experiments that finally culminated with the Tuskegee experiment.

A. The Tuskegee Syphilis Study

A seminal event in the realm of race, genetics, and research is the Tuskegee Syphilis Study. The Tuskegee study began in 1932 at the behest of the United States Public Health Services [hereinafter USPHS] in collaboration with the Tuskegee Institute.³⁶ The study was entitled “Tuskegee Study of Untreated Syphilis in the Negro Male,” which aimed to study the effects of syphilis on black males.³⁷ These results would then be used to validate certain drug treatments targeted for minorities.³⁸

There were 600 subjects involved in the study; of that number 399 had syphilis while 201 were disease free.³⁹ Black men, most of which were sharecroppers, between 25 and 60 years old were targeted for the study, especially those who tested positive for the disease.⁴⁰ The black men were told they were being treated for “bad blood” and subjected to research without their

34. Durrenda Ojanuga, *The Medical Ethics of the Father of Gynaecology, Dr J Marion Sims*, 19 J. MED. ETHICS 28, 29 (1993).

35. *Id.*

36. American Health Lawyers Association, *Patient-Tailored Medicine, Part One: The Impact of Race and Genetics on Medicine*, Vol. 2 No. 1 J. HEALTH & LIFE SCI. L. 1, 11 (2008); see also CDC, *U.S. Public Health Services Syphilis Study at Tuskegee: The Tuskegee Timeline*, available at <http://www.cdc.gov/tuskegee/timeline.htm> (2011) [hereinafter *The Impact of Race & Genetics*].

37. *Tuskegee Timeline*.

38. *Id.*

39. *Id.* see also Tuskegee Syphilis Study Ad Hoc Advisory Panel, *Final Report: Report on Charge I-A* (Apr. 28, 1973), biotech.law.lsu.edu/cphl/history/reports/tuskegee/report1.pdf [hereinafter *Report on Charge I-A*] stating that the researchers never actually documented the reason for the study and that the subjects to the study were not given information about possible effects of the study.

40. Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Experiments*, in TUSKEGEE'S TRUTHS: RETHINKING THE TUSKEGEE SYPHILIS STUDY 1, 15, 18 (Susan M. Reverby ed., University of North Carolina Press) (2000), available at <http://www.sociology101.net/readings/Racism-And-Research.pdf> [hereinafter *Racism and Research*].

informed consent.⁴¹ Unfortunately, the treatments involved did not cure the disease and the treatments that were supposed to only last six months went on for forty years.⁴² The men received medical exams, free food, and burial insurance as compensation for their participation in the study.⁴³

The study was conducted in Macon County, Alabama.⁴⁴ Macon County was particularly interesting for the researchers because evidence obtained during demonstration studies during 1930-1932 showed a high rate of syphilis among the black population in Macon.⁴⁵ These initial demonstration studies were funded by the Julius Rosenwald Fund.⁴⁶ Culturally, this population was poorly viewed and vulnerable because the illiteracy rate was pervasive.⁴⁷ Later research was financially supported by the USPHS and a grant from the Milbank Memorial Fund which gave \$50 to each of the subjects for their participation in the study.⁴⁸

The fact still remains, “treatment [that] could have cured them was deliberately withheld, and many of the men were prevented from seeing physicians who could have cured them.”⁴⁹ Penicillin became available in the early 1950s which could effectively treat the disease.⁵⁰ In 1969, the Tuskegee study was reaffirmed by the Center for Disease Control and even gained

41. *Tuskegee Timeline*.

42. *Id.*

43. *Id.*

44. Tuskegee University, *About the USPHS Syphilis Study*, available at http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx (2013).

45. *Report on Charge I-A* at 2.

46. *Racism and Research* at 2-3.

47. *Id.*

48. *Id.*

49. *Racism and Research* at 1.

50. *Id.* See also *Tuskegee Timeline* which states that in 1945 Penicillin was accepted as the preferred treatment for syphilis, 1947 USPHS established “Rapid Treatment Centers” to treat syphilis, but the men involved in the study were prohibited from obtaining treatment.

support of medical associations such as the American Medical Association and National Medical Association.⁵¹

The study did not end until 1972 when the Department of Health, Education, and Welfare [hereinafter HEW] insisted that the study cease after news media reported on the existence of the study.⁵² Only seventy-four of the subjects were alive when the study was brought to public attention.⁵³ HEW appointed an investigatory committee which found, among other things, that the study was unethical and the benefits of the study were not justified in comparison to the enormous risk undertaken by the subjects.⁵⁴ The study “has come to symbolize racism in medicine, misconduct in human research, the arrogance of physicians, and government abuse of black people.”⁵⁵

In 1997, President Clinton apologized on behalf of the nation and recognized that this atrocity had far reaching effects that extended beyond the participants in the study.⁵⁶ President Clinton remarked, “an apology is the first step, and we take it with a commitment to rebuild that broken trust.”⁵⁷ The broken trust that continues to permeate in the African American community is a contributing factor that leads to lower level of black participation in medical studies.⁵⁸ This mistrust and fear of medical researchers is now entrenched in the values and perceptions in the African American community.⁵⁹

51. *Id.*

52. *Tuskegee Timeline.*

53. *Racism and Research* at 1.

54. *Tuskegee Timeline.*

55. *Under the Shadow* at 1773.

56. The White House, Office of the Press Secretary, *Remarks by the President in Apology for Study Done in Tuskegee* (May 16, 1997), clinton4.nara.gov/textonly/New/Remarks/Fri/19970516-898.html.

57. *Id.*

58. *Under the Shadow* at 1773.

59. *The Impact of Race and Genetics* at 14, see also Ronald Roach, *History's Burden: After Decades of Neglect, an Academic Research Agenda is Being Built Around Health Disparities*, 20 BLACK ISSUES HIGHER EDUC. 1, 18 (May 8, 2003), available at findarticles.com/p/articles/mi_m0DXK/is_6_20/ai_101939864 [hereinafter *History's Burden*] which provides insight on the impact of the Tuskegee experiment with respect to medical and public health professionals who attempt to treat diseases in the African American community; Shannon

B. The Current Paradigm for Drug Development & Clinical Trials

Over time many legal and ethical principles have evolved to protect patients who participate in clinical research. This section will examine international codes of ethics and regulatory practices in the United States. The Nuremberg Code, the Declaration of Helsinki, the Protection of Human Subjects regulation of 2009 and the NIH Revitalization Act of 1993 provide domestic and international protections to patients who participate in clinical research. Many researchers abide by the Nuremberg Code and Declaration of Helsinki even though they are aspirational in nature because the United States has not formally adopted these codes of ethics. Still, the Nuremberg Code and Declaration of Helsinki were influential in the United State's effort to develop policies to guide research domestically.

1. International Code of Ethics

The Nuremberg Code was implemented in response to the atrocities that occurred on concentration camps in Nazi Germany.⁶⁰ The Nuremberg Code provides guidelines that should be followed when conducting clinical research, most importantly the necessity for voluntary and informed consent.⁶¹ This requires that participants are legally able to consent and freely acquiesce to participation without coercion, duress, or other unethical factors.⁶² In addition, the experiment should yield fruitful results for the good of society.⁶³ Not only should the experiment

Mortland, *Local Health Officials Rally to Stem Black's Cancer Fears*, CRAIN'S CLEVELAND BUS., Aug. 28, 2006, at 3 discussing African Americans mistrust of oncologist and attempts to remedy the issue by targeting minority populations to dispel widely held views.

60. People & Events: The Nuremberg Trials, PBS, <http://www.pbs.org/wgbh/amex/nuremberg/> (last visited March. 13 2013).

61. Office of Human Subjects Research, Regulations and Ethical Guidelines, Nuremberg Code, Nat'l Insts. Health, available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html>.

62. *Id.*

63. National Institutes of Health, "*Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*," Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949., available at <http://history.nih.gov/research/downloads/nuremberg.pdf>

yield fruitful results, but the experiment should not involve physical or mental suffering.⁶⁴ However, the Nuremberg Code is not a part of legal jurisprudence in the United States; therefore, researchers are not obligated to follow its mandate although it is the norm.⁶⁵

Likewise, the Declaration of Helsinki is not legally binding in the United States but provides ethical principles for researchers.⁶⁶ Similar to the Nuremberg Code, the Declaration of Helsinki is concerned with voluntary participation and informed consent.⁶⁷ “It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research.”⁶⁸ The Declaration of Helsinki requires that the protocol include the design and performance of each study and any potential conflicts that may arise between physicians and institutions financially supporting the endeavor.⁶⁹ The Nuremberg Code and Declaration of Helsinki were influential in the United State’s efforts to deal with unethical practices in research.⁷⁰

2. U.S. Regulatory Protections

The United States passed the Protection of Human Subjects⁷¹ to address patient participation in research and the National Institutes of Health Revitalization Act of 1993 to

64. *Id.*

65. *See Generally* Ravindra B. Ghooi, *The Nuremberg Code – A Critique*, 2:2 *Perspect. Clin. Res.* 72 (2011).

66. World Med. Ass'n, *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (2008), available at <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

67. *Id.*

68. World Medical Association, *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, last accessed (May 9, 2013) available at <http://www.wma.net/en/30publications/10policies/b3/>.

69. *Id.* at para. 14.

70. Matthew Anderson, *FDA Abandons Declaration of Helsinki for International Clinical Trials*, *The Social Medicine Portal*, (2008) available at <http://www.socialmedicine.org/2008/06/01/ethics/fda-abandons-declaration-of-helsinki-for-international-clinical-trials/>.

71. 45 C.F.R. § 46 (2009).

require researchers to include minorities in research.⁷² This section will now examine U.S. regulations that provide protections to participants in clinical trials.

i. The Common Rule

The Protection of Human Subjects of 2009, also known as the Common Rule, is codified in the Code of Federal Regulations Title 45 Part 46.⁷³ The Common Rule applies to research involving human subjects that is financed by federal government funding; takes place at a federally funded institution; or conducts research to support an application to the FDA.⁷⁴ The Common Rule provides detailed requirements that researchers must abide by, and include but are not limited to, requirements for informed consent and the establishment of an Institutional Review Board [hereinafter IRB] for oversight.⁷⁵

More specifically, each institution covered by the Common Rule must have at least one IRB, and before the covered research can begin research he or she must obtain approval from the IRB.⁷⁶ The IRB is to function as an independent body whose goal is to protect the safety and welfare of the participants involved in the research by ensuring that the researchers are compliant with federal regulations.⁷⁷ Most important, the IRB is tasked with ensuring that possible risks to the participants are minimized “by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.”⁷⁸

72. National Institutes of Health Revitalization Act, Pub. L. No. 103-43, § 492B(a)(1) (1993) [hereinafter Revitalization Act].

73. 45 C.F.R. § 46 (2009).

74. *Id.* at § 46.101 (2009).

75. *Id.* at §§ 46.103, 46.116 (2009).

76. *Id.* at § 46.109 (2009).

77. *Id.* at § 46.107 (2009).

78. *Id.* at § 46.111(a)(1) (2009).

From a patient perspective, the Common Rule provides legal protection even when informed consent is followed.⁷⁹ The Common Rule states “No informed consent . . . may include exculpatory language through which the subject . . . is made to waive . . . any of the subject's legal rights, or . . . to release the investigator, the sponsor, the institution or its agents from liability for negligence.”⁸⁰ The provision is particularly important because if the patient is able to prove that the researcher fell below the acceptable standard in the performance of the research he or she may have a cause of action. Similarly, the NIH Revitalization Act of 1993 provides protections to ensure that minorities represented in clinical research.

ii. NIH Revitalization Act of 1993

Because of the events blacks experienced with respect to clinical research, the legislature implemented the Revitalization Act of 1993. Public Law 103-43 National Institutes of Health Revitalization Act of 1993 [hereinafter Revitalization Act], requires that members of minority groups be included as research participants in clinical research.⁸¹ In addition, the statute requires the National Institutes of Health [hereinafter NIH] to develop guidelines that governs when inclusion of minorities is inappropriate, “the manner in which clinical trials are required to be designed and carried out,” and “the operation of outreach programs.”⁸² The Revitalization Act also tasks the Director of NIH with the responsibility of ensuring that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect members of minority groups differently than other study participants.⁸³ This provision is especially important as it requires cross comparison between groups and

79. Matthew P. Gordon, *A Legal Duty to Disclose Individual Research Findings to Research Subjects?*, 64 Food Drug L.J. 225, 231—32 (2009).

80. 45 C.F.R. § 46.116 (2009).

81. *Id.*

82. *Id.* at § 492B(d)(1).

83. *Id.* at § 492B(c).

prevents researchers from isolating certain populations, unless an exception applies, without cross referencing the drug's effects on members of other groups.⁸⁴

The Revitalization Act advances the position that minorities should be included in research by requiring that “the Director of the Office of Research on Minority Health, conduct or support outreach programs for the recruitment of members of minority groups as subjects in the projects of clinical research.”⁸⁵ The Revitalization Act applies broadly except in cases where minority participation in the research “is inappropriate with respect to the health of the subjects, is inappropriate with respect to the purpose of the research, or is inappropriate under such other circumstances” identified by the Director of NIH.⁸⁶ Similarly, minority participation in research is exempted where there is scientific evidence establishing no significant difference between the impacts the variables studied in the trial would have on minorities and the impact the variables would have on participants if the inclusion was not required.⁸⁷

The NIH stands firm behind the policy that minorities should be included in clinical research “unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.”⁸⁸ While the NIH policy is positive in theory and the federal statute establishes procedural requirements such as informed consent and other patient protections, these policies and laws are without effect if minorities do not participate in

84. *Id.* at § 492B(d).

85. *Id.* at § 492B(a)(2).

86. *Id.* at § 492B(b).

87. *Revitalization Act* at § 492B(d)(2).

88. NIH, *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, Amended October 2001 available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

the research. “Black Americans tend to be under-represented in clinical trials, which are responsible for most advances in medicine.”⁸⁹

In summation, international ethical principles and domestic regulations work together to provide patient protection. Researcher institutions that receive federal funding are incentivized to adhere to the preapproved clinical protocol so that they can continue to receive federal funds. In addition, IRBs are in place and provide independent oversight over the clinical process. The Common Rule specifically protects participants because researchers cannot provide oral or written exculpatory language to absolve themselves of liability. Even more, if a participant can prove that the researcher was negligent, despite providing informed consent, he or she can recover damages.

However, these legal and regulatory safeguards fall short of protecting participants because minorities are not participating in research. While the Revitalization Act mandates that minorities are included in research, African Americans remain disproportionately underrepresented. African American’s perspectives on the adequacy of legal and ethical protections create a barrier that prevents them from participating in clinical researchers. These perspectives are the subject of the next section.

C. Minority Perspectives on the Adequacy of Protections in Clinical Trials

According to 2011 census data, African Americans make up approximately 13.1% of the United States population.⁹⁰ As recent as 2009, African Americans comprise 15% of the 28.1%

89. Amanda Gardner, *Black Americans Still Wary of Clinical Trials Study Shows Distrust of Researchers Lingers from Tuskegee Experiment*, U.S. News & World Report, Jan. 14, 2008, available at <http://health.usnews.com/usnews/health/healthday/080114/black-americans-still-wary-of-clinical-trials.htm>.

90. US Census Bureau, *State and County Quick Facts USA*, available at <http://quickfacts.census.gov/qfd/states/00000.html>.

of minorities who participate in domestic clinical research.⁹¹ Minority distrust of clinical researchers is one of the reasons African Americans do not participate in research.⁹² “For many, this project [Tuskegee] represents the epitome of how racism is reflected in medicine and medical research as it is in general society.”⁹³ Factors that weigh African American participation in research include “distrust owing to historical research abuse and institutional racism, lack of information and understanding of research and studies and informed consent, insufficient recruitment efforts by researchers, social stigma, and financial considerations.”⁹⁴

In the professional realm, African Americans are underrepresented in the fields of medical and mental health, which further perpetuates levels of mistrust.⁹⁵ Corbie-Smith and fellow researchers raise a very important point that was highlighted in their study of African American perceptions of clinical research -- “regardless of whether the instances participants provided as explanations are historically accurate, every instance is perceived as “real” in their minds.”⁹⁶ The past still haunts many African Americans and dealing with those deeply rooted ideologies is an important step in increasing minority participation in research.⁹⁷ “Knowledge of research procedures and purposes is often linked to access to health care.”⁹⁸ But, Corbie-Smith

91. Department of Health and Human Services National Institutes of Health, *Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research Comprehensive Report: Tracking of Human Subjects in Fiscal Year 2009 and Fiscal Year 2010*, (2011) available at <http://orwh.od.nih.gov/research/inclusion/pdf/Inclusion-ComprehensiveReport-FY-2009-2010.pdf>.

92. Sharde C. Thomas, *It's Not You It's Me: Necessity of Including Cultural Factors in Clinical Research*, 30 *LAW & INEQUALITY* 179, 189 (2012).

93. Marcia Killien et. al, *Involving Minority and Underrepresented Women in Clinical Trials: The National Centers of Excellence in Women's Health*, 9 *J. WOMEN'S HEALTH & GENDER-BASED MED.* 1061, 1063 (2000).

94. Hsin-hsin Huang and Angela D. Coker, *Examining Issues Affecting African American Participation in Research Studies*, 40-4 *J. BLACK STUDIES* 619 (2010).

95. *Id.* at 622.

96. Corbie-Smith et. al, *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 *J. GENERAL INTERNAL MEDICINE* 537, 543 (1999).

97. Hsin-hsin, *supra note* 94 at 622.

98. V.S. Freimuth, S.C. Quinn, S.B. Thomas, G. Cole, E. Zook, and T. Duncan, *African American's Views on Research and the Tuskegee Syphilis Study*, 52 *SOCIAL SCIENCE & MEDICINE*, 797-808 (2001).

found that African Americans have an increased likelihood of being distrustful of physicians.⁹⁹ Physicians can serve as pivotal players in research protocols because they often are aware of research and can recommend participation in the studies. However, because African Americans are distrustful of physicians, their level of distrust will override their inclination to participate in the study.¹⁰⁰

Moreover, minority perspectives are shaped by the information that is available to them.¹⁰¹ Minorities do not participate in research because of lack of access to primary care physicians who often suggest participation in clinical research and their beliefs that studies do not apply to them, which in turn decreases minority participation in studies.¹⁰² In addition, because most people do not trust what they cannot understand, minorities are leery of participating in clinical trials when they cannot understand the informed consent documents.¹⁰³ African Americans, in particular, are concerned with social stigmatization and other consequences so they shy away from medical attention.¹⁰⁴

Conversely, not all African Americans are reluctant to participate in clinical research. For those who choose to participate, literature suggests that altruism and volunteerism are contributing factors.¹⁰⁵ Another motivating factor is family encouragement.¹⁰⁶ However, one of

99. See G. Corbie-Smith & SB Thomas, *Distrust, Race, and Research*, 62 ARCH INTERN MED 2458 (2002).

100. *Id.*

101. *Id.* at 623.

102. V.S. Freimuth, S.C. Quinn, S.B. Thomas, G. Cole, E. Zook, and T. Duncan, *African American's Views on Research and the Tuskegee Syphilis Study*, 52 SOCIAL SCIENCE & MEDICINE, 797-808 (2001); See also Y.R. Smith, A. M. Johnson, L.A. Newman, A. Greene, T.R.B. Johnson, & J. L. Rogers, *Perceptions of Clinical Research Participation Among African American Women*, 16 J. Women's Health 423 (2007).

103. S.E. Mason, *Offering African Americans Opportunities to Participate in Clinical Trials Research: How Social Workers Can Help*, 1 J. TRANSCULTURAL NURSING 40 (2005).

104. Hsin-hsin, *supra note 94* at 624.

105. *Id.*

106. *Id.*

the leading barriers to minority participation in research is financial constraint; so for those who participate in clinical protocols, financial incentive is often a deciding factor.¹⁰⁷

Nevertheless, efforts that encourage participation are curbed when “pharmaceutical companies discourage the recruitment of diverse populations.”¹⁰⁸ Instead, research institutions should focus on resolving negative perceptions. It is difficult to debunk negative perceptions and attitudes when companies continue to contribute to those negative perceptions by discouraging participation in research. The NIH has identified circumstances when minority participation is excluded.¹⁰⁹ Therefore, efforts to discourage participation should be redirected to debunking myths in the minority community.

III. Health Indicators and Access to Drugs

The following section will examine health indicators specifically access to drugs. Health indicators, to be fully discussed below, identify disparities in health by using measurable factors. Access to health is one of the measurable health indicators. Lack of access to health in turn creates disparities in health and a trickledown effect. Lack of access creates disparities in health care treatment which then impacts health care outcomes such as treatment for particular diseases and life expectancies in certain populations. This section will now define access as a health indicator and followed by an analysis that explores the impact that results because of lack of access to health care treatment and prevention.

107. See Thomas, *supra* note 92.

108. Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221, 227 (2003).

109. Revitalization Act at § 492B(d)(1)(A).

A. Determinants of Health as a Policy to Support Race-Based Medicine

Access to drugs, pharmaceuticals, and research is one means to measure health. “Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.”¹¹⁰ Research shows that the uninsured, women in particular, have a greater difficulty accessing health care and use fewer services and preventive care.¹¹¹ Approximately one in four blacks rely on Medicaid for healthcare in comparison to one in eight whites.¹¹² It is difficult for minorities to access care because factors such as low reimbursement rates, administrative burdens, and residential segregation between providers and patients create barriers to access.¹¹³

Health indicators are defined as “measurable characteristics that describe the health of a population; determinants of health; and health care access, cost, quality and use.”¹¹⁴ The health of a population can be measured in terms of life expectancy, mortality, disease incidence or prevalence and or any other health states.¹¹⁵ Health determinants are influenced by health behaviors, health risks factors, socioeconomic and physical environments.¹¹⁶ Health indicators are useful for measuring how certain identifiable groups access health care and health care related services.¹¹⁷

110. United Nations Development Group, *Indicators for Monitoring Development Goals*, United Nations (2003) available at <http://mdgs.un.org/unsd/mi/wiki/8-13-Proportion-of-population-with-access-to-affordable-essential-drugs-on-a-sustainable-basis.ashx?HL=access>.

111. Ruth A. Almeida, Lisa C. Dubay, & Grace Ko, *Access to Care and Use of Health Services by Low-Income Women*, 22-4 HEALTH CARE FINANCING REVIEW 27 (2001).

112. American Diabetes Association, American Lung Association, Families USA, Joint Center for Political and Economic Studies, National Association for the Advancement of Colored People (NAACP), National Council of La Raza (NCLR), National Medical Association, & National Urban League Policy Institute, *Medicaid: A Lifeline for Blacks and Latinos with Serious Health Care Needs*, (2011) available at <http://www.lung.org/assets/documents/publications/medicaid/medicaid-a-lifeline-for.pdf>.

113. See generally Almeida, *supra* note 111.

114. Health Indicators Warehouse, Department of Health & Human Services, Resources Glossary, available at <http://healthindicators.gov/Resources/Glossary>.

115. *Id.*

116. *Id.*

117. *Id.*

Researchers have examined three core areas as they relate to disparities in health.¹¹⁸ The first core area researchers have explored are disparities that involve differences in the type of treatment offered to patients.¹¹⁹ Socioeconomic factors have contributed to health disparities especially as it relates to access to care.¹²⁰ Not only do socioeconomic factors impact access to care, but socioeconomic factors also affect the type of treatment offered to the patient and is a determinate of whether the patient accepts the proposed treatment.¹²¹ At the intersection of health indicators and health disparities, researchers have been able to identify how race, socioeconomic factors, and biological factors impact access to and quality of care.¹²² Unfortunately, African Americans are less likely to receive medically appropriate care even when socioeconomic and access to care factors is controlled i.e. when examining African Americans to Caucasians in the same socioeconomic status.¹²³

A second core area of research has focused on particular conditions and the health outcomes that result from those various conditions.¹²⁴ These studies are particularly important for researchers in the pharmaceutical industry because it would support assertions that researchers make when holding that certain medicines are not fit for a particular population. The government requires that when certain racial or gender groups are excluded from research that the researcher provide evidence that the group would be harmed in some way or that the research would not be beneficial. Where a research can show that a particular treatment will harm a

118. Mary Anne Bobinski, *Inequities in Healthcare: Article: Health Disparities and the Law: Wrongs in Search of a Right*, 29 AM. J. L. AND MED. 363, 365 (2003).

119. *Id.*

120. Marian E. Gornick et al., *Understanding Disparities in the Use of Medicare Services*, 1 YALE J. HEALTH POL'Y L. & ETHICS 133 (2001).

121. *Id.*

122. *See generally*, Bobinski, *supra* note 118 at 366.

123. Eric C. Schneider et al, *Racial Disparities in the Quality of Care for Enrollees in Medicare Managed Care*, 287 JAMA 1288 (2002).

124. *See, e.g.*, Isaac J. Powell et al., *Disease-Free Survival Difference Between African-Americans and Whites After Radical Prostatectomy for Local Prostate Cancer: A Multivariable Analysis*, 59 UROLOGY 907 (2002); Vickie L. Shavers & Martin L. Brown, *Racial and Ethnic Disparities in the Receipt of Cancer Treatment*, 94 J. NAT'L CANCER INST. 334 (2002).

group s/he is insulated from governmental scrutiny. In fact, biology alone can create health disparities and not wrongdoing on the behalf of researchers.¹²⁵

The third core area of research explores disparities in health status for example differences in life expectancy and prevalence of certain diseases for certain groups.¹²⁶ Health status directly correlates with gender.¹²⁷ Men have a life expectancy that is five years less than that of women.¹²⁸ The Centers for Disease Control uses life expectancy to measure health.¹²⁹ From 1980 to 2008, life expectancy at birth increased six years for males rising from 70 to 76 and four years for females from 77 to 81 years.¹³⁰ However, African Americans still lag behind in life expectancy when compared to their Caucasian counterparts.¹³¹ African Americans have a life expectancy of 70 years for males compared to 78 years for Caucasian males and 77 years for African American females compared to 83 years for Caucasians females.¹³² “That disparities in health status mirror patterns of historical discrimination in society is at least cause for alarm, and perhaps action as well.”¹³³ There are many factors that impact health disparities and access to health care and it is crucial that the actual cause is identified to remedy and address the problems African Americans face as identified by health indicators. One way to identify and address health problems in the African American community is through race-based medicine.

125. Nicholas H. Feiback et al., *Differences Between Women and Men in Survival After Myocardial Infarction*, 263 JAMA 1092 (1990).

126. Bobinski, *supra* note 118 at 366.

127. *Id.*

128. Joseph Nordqvist, *Female Life Span Going Down in Some Parts of the U.S.*, Medical News Today, Mar. 5, 2013 available at <http://www.medicalnewstoday.com/articles/257187.php>.

129. NAT'L CTR. FOR HEALTH STAT., Health, United States, 2011, Chartbook on Trends in the Health of Americans Table 22, available at <http://www.cdc.gov/nchs/data/hus/hus11.pdf>.

130. *Id.*

131. *Id.*

132. *Id.*

133. Bobinski, *supra* note 118 at 367.

B. Race-Based Medicine a Misunderstood Clinical Research Practice

Race-based medicine is a subset of pharmacogenomics, which involves the sequencing of the human genome to better understand disease and pharmaceutical mechanisms for an individual patient.¹³⁴ Race-based medicine can be defined as “screening, diagnosis, or treatment based on the appointment of an individual to a specific subpopulation associated with his physical characteristics, language, or, perhaps, surname, which is presumed to serve as a marker of the geographic origins of one’s ancestors.”¹³⁵ One goal of race-based medicine is to explore racial ancestry to better identify genetic predispositions for diseases.¹³⁶ It is crucial that patients and researchers understand the difference between social race and biological race.¹³⁷ Social race as distinguished from biological race is the ideology that taking an individual’s perception and combining society’s perception of the individual impact the ethnic or racial group within which the individual is a member.¹³⁸ On the other hand, biological race examines race in the context of ancestry.¹³⁹ Although there is a history of racially motivated research, some argue that race is no longer a factor that impacts research.¹⁴⁰

Race-based medicine is highly debated both in theory and in practice because on the one hand race-based medicine could advance medicine, but on the other hand it could negatively perpetuate stereotypes and ideologies of certain groups. “Although it is recognized that ideology influences the social meaning of race, it is usually assumed that there is a separate, prior

134. Benjamin Bates, Kristan Poirot, Tina M. Harris, Celeste M. Condit, and Paul J. Achter, *Evaluating Direct-to-Consumer Marketing of Race-Based Pharmacogenomics: A Focus Group Study of Public Understandings of Applied Genomic Medication*, 9 J. HEALTH COMM. 541, 542 (2004).

135. Janet Brewer, *Diseases of Place: Legal and Ethical Implications of Surname and Ethnicity as Predictors of Disease Risk*, 9 QUINNIPIAC HEALTH L.J., 155 (2006).

136. Dorothy E. Roberts, *Race, Pharmaceuticals, and Medical Technology: Is Race-Based Medicine Good for Us? African American Approaches to Race, Biomedicine, and Equality*, 36 J.L. MED. & ETHICS 537 (2008).

137. *Id.* at 539.

138. Sally Satel, *Race and Medicine Can Mix Without Prejudice: How the Story of BiDiI Illuminates the Future of Medicine*, available at http://www.medicalprogresstoday.com/spotlight/spotlight_indarchive.php?id=449.

139. *Id.*

140. Roberts, *supra note* 136 at 539.

scientific understanding of race that is not contaminated by politics.”¹⁴¹ Critics of race-based medicine argue that race should not be used because “race has no coherent meaning, and therefore, reliance upon it for research or treatment purposes can be confusing at best and can lead to significant adverse consequences at worst.”¹⁴² However, the truth remains that there are differences in life expectancy between racial groups, differences in metabolic rates of nicotine from cigarette smoking, and differences in hypertension rates.¹⁴³ Examining how race and other health indicators factor into overall health is important so that healthcare players such as lawmakers, researchers, doctors, and community activist; can better close the divide between racial groups and health care disparities.

Scholar of race, gender and law, Dorothy Roberts, identifies “conservative colorblind ideologists” as those who assert that differences between racial groups are based on unbiased market operations, that racism is no longer a factor socially, and that social policies should not use race as a basis for policy determinations.¹⁴⁴ Conservative colorblind ideology is an extreme view for some to conceptualize. However, there is some merit to the idea in the biological research realm. In biological research, race remains a factor in medical research and because of these differences between groups it is important for researchers to fully explore these differences when developing medicines.¹⁴⁵

141. *Id.*

142. Sharona Hoffman, “Racially-Tailored” Medicine Unraveled, 55 Am. U.L. Rev. 395, 410 (2005).

143. See NAT’L CTR. FOR HEALTH STAT., Health, United States, 2011, Chartbook on Trends in the Health of Americans Table 22, available at <http://www.cdc.gov/nchs/data/hus/hus11.pdf> (describing differences in life expectancy rates blacks living shorter lives than whites); Neal L. Benowitz et al., *Ethnic Differences in N-Glucuronidation of Nicotine and Cotinine*, 291 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1196 (1999) (study examined nicotine metabolizing rates in blacks and whites criticized for not enrolling a significant number of blacks in the study); and Richard S. Cooper et al., *An International Comparative Study of Blood Pressure in Populations of European vs. African Descent*, 3 BMC Med. 2 (2005), available at <http://www.biomedcentral.com/>.

144. Roberts, *supra note* 136 at 539.

145. *Id.*

Acknowledging the fact that there are differences between races is key in closing the gap in health disparities. The next step is to make clear that while there are biological differences between groups, the race of the individual will not interfere with the ethical obligations of the researcher. The conservative's view of racial colorblindness intersects with the identity-based ideologist because both groups share the view that race matters in medicine. Identity-based ideologists are race conscious and assert that programs that use race as a basis for funding are important for advancing medicine.¹⁴⁶ Race-conscious efforts are implemented to correct past wrongs and in doing so also advance current colorblind paradigms.¹⁴⁷ One example that has been particularly beneficial for African Americans is the drug BiDil. BiDil is a drug specifically targeted at African Americans and has created an alliance between the pharmaceutical world and racial organizations such as the National Association for the Advancement of Colored People (NAACP). As a result, the pharmaceutical company and national association can work together to close the gap in health disparities.¹⁴⁸

IV. BiDil

The drug BiDil has an interesting past despite its positive results in the African American community. The first study of BiDil failed to receive Federal Drug Administration [hereinafter FDA] approval.¹⁴⁹ The first FDA application was submitted in 1997, but the results failed to show sufficient statistical efficacy for a multiracial population with heart disease.¹⁵⁰ "On the recommendation of members of FDA's advisory committee, NitroMed re-examined the clinical

146. S. Epstein, *Inclusion: The Politics of Difference in Medical Research* (Chicago: University of Chicago Press, 2007).

147. *Id.*

148. NAACP, "NAACP and NitroMed Announce Partnership to Narrow Disparities in Cardiovascular Healthcare," December 14, 2005, available at http://findarticles.com/p/articles/mi_m0EIN/is_2005_Dec_14/ai_n15934865.

149. Sheldon Krinsky, *The Short Life of a Race Drug*, 379-9811 THE LANCET 114 (2012) available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)60052-X/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60052-X/fulltext).

150. *Id.*

trial data along racial lines.”¹⁵¹ It was from this data that the researchers began a second study that later would receive FDA approval. The drug is criticized for promoting counterproductive healthcare policy. The FDA, by approving BiDil, also approved a biological model for race.¹⁵² “Because the FDA had no clinical evidence on which to base its drug approval for a specific race, the approval is implicitly based on an assumed biological difference between black and nonblack patients.”¹⁵³ The clinical researchers failed to cross compare populations to determine whether there was a significant difference when determining the efficacy of the drug.¹⁵⁴ This section will now examine how the drug BiDil was developed and its social, political, and commercial implications.

1. Development of the Drug BiDil

The FDA announced in June 2005 that it approved for the first time a pharmaceutical drug specifically targeted for African Americans.¹⁵⁵ BiDil is a combination of two generic drugs hydralazine and isosorbide dinitrate.¹⁵⁶ BiDil works to treat heart failure by relaxing the blood vessels surrounding the heart.¹⁵⁷ The drugs themselves are not new to the market, but rather their combination and concentration is a new drug. It is widely viewed by the public as the world’s first “ethnic” drug.¹⁵⁸

151. *Id.*

152. Kirsten Bibbins-Domingo & Alicia Fernandez, *BiDil for Heart Failure in Black Patients: Implications of the U.S. Food and Drug Administration Approval*, 146 *Ann. Intern. Med.* 52, 54.

153. *Id.*

154. Jonathan Kahn, *From Disparity to Difference: How Race-Specific Medicines May Undermine Policies to Address Inequalities in Health Care*, 15 *S. CAL. INTERDIS. L.J.* 105, 106 (2005).

155. Press Release, U.S. Food and Drug Admin., *FDA Approves BiDil Heart Failure Drug for Black Patients* (June 23, 2005), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108445.htm>.

156. Stephanie Saul, *F.D.A. Approves a Heart Drug for African Americans*, *N.Y. TIMES* (June 24, 2005), available at <http://www.nytimes.com/2005/06/24/health/24drugs.html?ref=bidildrug>.

157. Dorothy E. Roberts, *What’s Wrong with Race-Based Medicine?: Genes, Drugs, and Health Disparities*, 12 *MINN. J.L. SCI. & TECH.* 1 (2011).

158. Kahn, *supra note* 154 at 105.

The study was entitled the African American Heart Failure Trial [hereinafter A-HeFT].¹⁵⁹ The study enrolled 1,050 black patients who had New York Heart Association class III or IV heart failure with dilated ventricles.¹⁶⁰ A-HeFT was a randomized, placebo-controlled, double-blind trial with patients recruited at 161 centers in the United States.¹⁶¹ Half of the study participants were treated with the combination drug and the other half the placebo along with standard therapy used for heart failure.¹⁶² This study in comparison to the unethical studies in the early 20th century were reviewed and approved by the institutional review board at each site and all patients gave written informed consent.¹⁶³ The study sponsor was NitroMed, a Massachusetts based biotechnology firm.¹⁶⁴

This study is important for two reasons. First, the study was proven efficacious for a group that traditionally lacks access to proper medical care. Second, the study is important because it provides empirical evidence that researchers are able to implement ethical studies that do not compromise the lives of the study participants. In the A-HeFT study, independent committees assessed all primary and secondary end points, reviewed data on safety, and oversaw the two prespecified interim analyses, which were performed solely to assess the adequacy of the sample size.¹⁶⁵

Although the study was terminated prematurely because many of the patients on the placebo experienced higher mortality, the results showed that patients who were treated with the drug combination hydralazine and isosorbide dinitrate along with standard therapy for heart

159. *Id.*

160. Anne L. Taylor et. al, *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351-20 NEW ENG. J. MED. 2049 (2004).

161. *Id.*

162. *Id.*

163. *Id.*

164. Press Release, NitroMed, *NitroMed Receives FDA Letter on BiDil(R) NDA, a Treatment for Heart Failure in Black Patients* (Mar. 8, 2001), <http://www.nitromed.com/prpress/03-08-01.html>.

165. *Id.*

failure had an increased chance of survival among black patients with advanced heart failure.¹⁶⁶ While all of the study participants were African American, the trial investigators presented that drug as effective in other racial groups as well.¹⁶⁷

The A-HeFT study published by the New England Journal of Medicine establishes that the drug is efficacious in the population studied, African Americans.¹⁶⁸ There was a 43% reduction in mortality rate in the group given the combination drug, supporting the conclusion that the drug controls heart failure.¹⁶⁹ The drug BiDil is widely criticized on social and political levels in spite of the drugs proven efficacy in the African American population.

2. Criticisms of BiDil

Critics of the A-HeFT study do not believe that the drug can be marketed as beneficial for African Americans because there was no comparison population.¹⁷⁰ “The only responsible claim that can be made on the basis of these trials is that BiDil works in some people who have heart failure.”¹⁷¹ The study has been criticized on three levels: scientific, commercial and political.¹⁷² “By claiming that race, a political grouping, is important to the marketing of drugs and that race-based drugs can reduce health disparities, which are caused primarily by social inequality, those who promote racialized medicine have made it a political issue.”¹⁷³

Scientifically there are widespread criticisms to the use of race-based medicine; the more important question to explore is whether race-based medicine can reduce health disparities.

166. *Id.*

167. Taylor et al, *supra* note 160; see also Denise Gellene, Heart Pill Intended Only for Blacks Sparks Debate, L.A. Times, June 16, 2005, available at <http://www.latimes.com/business/la-fi-bidil16jun16.1.5518742.story?coll=la-headlines-business>. Stating that BiDil was not a race-based drug, but rather the data directed the study which indicated that the drug was particularly effective in African Americans.

168. Taylor et. al, *supra* note 160.

169. Taylor, *supra* note 160.

170. Kahn, *supra* note 154 at 106.

171. *Id.*

172. Roberts, *supra* note 157 at 2.

173. *Id.*

Medical research should by no means perpetuate stereotypes and racism, but if race-based medicine can close the gap in the health indicators that relates to access to care, perhaps race-based medicine is a solution and not an actual problem. Next, this paper will address whether the critiques of BiDil address closing the gap in health disparities or are aimed at some other social issue. It is important, as highlighted earlier, to maintain a dividing line between race as a sociological issue and race as a biological/medical issue.

In the political arena, the FDA is criticized for approving the drug BiDil because the drug is targeted for a specific population, African Americans.¹⁷⁴ Historically, the FDA has discouraged clinical research practices that take advantage of marginalized groups.¹⁷⁵ It is argued that the FDA's decision "may be a setback to scientific discourse on therapeutics and may be specifically deleterious to efforts aimed at addressing disparities in health and health care."¹⁷⁶ BiDil has further been criticized for exploiting the African American community for corporate profit and to set a poor precedent of racial segregation in medicine.¹⁷⁷ Even more, the drug was marketed as a race specific treatment, but in reality there was evidence that the drug was effective across racial lines.¹⁷⁸

Commercially, the drug is criticized for its price because the generic drug was priced significantly lower at approximately \$1.50-\$3.00 while BiDil was priced at \$5.40-\$10.80 per day for treatment.¹⁷⁹ It would seem that if the goal were to increase access to health care and decrease disparities in the provision of health, the drug manufacturer would have priced the drug

174. Kirsten Bibbins-Domingo & Alicia Fernandez, *BiDil for Heart Failure in Black Patients: Implications of the U.S. Food and Drug Administration Approval*, 146 ANN. INTERN. MED. 52 (2007).

175. See *infra* section () discussing historical research practices that took advantage of blacks.

176. Bibbins-Domingo & Fernandez *supra* note 152.

177. Joon-Ho Yu, Sara Goering, & Stephanie Fullerton, *Race-Based Medicine and Justice as Recognition: Exploring the Phenomenon of Bidil*, 18:1 CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 57, 59 (2009).

178. J. Kahn & P. Sanker, *Being Specific about Race-Based Medicine*, 25:5 Health Affairs, 375 (2006).

179. S. Saul, *Maker of Heart Drug Intended for Blacks Bases on Price on Patients' Wealth*, N.Y. TIMES Jul. 8 2005 available at <http://www.nytimes.com/2005/07/08/business/08hdug.html>.

in a range that was affordable for the population.¹⁸⁰ Despite the discounts and gratuitous availability of the drug for certain groups, cardiologists argued that the drug cost exceeded many patients' financial ability to pay.¹⁸¹ However, accounting for insurance and other factors it is arguable whether the cost of the drug is commercially exploiting the African American population.

Researchers have attempted to remedy a healthcare disparity by disseminating information that may not be based on scientific evidence.¹⁸² The question then becomes are researchers advancing genetic revolution or are they perpetuating stereotypes?¹⁸³ The FDA is sending mixed signals by approval of the drug BiDil. On the one hand, researchers are required to follow certain clinical guidelines when race is a factor.¹⁸⁴ On the other hand, the FDA has approved the use of race as a factor when it seems to decrease health disparities, but it is argued that this erodes the advancements that were made to create equal treatment in the clinical research setting.¹⁸⁵

V. Race-Based Medicine as a Means to Reduce Health Disparities

Despite the controversy surrounding the drug BiDil, there are benefits to the drug's use. There are many theories that describe why African Americans are more likely to die of heart failure in comparison to whites.¹⁸⁶ Some contributing factors to higher prevalence of heart failure in African Americans in comparison to whites include delay in diagnosis treatment,

180. *Id.*

181. *Id.*

182. *Id.* at 125.

183. Amy Harmon, *In DNA Era, New Worries About Prejudice*, N.Y. Times Nov. 11, 2007 available at <http://www.nytimes.com/2007/11/11/us/11dna.html?ref=bidildrug>.

184. *Id.*

185. *Id.*

186. Howard Brody and Linda M. Hunt, *BiDil: Assessing a Race-Based Pharmaceutical*, 4-6 ANN. FAM. MED. 556 (2006).

physical inactivity, and smoking.¹⁸⁷ A group of social scientists reviewing genomic science argue that “we must continue to do research on race in medicine because whatever its biological basis race remains a very important social construct, and as such, it has tremendous power to influence health and illness.”¹⁸⁸ There are social and cultural factors that can contribute to higher prevalence of certain diseases in certain populations and exploring drugs such as BiDil allows researchers to examine these crucial contributing factors.¹⁸⁹ “Simply eliminating race as a variable in medical research would undermine our ability to detect these factors and can therefore hardly be helpful in reducing the serious disparities that remain a problem in American medicine.”¹⁹⁰

The development of the drug BiDil is a reason to celebrate not only for the scientific advancement, but also for the cultural and social advancement.¹⁹¹ In light of the historical injustices surrounding African Americans and scientific research, the development of BiDil should be seen as a step in the direction of removing discrimination in research.¹⁹² When race is a contributing factor in research it is not to perpetuate racism or discrimination, but rather race is a “placeholder” so that researchers can fully examine differences among groups of people.¹⁹³ “Finding these variations (and their physiological manifestations) and then linking these variations to differences in therapeutic efficacy” is the benefit race-based medicine.¹⁹⁴

187. *Id.* at 556-557.

188. P Sankar, MK Cho, CM Condit, et al., *Genetic Research and Health Disparities*, 291 JAMA 2985 (2004).

189. *Brody and Hunt*, supra note 186 at 557.

190. *Id.*

191. *Id.* See also Stephanie Saul, *F.D.A. Approves a Heart Drug for African Americans*, N.Y. TIMES (June 24, 2005) at <http://www.nytimes.com/2005/06/24/health/24drugs.html?ref=bidildrug&r=0> stating that black political and scientific groups support the development of the drug BiDil viewing it as a way to redress years of inequality in medical treatment and outcomes.

192. *Id.*

193. M. Gregg Bloche, *Race-Based Therapeutics*, 351 N. ENG. J. MED. 2035 (2004).

194. *Id.*

Race-based medicine as a research approach is most supported by the development of the drug BiDil.¹⁹⁵ Creating BiDil is one of the first attempts to remedy claims of misrecognition in research and also increase minority participation in clinical trials.¹⁹⁶ African Americans have distrusted researchers since the occurrence of the racially charged atrocious acts, slavery and the Tuskegee experiment.¹⁹⁷

BiDil should be viewed as not only a drug development, but also as a socially progressive movement that can increase minority participation in research and also prove that researchers respect African Americans and have their best interest in mind. In the following section, I will explore recommendations for dealing with lack of minority participation in clinical trials by way of public health and community based approaches that educate and encourage minorities to trust their physicians and researchers.

VI. Recommendations and Conclusion

Remedying past discrimination in clinical research to encourage minorities seems like a formidable task. “The family medicine community ought to encourage continued action to reduce health disparities, to promote research that addresses the psychological and social contributors to ill health alongside the biological factors.”¹⁹⁸ Unfortunately, minorities remain very distrustful of physicians and clinical researchers. Racial tensions have loomed among African Americans for decades, but if race-based medicine can remedy health disparities it should be pursued. One perspective to address this challenge is a public health perspective. The World Health Organization (WHO) defines public health as “all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a

195. *Id.*

196. *Yu, Goering and Fullerton*, supra note 2 at 62.

197. Discussed in II.A, supra page 5.

198. *Brody and Hunt*, supra note 186 at 560.

whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases.”¹⁹⁹ Disparities in health care access trickle down and have various effects on African Americans. Public health would support measures that prevent disease and prolong life among populations, in this case African Americans. Public health initiatives that promote increased transparency in clinical trials would help to develop bonds of trust between minorities and researchers.

In 2010, the University of Minnesota received a \$3.8 million dollar grant from the National Institutes of Health’s National Cancer Center on Minority Health and Health Disparities.²⁰⁰ Researchers are aware that, while there are racial differences in prevalence among diseases, social and environmental factors also impact health disparities.²⁰¹ “We need not shy away from the potential benefits of race-conscious therapeutics, but we should manage its downside risks, greater awareness among physicians and the public that race is at best a placeholder for other predispositions, and not a biologic verity, would be a first step.”²⁰² Medical researchers and clinical researchers alike should not avoid racial differences in groups because it does these groups a disservice. Instead, researchers should face these racial differences head on to further understand why certain diseases are more prevalent among minorities. The efforts at the University of Minnesota are one step in that direction. The University of Minnesota has identified a group of people, African Americans, who suffers with a health issue and aims to help remedy that issue by educating minorities and encouraging participation in clinical trials.

199. World Health Organization, Public Health, available at <http://www.who.int/trade/glossary/story076/en/>.

200. Justin Paquette, Caroline Marin, Laurel Herold, Matt DePoint, Miranda Taylor, *Medical Schools Partner to Tackle Barriers to Minority Participation in Cancer Clinical Trials*, Health Sciences Academic Health Center available at <http://health.umn.edu/media/releases/empact/>.

201. *Id.*

202. *Bloche*, supra note 193.

In addition to university sponsored events, primary care physicians assist in building trust among minorities. Physicians interact with patients on a one-on-one level and are better able to address distrustful concerns. To address patient distrust, physicians should increase dialogue and find out what concerns minorities face. Preconceived notions and ideas about researchers may be deeply engrained in African American culture, but physicians should take the angle that quality of life increases with better health and with better health researchers must understand how to remedy health issues and without minority participation in research there is no way to understand why illnesses plague that group.

Moreover, legislative initiatives that subsidize costs to increase minority participation in research would encourage pharmaceutical companies to expend more money on minority recruitment. In pediatrics for example the government awards financial incentives for research. The Best Pharmaceuticals for Children Act passed in 2002 provides pharmaceutical companies with extended market exclusivity on drugs developed for children.²⁰³ Because manufacturers have longer market exclusivity on drugs they are able to increase profit which is also an incentive for pharmaceutical companies to research illnesses facing children. Similarly, the government should offer some incentive, be it longer market exclusivity or the government subsidizing costs to address distrust among minorities to in turn increase participation.

All in all, it is challenging remedying distrust in African Americans because of past events and distrustful attitudes carrying from generation to generation. On a simpler level, having participants in research attest to their experiences in clinical trials could help debunk negative ideologies. The fact remains that there are health care disparities; however, taking a public health approach, encouraging relationships between primary care physicians and patients and increasing financial incentives could begin to remedy distrustful attitudes. Addressing the

203. Best Pharmaceuticals for Children Act, Pub. L. No. 110-85 (2007).

issue head-on will then allow greater freedom in clinical research so that researchers can examine race-based issues without public outcry and distrust.