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## COULD BIOBANKING BE A MEANS TO INCLUDE “HEALTH CARE HAVE-NOTS” IN THE GENOMICS REVOLUTION?

Michael J. Malinowski\*

### INTRODUCTION

The United States invests tens of billions of taxpayer dollars in basic research annually,<sup>1</sup> while clinical research is financed largely by the commercial sector and with a focus on market consumption of resulting products.<sup>2</sup> Populations without economic means or a loud political voice traditionally have been marginalized in clinical research, including children,<sup>3</sup> women,<sup>4</sup> and many minority groups.<sup>5</sup> For the

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<sup>1</sup> Investment through NIH alone was \$28 billion in 2004, and \$28.6 billion has been budgeted for 2005. Jonathan Weisman, *2006 Cuts in Domestic Spending on Table*, WASH. POST, May 27, 2004, at A1; *Drug Development: Medicine Price Hike Highlights Controversy of Government Funding Drug Research*, HEALTH & MED. WK., June 14, 2004, at 325.

<sup>2</sup> See generally PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2005 (2005) [hereinafter PHRMA], available at <http://www.phrma.org/publications/publications//2005-03-17.1143.pdf>. Gordon Duval, *Institutional Conflicts of Interest: Protecting Human Subjects, Scientific Integrity, and Institutional Accountability*, 32 J.L. MED & ETHICS 613 (2004); Thomas Bodenheimer, *Uneasy Alliance-Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539 (2000).

<sup>3</sup> The U.S. Government has introduced an incentive, a quid pro quo, to inspire pharmaceutical companies to gather clinical data on the impact of their products on children through the pediatric exclusivity. Janet Fricker, *Too Much Too Young*, NEW SCIENTIST, Feb. 20, 1999, at 18. Pharmaceutical sponsors are granted patent extensions in exchange for compiling this data. See *id.* A dearth of pediatric clinical data for pharmaceuticals routinely prescribed to children inspired this reform. See *id.* See also Jennifer Powell, *Law, Docs Eye Safer Drugs for Kids*, BOSTON HERALD, June 10, 2001, at 27.

<sup>4</sup> See generally NIH, Office of Extramural Research, NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, available at [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). Supportive data is available via the Office on Women's Health, Department of Health and Human Services, <http://www.4woman.gov/owh/> and the "Women's Health" pages of the National Institutes of Health Internet site, <http://health.nih.gov/search.asp/28>.

purposes of this article, these groups will be referred to as “Health Care Have-Nots” (“HCHNs”). Some of the HCHNs have been exploited in clinical research studies, including studies sponsored and even directly conducted by the U.S. government.<sup>6</sup> The Food and Drug Administration (“FDA”) has routinely approved and overseen human clinical trials performed without demographic representation from the HCHNs and, subsequently, authorized the market entry of resulting products as treatments for diseases prevalent in the general population and among HCHNs.<sup>7</sup>

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<sup>5</sup> See generally, *AHRQ's Role in Eliminating Racial and Ethnic Disparities in Health Care Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources*, 107th Cong. ( May 21, 2002) (statement of Dr. Carolyn Clancy, Acting Director, AHRQ), available at <http://www.hhs.gov/asl/testify/t020521.html>. See generally INSTITUTE OF MEDICINE, *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE* (Brain D. Smedley et al. eds., 2003), available at <http://www.iom.edu/report.asp?id=4475> [hereinafter *UNEQUAL TREATMENT*]; AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ), *STRATEGIES FOR IMPROVING MINORITY HEALTHCARE QUALITY* (2004), available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/minqual/minqual.pdf> (last visited Sept. 23, 2005) [hereinafter *AHRQ REPORT*]; AHRQ, *Fact Sheet: Addressing Racial and Ethnic Disparities in Health Care*, available at <http://www.ahrq.gov/research/disparit.htm> [hereinafter *Fact Sheet*]. The IOM Report findings are damning:

The report says a large body of research underscores the existence of disparities. For example, minorities are less likely to be given appropriate cardiac medications or to undergo bypass surgery, and are less likely to receive kidney dialysis or transplants. By contrast, they are more likely to receive certain less-desirable procedures, such as lower limb amputations for diabetes and other conditions.

*Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Institute of Medicine, <http://www.iom.edu/?id=15962> (last visited Jan. 14, 2006).

<sup>6</sup> Most notable is the Tuskegee syphilis project funded by the Public Health Service over three decades. See generally Nancy Jecker, *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study*, 343 *NEW ENG. J. MED.* 1581 (2000); Patricia A. King, *Reflections on Race and Bioethics in the United States*, 14 *HEALTH MATRIX* 149 (2004); Barbara L. Bernier, *Class, Race and Poverty: Medical Technologies and Sociopolitical Choices*, 11 *HARV. BLACKLETTER L. J.* 115, 122-125 (1994).

<sup>7</sup> This observation is representative of the U.S.'s free market system, which has proven to be extremely productive. See generally PHRMA, *supra* note 2. Drug sponsors are allotted free-market discretion, and, subsequent to approval of their products, physicians are allotted discretion to prescribe off-label. “In fact, Congress recognized the realities of off-label prescribing when it authorized Medicaid reimbursement of pharmaceuticals for uses that appear in certain medical compendia, even if the FDA has not approved that use for inclusion in labeling.” See Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental*

Contemporary biomedical research and development (“R&D”) in the U.S. is centering on the genomics revolution—an initiative to understand gene and protein function as a means to intervene in the biological pathways of disease and medical treatment, and to develop more effective human health therapies.<sup>8</sup> Thus far, genomics has been adding dimensions of precision to human health care product development, fractioning traditional disease groups and markets,<sup>9</sup> and raising health care costs.<sup>10</sup> Bioinformatics, the combination of information technology and biology, is the primary means to make medical sense out of the map of the human genome, and bioinformatics capabilities continue to expand.<sup>11</sup> Consequentially, the demand for access to human biological samples and medical information never has been greater, and this demand has given rise to ambitious biobanking initiatives—efforts to compile organized collections of DNA samples and accompanying medical information from human populations.<sup>12</sup>

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*Therapy*, 28 AMER. J. L. AND MED. 361, 398 (2002) (citing 42 U.S.C. §§ 1396r-8(k)(6), 1395x(t)(2)(B) (2000)) (authorizing Medicare reimbursement for off-label uses of oncology drugs if consistent with medical compendia or the peer-reviewed literature).

<sup>8</sup> See generally Symposium, *The Genomics Revolution? Science, Law, and Policy*, 66 LA. L. REV. 1 (2006) [hereinafter *Genomics Revolution*] (live conference transcripts on file with author).

<sup>9</sup> Michael J. Malinowski, *Taking Genomics to the BioBank: Access to Human Biological Samples and Medical Information*, 66 LA. L. REV. 43, 46 n.15 (2006).

<sup>10</sup> Given the precision introduced by genomics, smaller groups will have to shoulder resulting R&D drug costs. See generally Jeffrey L. Moe, *Commercialization Considerations for Individualized Diagnostic and Drug Therapies Resulting from Pharmacogenomics*, 66 LA. L. REV. 103 (2005). This trend is likely to continue until technology evolves to enable actual elimination of diseases rather than turning them into chronically treated conditions. Michael McGinnis, *Trends in Population Health—are they influenced by medical and scientific advances?* 66 LA. L. REV. 9, 19-20 (2006).

<sup>11</sup> See generally *Genomics Revolution*, supra note 8; POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES (Bartha Maria Knoppers ed., 2003); Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients’ Genetic Profiles*, 43 JURIMETRICS 1, 4-11 (2002); Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, 2 HOUSTON J. HEALTH L. & POL’Y 231 (2003); PHRMA, supra note 2. Bioinformatics is the integration of biology and information technology to identify gene and protein structure and function, usually with the ultimate objective of discovering drug targets. See D.E. Winickoff, *Governing Population Genomics: Law, Bioethics, and Biopolitics in Three Case Studies*, 43 JURIMETRICS 187, 189 (2003).

<sup>12</sup> Biobanking is an extension of the practice for more than a century of collecting human biological materials and building repositories for research use. See generally

This article will explore the extent to which groups left out of the genomics revolution could gain access through biobanking.<sup>13</sup> The premise is that groups seeking access to the forefront of biomedical R&D might draw upon case studies and the technology transfer experiences of universities during the 1990s. This was a period of transition from historic division between academia and industry to intense integration of interests and collaborations among academia, industry, and government to advance commercial biotechnology.<sup>14</sup> The primary objective of this article is to probe the implications of active biobanking by HCHNs.

Part I of this article will present an overview of the state of healthcare finance in the U.S. and the realities of unequal health care access and treatment. The HCHNs will be identified, and the message is twofold. First, the costs of health care in the U.S. are rising and shifting, causing more people to be uninsured and underinsured.<sup>15</sup> Second, this trend threatens to exacerbate significant existing inequalities in access to health care based upon race and ethnicity.<sup>16</sup> Part I also will summarize the U.S. legacy of first exploitation and then relative exclusion of HCHNs in biomedical R&D.

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ALLEN BUCHANAN, *An Ethical Framework for Biological Samples Policy*, in NATIONAL BIOETHICS ADVISORY COMMISSION, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, VOLUME II COMMISSIONED PAPERS, at B-1 (2000) [hereinafter NBAC COMMISSIONED PAPERS], available at <http://www.georgetown.edu/research/nrcbl/nbac/hbmII.pdf>; Elisa Eiseman, *Stored Tissue Samples: An Inventory of Sources in the United States*, in NBAC COMMISSIONED PAPERS, *supra*, at D-1; David Korn, *Contribution of the Human Tissue Archive to the Advancement of Medical Knowledge and the Public Health*, in NBAC COMMISSIONED PAPERS, *supra*, at E-1. See Symposium, *Regulation of Biobanks*, 33 J. L. MED. & ETHICS 1 (Mark Rothstein & Bartha Knoppers eds., 2005) [hereinafter *Biobanks*] (providing an excellent, timely treatment of biobanking).

<sup>13</sup> This article builds upon two collaborations with Professor Bartha Knoppers that involved written symposia. See generally *Genomics Revolution*, *supra* note 8; *Biobanks*, *supra* note 12.

<sup>14</sup> See Michael J. Malinowski, *Technology Transfer and Development Agreements*, in BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION § 3.02[C] (1999). See generally Michael J. Malinowski, *Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 WIDENER L. SYMP. J. 47 (2001).

<sup>15</sup> Emily Friedman, *Health Insurance, the Uninsured and Hospitals: Collision Course*, FRONTIERS HEALTH SERVICES MGMT., July 1, 2005, at 3; Thomas Bodenheimer, *High and Rising Health Care Costs*, 142 ANNALS OF INTERNAL MED. 847 (2005).

<sup>16</sup> See *supra* notes 5, 25-34 and accompanying text.

Part II will shift focus to the present and future of biomedical R&D, which is centering on population genetics and biobanking. This discussion will introduce case studies that illustrate how some HCHNs are gaining access to the forefront of the genomics revolution through technology transfer and development in biobanking. Part II will introduce proposals to increase biobanking by HCHNs as a means to widen their access to both participation in genomics research and the resulting health care innovations. This discussion also will directly address the consequential implications of encouraging race-based research and medicine. The article concludes that biobanking presents an opportunity to increase positive participation of HCHNs in the genomics revolution and encourages embracing that opportunity, but with caution given the U.S. legacy of race-based medicine and research and the lingering presence of that legacy as documented by the IOM and the AHQR.<sup>17</sup>

## I. THE HCHNS IN U.S. HEALTH CARE AND BIOMEDICAL R&D

The state of health care finance in the U.S. is infamous and worsening: forty-five million people are uninsured, most of them working, and many millions more are underinsured;<sup>18</sup> costs are rising significantly and shifting from employers to employees;<sup>19</sup> a \$62 trillion shortfall is projected for Medicare, due largely to the new prescription drug benefit;<sup>20</sup> states are slashing programs to offset their shortfalls;<sup>21</sup> the Bush Administration is granting Medicare program waivers almost

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<sup>17</sup> See *supra* notes 5, 25-34 and accompanying text.

<sup>18</sup> Shannon S. Venable, *A Call to Action: Georgia Must Adopt New Standard of Care, Licensure, Reimbursement and Privacy Laws for Telemedicine*, 54 EMORY L.J. 1183, 1183-1184 (2005).

<sup>19</sup> Anne D'Innocenzo, *Health Care Costs Continue to Shift*, CHARLOTTE OBSERVER, Sept. 14, 2005, at 3D; Glen Singer, *Survey Shows Employers Will Shift Burden of Health Benefits Increase*, SUN-SENTINEL, Aug. 27, 2004; Anne D'Innocenzo, *Employers Shift Health Costs-Workers Will Take Larger Share in 2006*, COM. APPEAL, Sept. 14, 2005, at A3; *Study Shows Impact of 6 Years of Double-Digit Medical Rate Increases*, MANAGED CARE WKLY. DIGEST, Mar. 28, 2005, at 103.

<sup>20</sup> Alan Fram, *Deficit Could Hit Record \$477B*, CINCINNATI POST, Jan. 26, 2004, at A2; Robert Pear and Edmund L. Andrews, *White House Says Congressional Estimate of New Medicare Was Too Low*, N.Y. TIMES, Feb. 2, 2004, at A14; *Staggering Hidden Costs of Medicare Prescriptions*, NEW AMERICAN, Feb. 23, 2004, at 9; *The Medicare Alarm*, ALBANY TIMES UNION, Apr. 5, 2004, at A6.

<sup>21</sup> See *Recipients Brace for Medicaid Co-Payments*, CINCINNATI POST, June 27, 2005, at K5 (no author identified).

carte blanche to accommodate the same;<sup>22</sup> and the Administration has proposed cutting \$60 billion (two percent) from Medicaid over the next decade.<sup>23</sup> The situation is disparately worse for minority groups.<sup>24</sup> Both the Institutes of Medicine (“IOM”)<sup>25</sup> and the Agency for Healthcare Research and Quality (“AHRQ”) at the Department of Health and Human Services (“DHHS”) have documented that minority groups in the U.S. have significantly less access to health care, and the care they receive is of much lower quality.<sup>26</sup> Minority groups get less according to forty percent of access measures and more than sixty percent of quality measures, and only one-fifth of this disparity is attributable to a decline in insurance coverage.<sup>27</sup> AHRQ has determined that “Race and ethnicity influence a patient’s chance of receiving many specific procedures and treatments.”<sup>28</sup> Illustrations include:

- “*Heart disease.* African Americans are 13 percent less likely to undergo coronary angioplasty and one-third less likely to undergo bypass surgery than are whites.”<sup>29</sup>
- “*Asthma.* Among preschool children hospitalized for asthma, only 7 percent of African American children . . . , compared with 21 percent of white children, are prescribed routine medications to prevent future asthma-related hospitalizations.”<sup>30</sup>
- “*Breast cancer.* The length of time between an abnormal screening mammogram and the follow-up diagnostic test to determine whether a woman has breast cancer is more than

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<sup>22</sup> *Id.*

<sup>23</sup> Josh Goldstein, *U.S. Medicaid Cutbacks Would Hurt States Twice*, PHIL. INQUIRER, Feb. 8, 2005, at C1; *How Bush’s Budget Goes Wrong*, BUS. WK., Feb. 28, 2005, at 112; Robert Pear, *Governors Prepare to Fight Medicaid Cuts*, N.Y. TIMES, Feb. 27, 2005, at 27.

<sup>24</sup> See generally Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221 (2003); Barbara A. Noah, *Racial Disparities in the Delivery of Health Care*, 35 SAN DIEGO L. REV. 135 (1998); Barbara A. Noah, *Racist Health Care?*, 48 FLA. L. REV. 357 (1996).

<sup>25</sup> See generally UNEQUAL TREATMENT, *supra* note 5.

<sup>26</sup> See AHRQ Report, *supra* note 5; Fact Sheet, *supra* note 5.

<sup>27</sup> See Fact Sheet, *supra* note 5.

<sup>28</sup> See *id.* (emphasis added).

<sup>29</sup> *Id.* (emphasis added).

<sup>30</sup> *Id.* (emphasis added).

twice as long in Asian American, black, and Hispanic women as in white women.”<sup>31</sup>

- “*Human immunodeficiency virus (HIV) infection.* African Americans with HIV infection are less likely to be on antiretroviral therapy, less likely to receive prophylaxis for *Pneumocystis pneumonia*, and less likely to be receiving protease inhibitors than other persons with HIV.”<sup>32</sup>
- “*Nursing home care.* African American residents of nursing homes are all far less likely than white residents to have sensory and communication aids, such as glasses and hearing aids.”<sup>33</sup>

Exclusion of minority groups is an overarching theme in the U.S.’s biomedical research legacy. Exploitation is a second major theme. The latter is synonymous with the Tuskegee study,<sup>34</sup> a Public Health Service study which spanned four decades and traced the course of untreated syphilis in African American males:

Initiated in 1932, the research targeted poor African-American sharecroppers suffering from syphilis, but was presented to subjects as a study of “bad blood.” The study continued until a July 26, 1972 New York Times story, “Syphilis Victims in U.S. Study Went Untreated for 40 Years” exposed it as “the longest non-therapeutic experiment on human beings in medical history.”<sup>35</sup>

The study, which confirmed the apprehensions of African Americans and other minorities about participating in biomedical research and compelled an apology from the United States government under the

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<sup>31</sup> *Id.* (emphasis added).

<sup>32</sup> Fact Sheet, *supra* note 5 (emphasis added).

<sup>33</sup> *Id.* (emphasis added).

<sup>34</sup> See *supra* note 6; Dorothy E. Roberts, *The Nature of Blacks’ Skepticism About Genetic Testing*, 27 SETON HALL L. REV 971, 974 (1997). See generally JAMES H. JONES, *BAD BLOOD, THE TUSKEGEE SYPHILIS EXPERIMENT* (1993).

<sup>35</sup> PRICEWATERHOUSECOOPERS LLP, INSTITUTIONAL REVIEW BOARD (IRB) REFERENCE BOOK 12 (Michele K. Russell-Einhorn & Thomas Puglisi eds., 2001) [hereinafter IRB REFERENCE BOOK].



Clinton Administration,<sup>36</sup> encompassed 600 men, 399 with latent syphilis and a control group of 201 without the disease.<sup>37</sup> These men were “encouraged” to participate through free meals, medical examinations, and burial insurance.<sup>38</sup> “In a reprehensible breach of ethics, investigators took specific steps to ensure that subjects were denied access to effective treatment, even after penicillin became widely available, to preserve the integrity of the research.”<sup>39</sup>

Discrimination is a third major theme in the U.S.’s history of treatment of minorities in medicine and biomedical R&D. A notable and often-referenced example are the 1970s screening programs for sickle cell trait which resulted in employment and insurance discrimination against African Americans and restrictions on their reproductive decision-making.<sup>40</sup>

The absence of just representation of minority groups in biomedical research and the delivery of health care has been acknowledged by the United States Government and inspired corrective measures. These measures include the establishment and ongoing work of the AHRQ.<sup>41</sup>

## II. A PROPOSAL TO BIOBANK TO WIDEN ACCESS FOR HCHNS

Population genetics is a means to engage in genomics and proteomics, the understanding of gene and protein function, respectively.<sup>42</sup> Genomics occupies a central position in biomedical R&D, and there is reason to believe that genomics will hold that position well into the foreseeable future.<sup>43</sup> Bioinformatics capabilities have made it possible to extract extraordinary amounts of information from any given sample, and to process voluminous amounts of information from large numbers

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<sup>36</sup> See *id.* “Finally, on May 6, 1997, nearly 20 years after the New York Times exposé [sic] and 65 years after the Syphilis Study began, surviving subjects and the members of the Tuskegee Study Legacy Committee gathered at the White House to witness a long-awaited apology from President Clinton on behalf of the United States Government.” *Id.* at 13. See generally Jones, *supra* note 34.

<sup>37</sup> *Id.* at 13 (emphasis added).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* at 12-13.

<sup>40</sup> See generally Mark R. Farfel & Neil A. Holtzmann, *Education, Consent and Counseling in Sickle-Cell Screening Programs: Report of a Survey*, 74 AM. J. PUB. HEALTH 373 (1984).

<sup>41</sup> See Agency for Healthcare Research and Quality (AHRQ), <http://www.ahrq.gov>.

<sup>42</sup> See generally *Genomics Revolution*, *supra* note 8.

<sup>43</sup> See generally *id.*

of samples.<sup>44</sup> These capabilities, which continue to expand by multiples, are heightening demand for access to samples and accompanying medical information.<sup>45</sup> The combination of bioinformatics capabilities and biobanks could prove a primary means to make medical sense out of the map of the human genome.<sup>46</sup>

Some HCHNs already are gaining access to the forefront of the genomics revolution through technology transfer and development arrangements to engage in biobanking. Two of the more relevant case studies are biobanking initiatives by PXE International (“PXE”) and Howard University (“Howard”).<sup>47</sup> PXE is a nonprofit foundation established to use biobanking to encourage researchers to study and develop therapies for pseudoxanthoma elasticum, a very rare hereditary connective tissue disorder that afflicts skin and eyes.<sup>48</sup> Although PXE has adopted an aggressive IP retention policy,<sup>49</sup> its biobank still has attracted a number of laboratories globally.<sup>50</sup> As a case study, PXE illustrates that, though we live in an age of academia-industry integration, scientific accomplishment, peer esteem, and dreams of Nobel prizes remain powerful influences. There are researchers who will embrace the means to do breakthrough research even if the quid pro quo for access is relinquishing financial gains from commercial exploitation.

Similar to PXE, Howard University, a private university with a historic focus on African-Americans, has announced plans to biobank with the objective of influencing what research is undertaken—namely to encourage research on diseases with a distinguishably high incidence rate among those of African descent.<sup>51</sup> Howard is gathering DNA samples from 25,000 people, drawing from its global alumnae network

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<sup>44</sup> See Robert Wells, *Intellectual Property/Ownership Interests*, 66 LA. L. REV. 69, 73 (2005).

<sup>45</sup> See generally NBAC COMMISSIONED PAPERS, *supra* note 12.

<sup>46</sup> See generally Alan E. Guttmacher & Francis S. Collins, *Welcome to the Genomic Era*, 349 NEW ENG. J. MED. 996 (2004). See also Noah, *supra* note 11, at 4-11; Malinowski, *supra* note 11, at 231-43.

<sup>47</sup> David E. Winickoff, *Governing Population Genomics: Law, Bioethics and Biopolitics*, 43 JURIMETRICS J. 187, 223 (2003).

<sup>48</sup> PXE International, <http://www.pxe.org> (providing further information about this condition and PXE).

<sup>49</sup> Winickoff, *Biopolitics*, *supra* note 47, at 224.

<sup>50</sup> See *id.*

<sup>51</sup> See Capstone Online, College of Medicine and First Genetic Trust Form Biobank: Data to Advance Study of Disease Risks Among People of African Descent (June 2, 2003), <http://www.howard.edu/newsevents/Capstone/2003/June/news2.htm> (last visited Jan. 14, 2006).

and patients at hospitals affiliated with its College of Medicine.<sup>52</sup> Howard is building this biobank, called the Genomic Research in the African Diaspora Biobank (“GRAD Biobank”), in collaboration with First Genetic Trust, a commercial biobanker.<sup>53</sup> In addition, biobanking already has proven a means of entry into the genomics revolution for the populations of Iceland and Estonia,<sup>54</sup> and several other nations are undertaking biobanking endeavors.<sup>55</sup> A number of teaching hospitals in the U.S.<sup>56</sup> and the State of Utah<sup>57</sup> are doing the same.

Methodologies for organizing biobanks tend to be disease-centered (*e.g.*, PXE<sup>58</sup>), nation-centered (*e.g.*, deCode’s biobank that encompasses the vast majority of the population of Iceland<sup>59</sup>), ancestry-centered (*e.g.* the International Haplotype Mapping Project (“HMP”) or “HapMap” approach<sup>60</sup>), or ethnicity-centered (*e.g.*, Howard University’s effort<sup>61</sup>). Avoiding explicit use of race in biobanking and related research may help avoid readily reverting to social and cultural notions of race. However, these notions are too ingrained to be removed from popular thought simply by avoiding the terminology, or even by doing so and shifting to more scientifically sound methodologies such as ancestry.<sup>62</sup> Consider that popular interest in

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<sup>52</sup> Alan Pollack, *Big DNA Files to Help Blacks Fight Diseases*, N.Y. TIMES, May 27, 2003, at A1, A20.

<sup>53</sup> First Genetic Trust, <http://www.firstgenetic.net>.

<sup>54</sup> See generally Mylene Deschenes & Clemantine Sallee, *Accountability in Population Biobanking: Comparative Approaches*, 33 J.L. MED & ETHICS 40 (2005).

<sup>55</sup> See generally *id.* See also Bartha Maria Knoppers, *Biobanking: International Norms*, 33 J.L. MED & ETHICS 7, 7 (2005); Malinowski, *supra* note 9, at 47-50.

<sup>56</sup> Several major hospitals, including Duke University Medical Center, are collaborating with Ardais Corporation to engage in biobanking. Ardais, <http://www.ardais.com/partners/partners.shtml>. See Michael J. Malinowski, *Technology Transfer in BioBanking: Credits, Debits and Population Health Futures*, 33 J. L. MED. & ETHICS 54, 57 (2005); Winickoff, *supra* note 47, at 207.

<sup>57</sup> The State of Utah, in conjunction with the University of Utah and the Huntsman Cancer Foundation, has formed GenData, a non-profit corporation, to engage in biobanking that utilizes the rich legacy of medical record keeping associated with Utah’s Mormon community. See BARRY R. FURROW ET AL., HEALTH CARE LAW 22-23 (2003).

<sup>58</sup> See *supra* notes 47-50 and accompanying text.

<sup>59</sup> See deCode, <http://www.decode.com> (providing more information about the company). See generally Henry T. Greely, *Iceland’s Plan for Genomics Research: Facts and Implications*, 40 JURIMETRICS J. 153 (2000).

<sup>60</sup> See *infra* notes 75-84 and accompanying text.

<sup>61</sup> See *supra* notes 47, 53-55.

<sup>62</sup> Professor Sharona Hoffman has observed that “[s]everal studies reveal that only half of physical anthropologists and less than one-third of cultural anthropologists

tracing ancestry through DNA among African Americans has been reported even though only a miniscule percentage of ancestral groups within the human species have been extensively decoded.<sup>63</sup> Social, cultural, and racial identity based upon historic norms appears to be the inspiration.<sup>64</sup> Scientific reality is that, especially with a legacy of migration, tribal integration, war, and conquests, ancestral matching for any individual is complicated given that contemporary population genetics is in its infancy and the entire human species has been decoded only sporadically and at the margins.<sup>65</sup> With only approximately 30,000 genes in the human genome (most expectations until completion of the map of the human genome reached 100,000+ active genes),<sup>66</sup> the human species is relatively young and genetically homogenous under present scientific standards,<sup>67</sup> which center largely on gene function.<sup>68</sup> Genetic matches to populations yet to be decoded may prove much closer than matches to the very limited number of populations already sampled extensively and added to any particular database established at this time. In fact, when the human species is comprehensively decoded genetically, which may take many years, present experience suggests that categorization based upon genetic commonality may vary

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maintain that homo sapiens can be categorized by biological ‘races.’” Sharon Hoffman, *Is There a Place for “Race” as a Legal Concept?*, 36 ARIZ. ST. L.J. 1093, 1123 (2004). She also makes a strong argument for “[d]ismantling the notion of ‘race.’” *Id.* at 1159. However, in this author’s estimation, removing the terminology from law alone is unlikely to cause even a meaningful crack in a notion so rooted in culture and society at least for a generation or two. The same is likely to prove true even if the notion is disproved by science.

<sup>63</sup> See generally Amy Harmon, *Blacks Pin Hope on DNA to Fill Slavery’s Gaps in Family Trees*, N.Y. TIMES, July 25, 2005, at A1, A17.

<sup>64</sup> See generally *id.*

<sup>65</sup> Kenneth Kidd, *Tensions in Process and Discovery, Remarks at Louisiana State University Law Center Symposium: The Genomics Revolution? Science, Law and Policy* (Feb. 6, 2004) (transcript on file with author). See Harmon, *supra* note 63, at A17.

<sup>66</sup> Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine—A Primer*, 347 NEW ENG. J. MED. 1512, 1514 (2002).

<sup>67</sup> Human beings share 99.9 percent of these genes meaning that, with whole genes as the level of measure, variation in the human population is just one tenth of a percent. Moreover, 90 to 95 percent of this variation appears at equal rates in every human population. Richard S. Cooper et al., *Race and Genomics*, 348 NEW ENG. J. MED. 1166, 1167 (2003); Noah A Rosenberg et al., *Genetic Structure of Human Populations*, 298 SCIENCE 2381, 2381 (2002).

<sup>68</sup> Kidd, *supra* note 65.

significantly from cultural and social norms.<sup>69</sup> From a clinical perspective, this entire exercise may prove much less significant than understanding how environmental exposures influenced by culture, social norms, socio-economics, and other factors interact with genetics to influence human health.<sup>70</sup>

Fortunately, there is an intense, ongoing debate over the scientific soundness of race-based research.<sup>71</sup> Contrary positions were presented in the November 2004 issue of *Nature Genetics*.<sup>72</sup> One position presented is that race has a genetic basis: DNA links people to geographic continents-regions that correspond with their self-identified racial classifications, and these populations have distinguishable genetic characteristics—such as the SCN5A gene carried by one in nine African Americans that confers a twenty-four-fold increase in sudden infant death syndrome (“SIDS”).<sup>73</sup> The counter position is that race lacks any reliable biological basis and, for meaningful science and medicine, links between genes and disease must be made directly rather than through the convoluted path cleared by social and cultural constructs such as race.<sup>74</sup>

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<sup>69</sup> See *id.* See generally Pilar N. Ossorio, *The Concept of Race in Social, Cultural and Political History, and the Potential Impact of Haplotype Mapping on the Future*, 66 LA. L. REV. 131 (2006).

<sup>70</sup> See Ossorio, *Concept of Race*, *supra* note 69 at 139-140; Richard S. Cooper et al, *Race and Genomics*, 348 NEW ENG. J. MED. 1166, 1169 (2003); Jonathan Kahn, *Getting the Numbers Right: Statistical Mischief and Racial Profiling in Heart Failure Research*, 46 PERSP. BIOLOGY & MED. 473, 480 (2003); Judith B. Kaplan & Trude Bennett, *Use of Race and Ethnicity in Biomedical Publication*, 289 JAMA 2709, 2712 (2003); Pamela Sankar et al., *Genetic Research and Health Disparities*, 291 JAMA 2985, 2987-88.

<sup>71</sup> See Hoffman, *supra* note 62, at 1113-1128. See also David Rotman, *Genes, Medicine, and the New Race Debate*, TECH. REV., June 2003, at 41, 48, 50.

<sup>72</sup> See Neil Risch et al., *Categorization of Humans in Biomedical Research: Genes, Race, and Disease* 3 GENOME BIOLOGY 1, 1 (2002), available at <http://genomebiology.com/content/pdf/gb-2002-3-7-comment2007.pdf>.

<sup>73</sup> Lynn B. Jorde & Stephen P. Wooding, *Genetic Variations, Classifications, and Race*, 28 NATURE GENETICS S28, S28 (2004). See also Esteban Gonzalez Burchard et al., *The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice*, 348 NEW ENG. J. MED. 1170, 1171 (2003). The SNC5A discovery was reported in the *Journal of Clinical Investigation* in February, 2006. See Thomas H. Maugh II, *Gene Raises Chance of SIDS*, ADVOCATE, Feb. 2, 2006, at 4A. Although African American children are three times more likely than Caucasian children to die from SIDS, the medical significance of this finding is tempered by the fact that SCN5A appears to count for only five percent of SIDS deaths in African American children. See *id.*

<sup>74</sup> See *id.* See also Robert S. Schwartz, *Racial Profiling in Medical Research*, 344 NEW ENG. J. MED. 1392, 1392 (2001).

This debate is arguably being developed most effectively through application associated with the HapMap Project undertaken by the NIH, National Center for Human Genome Research Institute (NCHGRI), to explore the methodology of population genetics research based upon ancestry.<sup>75</sup> HMP is a collaboration among scientists and funding agencies from Japan, the United Kingdom, Canada, China, Nigeria, and the United States.<sup>76</sup> The goal of HMP is to raise the concept of familial-pedigree studies up to the population level—to compare the genetic sequences of different individuals to identify chromosomal regions where genetic variants are shared.<sup>77</sup> HMP was commenced in October 2002, with Stage I planned for completion in fall 2005<sup>78</sup> The objective of this first phase of HMP was to analyze DNA from populations with African, Asian, and European ancestry.<sup>79</sup> Stage I encompassed collection of samples from just 270 people: Africans (thirty sets of familial samples from the Yoruba people of Ibadan, Nigeria); Japanese (forty-five unrelated individuals from the Tokyo area); Chinese (forty-five unrelated individuals from Beijing); and Europeans (thirty trio samples from European-Mormon families in the U.S.).<sup>80</sup> The sample selection was based consciously upon ancestry rather than any direct notions of race.<sup>81</sup> Nevertheless, HMP has advanced with thoughtful attention to the implications of race-genetics connections. An ethics committee, co-chaired by Dr. Bartha Knoppers and Dr. Ellen Wright Clayton, has vested tremendous effort to address implications and develop algorithms for population genetics that potentially carry far beyond HMP.<sup>82</sup> Professors Knoppers and Clayton also have made significant individual contributions by emphasizing at

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<sup>75</sup> See HapMap Project, <http://www.hapmap.org>. See National Human Genome Research Institute, <http://www.genome.gov>. See generally, Ellen Wright Clayton, *Implications for Existing Law/Regulations*, 66 LA. L. REV. 125 (2006); Ossorio, *supra* note 70, at 131.

<sup>76</sup> See About the HapMap, <http://www.hapmap.org/thehapmap.html.en>.

<sup>77</sup> See *id.* See also Clayton, *supra* note 75, at 127; Ossorio, *supra* note 70, at 132-33.

<sup>78</sup> HapMap Project, <http://www.hapmap.org>.

<sup>79</sup> See generally *Genomics Revolution*, *supra* note 8; HapMap Project, <http://www.hapmap.org>.

<sup>80</sup> See generally HapMap Project, <http://www.hapmap.org>. See also Ossorio, *supra* note 70, at 131-142.

<sup>81</sup> See generally HapMap Project, <http://www.hapmap.org>. See also HapMap Sample Populations, <http://www.hapmap.org/hapmappopulations.html.en>.

<sup>82</sup> See Guidelines for Referring to the HapMap Populations in Publications and Presentations, <http://www.hapmap.org/citinghapmap.html.en>. See also How Are Ethical Issues Being Addressed?, <http://www.hapmap.org/ethicalconcerns.html.en> (discussing ethics issues involving the HapMap Project).

conferences and in print that HMP is a pilot program to probe the scientific validity of ancestry-based population genetics.<sup>83</sup> A fundamental outcome of this application of population genetics is pragmatic identification of ethical, legal, social and other policy implications of the research, and pragmatic methodologies and algorithms sensitive to those implications have been developed.<sup>84</sup>

With all of the primary biobanking methodologies, including biobanking centered on diseases relatively more prevalent in populations identified as racial groups by popular cultural and social notions of race, there is a real possibility—arguably, a likelihood for the foreseeable future—of encouraging race-based medicine and race-based research in contemporary genomics.<sup>85</sup> Genetic science has proven a *powerful* influence, and this influence is destined to expand with advancement of the field of genomics.<sup>86</sup> As discussed above, IOM and AHRQ data on treatment disparities suggest that race-based medicine is a present reality.<sup>87</sup> The data indicate that race-based medicine is being practiced with influences other than good science and to the relative detriment of non-whites.<sup>88</sup> Moreover, there already are instances of race-based medicine where genomics is used to the detriment of non-white populations—for example, use of three loci, HLA A, B and D, for matching in renal transplants.<sup>89</sup> However, there also are documented instances where race-based medicine is being reported to improve outcomes to the benefit of HCHNs—most notably, the FDA's recent approval of BiDil among African Americans to prevent death from heart disease by lowering salt retention, and SCN5A screening to identify children with heightened risk of SIDS.<sup>90</sup> In addition, as summarized by Professor Hoffman,

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<sup>83</sup> See generally Clayton, *supra* note 75.

<sup>84</sup> See generally *id.*; Ossorio, *supra* note 70.

<sup>85</sup> See *id.* at 139-41.

<sup>86</sup> See generally DOROTHY NELKIN & SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* (1995); Sharona Hoffman, *supra* note 62; Michael J. Malinowski, *Choosing the Genetic Makeup of Our Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV. 125 (2003).

<sup>87</sup> See *supra* notes 25-33 and accompanying text.

<sup>88</sup> See *id.*

<sup>89</sup> C. Thomas Caskey, Haplotype Mapping and Its Applications, Remarks at Louisiana State University Law Center Symposium: The Genomics Revolution? Science, Law and Policy (Feb. 6, 2004) (transcript on file with author).

<sup>90</sup> See *supra* note 73 and accompanying text (discussion of SCN5A); *FDA Advisory Committee Recommends BiDil to Treat Black Patients with HF*, CARDIOVASCULAR DRUG NEWS, June 17, 2005; John Pope, *Heart Drug Study Triggers Questions—Test Results Promising for African Americans*, TIMES-PICAYUNE, Nov. 16, 2004, at A1. It

Today it is believed that members of different populations have higher susceptibilities to different diseases and respond differently to certain treatments. For example, “racial” differences have been demonstrated with respect to diabetes complications, and researchers have detected genetic differences among “racial” groups that relate to HIV, Crohn’s disease, and Alzheimer’s disease. In addition, one controversial study found that black patients with chronic heart failure did not respond well to a commonly used drug, leading some doctors to stop providing the medication to African-American patients.<sup>91</sup>

Many ongoing biobanking efforts are driven by HCHNs who, perhaps in conjunction with the goal of commercial returns, hope to build a basic science floor of inclusion for their bank populations that may spill over into medical outcomes favoring their populations. Even if the science proves disappointing and these clinical applications are not realized, third-party use of these biobanks and resulting revenues and IP rights introduce resources and a possibility to improve the health care of the donor populations. Examples already discussed include biobanking by Howard University,<sup>92</sup> deCode,<sup>93</sup> and Estonia.<sup>94</sup> The return could be direct or through arrangements that grant HCHN-related research institutions access to biobank users’ enabling technologies, or perhaps even a collaborative role in the research itself. For national biobankers in developing economies, a possible quid pro quo for access might be the establishment of a domestic research facility. Another possibility is construction of manufacturing facilities,

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is important to note that challenges have been raised to the biological soundness of this FDA’s BiDiI decision in light of the temptation of sponsors to manipulate clinical data to obtain even limited market entry and, subsequently, realize much broader markets through off-label use. *See* Pope, *supra*, at A1. *See generally* Jonathan Kahn, *How A Drug Becomes “Ethnic”*: Law, Commerce, and the Production of Racial Categories in Medicine, 4 YALE J. HEALTH POL’Y, L. & ETHICS 1 (2005). The data also may have been influenced by the study’s focus on a type of heart disease that happens to be prevalent in African Americans because of life style choices. *See id.*

<sup>91</sup> Hoffman, *supra* note 62, at 1119-1120. As suggested above, such medically meaningful associations with groups defined by cultural and social norms may prove more attributable to the interaction of genetics and environmental factors such as diet, socioeconomic background, and living conditions than genetic ancestry. *See supra* note 70 and accompanying text.

<sup>92</sup> *See supra* note 47 and accompanying text.

<sup>93</sup> *See supra* note 92 and accompanying text.

<sup>94</sup> *See supra* note 59 and accompanying text.



perhaps with incentives from entities such as the World Bank, with the capacity to at least satisfy domestic use of resulting commercial products on an at-cost basis and an obligation to do so—albeit with pharmaceutical sponsor oversight and host government assurances of full product accountability and recognition of IP rights. On the most pragmatic level, revenue could be generated and channeled into public health basics like vaccines, clean water, and sanitation.

Admittedly, questions about the enforceability of any such arrangement over time invite skepticism and pessimism. However, a number of recent events and circumstances suggest at least an environment of opportunity and the possibility of a break between the present/future and the past. These include fuller implementation of the Trade Related Intellectual Property Sections (“TRIPS”) of the General Agreement on Tariffs and Trade (“GATT”);<sup>95</sup> extensive global familiarity with technology transfer and development and government-industry-academia collaborations in the life sciences; the strengthening of international institutions such as the World Trade Organization, World Bank, and World Health Organization; and international pressures on pharmaceutical companies and governments to close the life science crevasse between developed and developing economies—all underscored by global epidemiological crises such as the threat of an avian flu pandemic as this article goes into print, and controversies such as access to AIDS drugs in African nations.<sup>96</sup>

Where there is commercial life science demand, there is opportunity.<sup>97</sup> This is a lesson made vividly clear by the university experience over the last fifteen years. With access to samples and medical information now at a premium and rising in value, HCHNs that engage in biobanking and apply technology transfer and development norms will have opportunities to access and reap benefits from the genomics revolution.<sup>99</sup> There are developed models, algorithms, and guidelines to draw from to undertake such biobanking, including some that address ethical, legal, and social implications in the complicated global setting.<sup>98</sup> Again, this is a major HMP contribution, and the HMP application of population genetics encompasses working

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<sup>95</sup> Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994).

<sup>96</sup> See generally JEFFREY SACHS, *THE END OF POVERTY: ECONOMIC POSSIBILITIES FOR OUR TIME* (2005).

<sup>97</sup> See Malinowski, *supra* note 9, at 51.

<sup>99</sup> See generally *id.*

<sup>98</sup> See generally *id.*

knowledge of many other biobanking case studies—Iceland, Estonia, and so forth—and international guidelines and norms.<sup>99</sup> For example, the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) has issued an International Declaration on Human Genetic Data,<sup>100</sup> the Council for International Organizations of Medical Sciences (“CIOMS”) has put forth ethical guidelines for biomedical research,<sup>101</sup> and the World Health Organization (“WHO”) has compiled a report on genetic databases.<sup>102</sup> Some academics also are providing thoughtful insights and guidance. For example, Professor Knoppers recently framed the global challenge of approaching biobanking with primarily public health norms rather than primarily with human subject norms that emphasize the rights of the individual.<sup>103</sup> An additional challenge is to expand the conceptual scope of public health beyond the traditional disease continuum—prevention to treatment—to encompass R&D.<sup>104</sup>

However, assuming such global biobanking by HCHNs is even achievable at this time, a fundamental question lingers: Would embracing the opportunity to engage in biobanking other than from a general population, disease-centered methodology inevitably reinforce notions of race-based genetics and medicine? The path to reaching comprehensive science will be incremental, and probably will include some confirmations of those notions, especially until a critical mass of population genetics is achieved. Although we are not genetically diverse relative to most other species,<sup>105</sup> our species has been impacted genetically through ancestry. Significant genotype-phenotype

<sup>99</sup> See generally Knoppers, *supra* note 55, at 7-14.

<sup>100</sup> UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION (UNESCO), INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (2003), available at [portal.unesco.org/en/...&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/...&URL_DO=DO_TOPIC&URL_SECTION=201.html).

<sup>101</sup> COUNCIL FOR INTERNATIONAL ORGANIZATION OF MEDICAL SCIENCES (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002), available at [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm).

<sup>102</sup> WORLD HEALTH ORGANIZATION (WHO), GENETIC DATABASES—ASSESSING THE BENEFITS AND THE IMPACT ON HUMAN RIGHTS AND PATIENT RIGHTS (2003), available at <http://www.law.ed.ac.uk/ahrb/publications/online/whofinalreport.rtf>.

<sup>103</sup> See generally Knoppers, *supra* note 55. As pointed out by Professor Parmet, the very nature of public health is population health. WENDY E. PARMET, *Introduction: The Interdependency of Law and Public Health*, in LAW IN PUBLIC HEALTH PRACTICE xxvi (Richard A. Goodman et al. eds., 2003).

<sup>104</sup> PUBLIC HEALTH LAW AND ETHICS: A READER 4 (Lawrence O. Gostin ed., 2002).

<sup>105</sup> See *supra* note 67 and accompanying text.

connections have been identified by working in ethnically-defined populations, such as the association of BRCA-1 mutations and a form of breast cancer through a study focused on Ashkenazi Jewish women and the identification of the gene that causes Huntington's disease by studying an isolated population with an extremely high incident rate of the disease.<sup>106</sup> Where groups are being studied, scientists are identifying genetic subtleties that impact human health.<sup>107</sup> Nevertheless, if the present majority opinion in the biological science community proves true, advancing genomics research through population genetics ultimately will disprove many long-held notions of race and culture.<sup>108</sup> Present science suggests no broad genetic reality to notions of race, especially in the absence of environmental influences.<sup>109</sup> Still, those notions are deeply rooted and, even when challenged by meaningful science, they are likely to linger. Aggressive biobanking, in addition to advancing the genomics revolution and introducing opportunities for HCHNs to participate, is likely to quicken confrontation of social-cultural notions of race through science in a comprehensive and definitive manner.

## CONCLUSION

The U.S. has a legacy of disparity in access for minorities in both human health research and medicine, and that legacy lingers on.<sup>110</sup> Now, contemporary science in the form of the genomics revolution, which has centered on population genetics and bioinformatics,<sup>111</sup> is forcing answers to one of societies' most controversial questions: Is there genetic reality to historic notions of race? Given that confronting this question is inevitable, the scientific *and* social agenda should be to move genomics forward in a responsible manner—to push through the present state of population genetics uncertainty into broadly meaningful genomics medicine, and to include more HCHNs along the way. Responsible biobanking is a means to advance these ambitious objectives, and it should be embraced accordingly.

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<sup>106</sup> See generally Sandra Soo-Jin Lee et al., *The Meaning of "Race" in the New Genomics: Implications for Health Disparities Research*, 1 YALE J. HEALTH POL'Y, L. & ETHICS 33 (2001).

<sup>107</sup> See, e.g., *supra* note 73.

<sup>108</sup> See generally Kidd, *supra* note 65.

<sup>109</sup> See *id.*; cf. *supra* note 74.

<sup>110</sup> See *supra* notes 18-41 and accompanying text.

<sup>111</sup> See *supra* notes 11-12, 43-47 and accompanying text.