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RACE, GENETICS, AND THE REGULATORY NEED FOR RACE IMPACT ASSESSMENTS

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Despite significant advances in race relations and the status of people of color, racial minorities face new challenges in the twenty-first century that are unmistakably connected to past injustices. An emerging concern is how human biotechnologies are being used to lend support to framing racial disparities and differences as distinctly biological rather than social phenomena. Previously discredited beliefs that inherent biological differences give rise to racial disparities in health and other social outcomes are under increasing reconsideration. In a nutshell, the color line that has and continues to divide racial groups is increasingly taking on, in the view of some, a genetic character.

But these new articulations of biological race have a different overtone from their predecessors. In the name of resolving racial disparities in health, shedding light on disrupted genealogies, and improving law enforcement, they explicitly reject the racial subordination that fueled past efforts to link social categories of race to inherent biological differences. Yet they may inadvertently lead to similar conclusions; various racial disparities—from why certain groups are sicker than others to why arrest and incarceration rates are higher among some populations—may come to be more meaningfully understood through genetic rather than social or environmental mechanisms.

It is important to note from the outset that there is some evidence that social categories of race may be genetically relevant to the extent that they may loosely correlate with geographical origin, broadly defined. This, in turn, may reflect the histories of isolation and evolution experienced by some groups. Yet there is also evidence that many biotech applications that use social categories of race treat them in a circular fashion; the presumption that social categories of race are biologically salient can shape research questions and agendas, as well as data collection and analysis. The preponderance of evidence shows that the distinct racial categories that society has created do not directly align with meaningful population differences. Nevertheless, this growing body of work concerning race and genetics has led to three key applications that may reinvent biological understandings of racial difference and disparity and adversely impact communities of color: race-based medicines, genetic ancestry tests, and DNA forensics.

While each of these applications has been examined individually, it is useful to consider them together to highlight a fundamental concern: that human biotechnology may give new life to the discredited idea that social categories of race reflect discrete biological differences between racial groups. In other words, it is important to ask: are twenty-first-century technologies reinventing nineteenth-century theories of racial difference? To examine this question, it is useful to explore developments in each of these three areas.

RACE-BASED MEDICINES

The Food and Drug Administration's (FDA) June 2005 approval of BiDil as a treatment for African Americans with heart failure was significant in that it marked the first time that regulatory approval had ever been given to a drug with a race-specific indication. Initially marketed by NitroMed as a way to address what were perceived as racial disparities in heart failure, BiDil quickly became the poster child of revamped efforts to approach race not merely as a social category, but as a biologically relevant mechanism for understanding human difference and health outcomes.

BiDil's approval represents at least three different claims about the relevance of race to health care and health disparities. It was (1) the first

drug to be patented as race-specific (a *legal* claim about race and biology), (2) the first to receive FDA approval as race-specific (a *regulatory* claim about race and biology), and (3) the first to be marketed as race-specific (an *economic* claim about race and biology). Although no genetic data were presented to the FDA, BiDil's FDA approval marked an important step in government giving legitimacy to framing racial difference as a proxy for significant genetic differences in human populations. Steven Nissen, chair of the FDA's Cardiovascular and Renal Drugs Advisory Committee that endorsed BiDil's approval, could not have been clearer in affirming this, noting that his committee took self-identified race in the clinical trial supporting BiDil's approval (A-HeFT) "as a surrogate for genomic-based medicine."[1]

Many ask, why not support BiDil, if it really helps African Americans who suffer from heart failure? The issue is that much of the evidence supporting this claim is not as convincing as it initially seems. For example, much of the moral impetus behind BiDil's approval was the frequently cited claim that there is a 2:1 racial disparity in heart failure mortality between blacks and whites. But blacks are not twice as likely to die from heart failure as anyone else. Legal scholar Jonathan Kahn, who followed the BiDil story very closely, traces this claim to a series of misquotes concerning what is now quarter-century-old data.[2] More recent data from the Centers for Disease Control and Prevention puts the ratio at 1.1:1. Essentially, there is little to no difference in population-wide mortality between blacks and whites.

Another concern is that the clinical trial used to support the claim that BiDil is a race-specific drug had significant flaws. The A-HeFT trial that propelled BiDil's FDA approval does not clearly support the claims of race specificity made by the drug's proponents. Any clinical trial that yields a 43 percent reduction in mortality is a stunning feat. Yet by only enrolling self-identified blacks, the trial strongly implies (and is indeed used to show) that it is *only* effective in African American populations. But this is simply not the case. Even Dr. Jay Cohn, the person who developed BiDil, acknowledges that nonblacks can receive a substantial benefit from the medication.[3] As Jonathan Kahn notes, "The only responsible scientific claim that can be made on the basis of these trials is that BiDil works in some people who have heart failure, period."[4]

Lastly, there is no evidence that race is a suitable proxy for genetic differences in drug response. While Dr. Nissen and other BiDil supporters argue that self-identified race can be used as a proxy for genetic differences until specific genetic variations are located, no genetic component to BiDil's ostensible race-specific efficacy has been found. Race-based medicine is based, in part, upon the idea that specific genetic variations that are most common within particular populations explain certain health disparities and that these disparities can be remedied with therapies that take such knowledge into consideration. BiDil's clinical trials arguably put the cart before the horse, replacing a scientific approach with the assumption that *perceived* racial difference equals genetic difference connected to heart failure.

The assumptions and missteps embedded in efforts to develop and market race-specific medicines raise several concerns. They contribute to three possible outcomes that may work against sensible approaches to addressing health disparities. First, social determinants of health might take a backseat. Scientific studies that root health disparities in genetic differences could obscure the social and environmental factors that affect groups' disparate health outcomes. Thinking about racial disparities in genetic terms deemphasizes how groups' poor treatment can lead to their poor outcomes. Second, claims about a genetic basis for racial disparities in health outcomes can quickly influence how we understand other social disparities. A key concern is the temptation to use the idea that racial disparities in health reflect inherent genetic differences to explain racial disparities in other areas such as employment, education, and criminal justice. These disparate outcomes might then be attributed to people's genes rather than barriers and privileges connected to social, economic, and political factors and access to resources. Lastly, race-specific medicines can shift the responsibility for resolving racial disparities in health from public health initiatives to private biomedical ventures. This is not to say that profit interests can never converge with genuine opportunities to reduce health disparities. But ceding the problem of racial disparities in health to biomedical companies might devalue public health mechanisms that can tackle these disparities' core social and environmental causes.

Although sales of BiDil have struggled significantly,[5] more race-based medicines may very well be around the corner. University College London biologists Sarah Tate and David Goldstein noted in a 2004 *Nature*

Genetics article that while controversial, "at least 29 medicines (or combination of medicines) have been claimed, in peer reviewed scientific or medical journals, to have differences in either safety or, more commonly, efficacy among racial or ethnic groups."[6] The Pharmaceutical Research and Manufacturers of America (PhRMA), the industry's trade group, released a report in December 2007 noting that its member companies "are developing 691 medicines for diseases that disproportionately affect African Americans or diseases that are among the top 10 causes of death for African Americans . . . [to] help close the health disparity."[7] While this report does *not* specifically pertain to medicines claiming to be genetically tailored for blacks, the report's framing contributes to a perspective that drug companies are promoting and that may become increasingly popular within the biomedical sciences: that health disparities are linked to group predispositions and susceptibilities that are best addressed through targeted medications.

GENETIC ANCESTRY TESTS

Genetic testing is often presented as a major breakthrough in healthcare, as DNA technologies may provide insight into individuals' predisposition for disease and the optimal use of certain drugs. A more questionable approach to these technologies is what some have termed "recreational genetics":[8] DNA tests focused not on health but on giving customers some type of ancillary information, such as insights into their genealogy. The marketing and sale of direct-to-consumer genetic ancestry tests is projected to become a growing industry over the next several years.

One sector is particularly booming: African Americans using genetic tests to discover their ancestral origins, often in an attempt to make an end-run around the genealogical dead end produced by the slave trade. Genetic ancestry tests examine individuals' DNA to see if they have genetic markers similar to those from populations found elsewhere in the world. Some genetic markers are found more frequently in certain populations than others, which may give clues to the geographical origin of an individual's particular genetic sequence.

The technological developments underlying the commercial viability of genetic ancestry tests stem in large part from population genetics,

an academic field that looks at how evolutionary forces shape groups' genetic makeup. But there is an often-unnoticed leap of logic between discussions of *group* genetic differences and genetic ancestry tests' ability to reliably say anything meaningful about *individual* ancestry. Group-based studies investigate frequency distributions of different populations' genetic variations whose boundaries are recognized as being inherently blurry; their applicability to the genealogy of any individual is limited. Moreover, there has been insufficient discussion on how translating academic research on groups and populations into commercial ventures on individual ancestry can breathe new life into biological notions of race.

Advocates of genetic genealogy tests rarely use the term "race," preferring terms such as "biogeographical ancestry" or "continental ancestry."[9] But from both scientific and consumer perspectives, genetic ancestry tests raise a series of important issues. Key among these are their likely social outcomes that (1) industry euphemisms such as "biogeographical ancestry" will more often than not be understood as "race" and that (2) the dissemination of the idea that social categories of race can somehow, even minimally, be genetically verified by a simple cheek swab.

Currently, genetic ancestry tests take three main approaches.

1. *Mitochondrial DNA* (*mtDNA*) tests rely on the fact that this specialized part of our DNA is passed only from mother to child (unlike most DNA, which is a mixture from both parents). It can therefore be used to test a direct maternal line.
2. *Y chromosome* tests analyze genetic markers passed from father to son to trace paternal ancestry.
3. *Admixture mapping* examines genetic markers on nonsex chromosomes that contain DNA from both parents to estimate a person's percentages of African, Native American, European, and East Asian ancestry. Significant methodological questions remain concerning these tests' accuracy.

Mitochondrial DNA and Y Chromosome tests can identify whether any two *individuals* are related with a high degree of certainty. However, they are also used to determine which genetic markers an individual might share with a population as a way to give customers a sense of their geographical origins as a proxy for what race they might be. This second use of mtDNA and Y chromosome tests has severe limitations. The reason

they are so limited is because both of these tests examine only a very small fraction of the genetic material contributing to an individual's genome. Each of our parents, grandparents, great-grandparents, etc., contributed to our genetic makeup. Going back seven generations, that is 128 great-great-great-great-great-grandparents that have an equal "say" in an individual's genome. Yet taken together, mtDNA and Y chromosome testing *only provide information about two of those ancestors* whose genetic information has been passed down throughout time, presumably unchanged. This raises the question, what about the other 126 contributors? These two tests discount the significance of these 126 contributors not because they are less important, but simply because these tests cannot access their information.

The third type of test, *admixture mapping*, is thought to resolve some of these problems. It checks 175 autosomal markers (autosomes being the 44 nonsex chromosomes inherited from both parents) that are thought to be related to certain ancestral backgrounds. The alleles, or genetic variants, used as markers with admixture mapping are "those that have the most uniqueness, or the largest differences in allele frequency among populations."[10] For example, after sampling populations from around the world, a database might show that one genetic marker is prevalent among samples from West Africans but not Native Americans, leading the admixture test to conclude that any person with this marker has some West African heritage. While most genetic markers do not reflect this type of variation, admixture mapping relies upon the few markers that do and are also connected to a geographically distinct population.[11] This blend of genetic information is thought to be able to convey a better sense of overall ancestry, but admixture mapping has its own limitations. For example, to talk about genes and ancestry in terms of percentages and mixtures seems to presume that racial purity exists, or existed at one time. This can give a misleading impression that genetically distinct populations are real (or were at some point) and that social categories of race are genetically verifiable.[12]

Genetic ancestry tests raise at least three concerns. First, there are no known genetic variations that are exclusive to any socially defined racial group. While researchers may be able to determine that certain genetic variations occur more or less frequently in certain geographically defined populations, they have not shown that these variations align discretely

with social categories of race that are largely defined by phenotype or other cultural norms. Second, there are significant limitations with the databases that these companies use. Inferences linking an individual's genetic background to a particular group of people are only as good as the underlying group samples used by genetic ancestry companies. The entire enterprise depends upon data from very small samples of people; what might appear to be clear markers of a certain group's ancestry may, after broader sampling, turn out not to define the group after all.[13] This is the likely reason why individuals who take genetic tests from multiple companies often receive conflicting results about their ancestral backgrounds.[14] Lastly, the claims made by these endeavors often go beyond the current state of the science. Genetic ancestry companies often make statements about their products' precision that are not scientifically supported; consumers can be misled about these tests' ability to accurately pinpoint their ancestral origins. Furthermore, these companies have proprietary interests in their tests and do not disclose the methods used to determine test results. Without more transparency, it is difficult to assess the scientific basis for their conclusions.

Using today's social categories of race and geographical distribution of populations as transcendent reference points from which to understand groups' past identities and locations is not only questionable science, but it also directly contradicts what we do know about the fluidity of social categorizations and migration patterns.[15] At best, using group-based population studies to speak to individuals' ancestral pasts provides a sliver of information about a person's ancestry. At worst, however, these commercial endeavors can give new legitimacy to racial typologies and revive discredited beliefs that social categories of race reflect fixed inherent differences.

DNA FORENSICS

DNA forensics is an important tool that has been used to identify perpetrators and to exonerate people previously found guilty on less reliable evidence. Hundreds of wrongful convictions have been overturned, including scores of people on death row.[16] However, a number of significant questions about DNA forensics are beginning to emerge. It is

important to note that the racial justice issues concerning DNA forensics are slightly different than those regarding race-based medicines and genetic ancestry tests. While aspects of DNA forensics leverage social categories of race to develop applications for identifying perpetrators[17] or understanding individual or group propensity for criminality,[18] it raises additional concerns over how new genetic technologies intersect with entrenched racial bias in the criminal justice system.

No one seriously doubts the reliability of DNA typing. Yet, a separate question involves the handling and interpretation of the underlying evidence. Among the issues:

Contamination—If a sample is mixed with other DNA (which can happen at any stage in collection, handling, and testing), both false positives and false negatives can result.

Clerical errors—Opportunities for introducing error arise during the procedures involved with logging samples and computer data entry.

Misinterpretation—When samples are small or old, they are particularly susceptible to being misinterpreted by laboratory personnel. Misinterpretation can also occur in cases of "mixtures," for example, when the DNA from the crime scene consists of a mixture from two or more individuals.

False matches—Random false matches do occur, most likely with close relatives.[19]

In addition to these issues, massive backlogs exist at forensic labs throughout the country. Employees are often under pressure to reduce these backlogs, which can create the conditions for more human error.

Another issue concerns the expanding use of DNA databases, which are at the heart of emerging controversies concerning DNA forensic technologies. These databases store the genetic profiles of felons and, in some jurisdictions, even people arrested or detained for felonies without ever being charged. Police argue that larger collections of genetic profiles will allow rapid identification of offenders who leave behind samples containing DNA and help solve cold or future cases. The rapid expansion of state and federal DNA databases has given rise to a new type of case in law enforcement: the cold hit, where the only evidence linking a suspect to a crime is that biological material left at a crime scene matches a

DNA profile in a database. As DNA databases grow, so too has the cold hit approach to solving crimes. While some take cold hits as unassailable proof of suspects' guilt, much closer scrutiny is warranted.

It is important to distinguish between what forensic scientists call full and partial matches. A full match occurs when crime scene evidence matches a known sample in a database across the thirteen loci standard introduced by CODIS (Combined DNA Index System, the FBI's national database). Matches across fewer than thirteen loci are known as partial matches.[20] Increasingly, partial matches are used even in cold hit cases as incriminating evidence. But new questions about partial matches are emerging. Bicka Barlow, a California attorney representing a defendant implicated in a rape/murder by a cold hit matching across thirteen loci, heard that Arizona's DNA database had two profiles that matched across nine loci. After filing a subpoena to find out more about this, she received a puzzling report: out of 65,493 offenders in Arizona's database in 2005, 122 pairs of people had genetic profiles matching at nine loci, 20 pairs matched at ten loci, one pair of siblings matched at eleven loci, and another pair of siblings matched at twelve.[21] Such findings seem implausible, given the accepted statistical norm that the odds of a random match happening between any two people across nine loci are one in several million. But therein lies the problem: cold-hit matches that occur *within databases* do not reflect the same odds as finding a match *within entire populations.*[22] A one in twenty million probability match to a cold hit in a large forensic database, for example, does not mean that the chances that the profile is not the suspect's is one in twenty million. One way to understand this is through what statisticians call "the birthday problem": although the probability that any one person has a particular birthday is 1 in 365, there is a 50 percent chance that two people will share a particular birthday in a group of twenty-three or more people.[23] While not a perfect parallel to DNA databases, the birthday problem illustrates the often-radically different chances of finding a match when probabilities are expressed in relation to the general population as opposed to a defined number of profiles in a database.

Familial searches within DNA databases are another emerging issue. This entails running an unknown DNA sample across a database to find partial matches that might not directly identify a particular suspect, but may be close enough to point to a suspect's family member who may be

responsible for the crime. Using partial matches to identify potential suspects radically expands the power and purpose of DNA databases from the individual to the family, implicating a number of people who may have nothing to do with the original crime. Given these databases' disproportionate composition—for example, it has been estimated that Blacks constitute 40 percent of the federal DNA database while only being 13 percent of the population—racial minorities are the most likely to be implicated in crimes they may very well not have committed.

Another development is the budding practice of molecular photofitting: "methods to produce forensically (or biomedically) useful predictions of physical features or phenotypes from an analysis of DNA variations . . . [to provide] a summary list of physical traits like height, weight, hair color, eye color, and race, and a fuzzy or low resolution picture."[24] Put differently, researchers are working on being able to produce a physical description and picture of a suspect simply by analyzing biological material left at a crime scene.

It is one thing when conflating social categories of race with genetic categories leads to less than accurate understandings of an individual's ancestry. It is quite another when these less than precise mechanisms become part of a criminal justice system where individuals' freedoms are at stake. While law enforcement uses all types of methods to produce leads, the presumed infallibility of DNA technologies can lead prosecutors, judges, juries, and others involved in the criminal justice system to think differently about the evidence in relation to the suspect. Further exacerbating the problem, many if not most defense attorneys lack expertise in forensic DNA analysis. This might lead them to not challenge prosecutorial assertions as vigorously as they might otherwise.

THE NEED FOR RACE IMPACT ASSESSMENTS

Racially tailored medicines, new ways of investigating individual ancestry, and expanding forensic tools for law enforcement are laudable attempts at harnessing the power of biotechnology to improve everyday life. But these and other developments also have the potential to negatively affect communities of color and, moreover, to distort public understandings of race.

We are at a critical moment. Whether new human biotechnologies turn out to disproportionately burden racial minorities and warp lay understandings of race depends heavily upon the care with which researchers, biotech companies, and policymakers treat race in their work. It is crucial that we require sound evidence for any claims attempting to link social categories of race to biological difference. Responsible regulation and oversight can go a long way toward ensuring that these products and services are based on sound scientific research, and that they do not promote unfounded biological theories of racial difference. How can this be accomplished?

To encourage more forethought in regulatory decision making and implementation, other fields have adopted impact assessments. One relevant example is the *health impact assessment*, which is a set of procedures, methods, and tools that can provide a framework for policymakers to predict, map, and mitigate adverse consequences stemming from a policy proposal.[25] For example, a health impact assessment of a proposal for a new factory would look at a number of ways it may affect the local population's health, such as whether emissions from the building are linked to adverse health outcomes and how best to contain them.

Similar regulatory assessments of the possible public impact of an innovation or initiative may be instructive for identifying and mitigating their possible adverse effects for racial minorities. *Race impact assessments* could encourage shared responsibility among multiple actors—such as regulators, researchers, institutional review boards, and affected communities and their representatives—in making sure that human biotechnologies are not used to promote unfounded biological understandings of race and that claims made about the relationship between race and genetics are legitimate.[26] Just as health impact assessments aim "to enhance recognition of societal determinants of health and of intersectoral responsibility for health,"[27] race impact assessments could promote recognition of the social construction of race and the social determinants of racial disparities.

What might such race impact assessments look like in the context of human biotechnology? As an example, legislators and regulators might rethink the Food and Drug Administration's traditional scope of safety and efficacy to convene expert committees that evaluate whether medicines like BiDil might reinforce biological understandings of race when

no biological or genetic mechanism has been identified. The composition of such a committee would have to accurately reflect the impacted stakeholders and constituents. Its assessment would not be limited to reviewing biostatistical evidence from clinical trials. It would also consider the effects race-specific medicines might have on broader commitments to racial justice, specifically in the context of past discrimination based on biological notions of race. This might encourage narrowly tailored mechanisms to ensure that a drug's beneficiaries have access without prematurely giving legitimacy to biological understandings of racial difference.

A race impact assessment of ancestry tests might lead federal or state governments to closely scrutinize marketing claims to ensure that they do not overstate the current state of the science. Such assessments might lead regulators to require genetic testing companies to limit their advertising to scientifically verifiable statements, and to give consumers adequate information about the tests' limitations. In the context of DNA forensics, a race impact assessment could shed light on policy shifts that might disproportionately affect certain communities, such as familial searching or including arrestees that have not been convicted in DNA databases. This assessment might encourage refinements and recalibrations that could lessen the burden on those communities while ensuring that law enforcement has the tools it needs.

The overall goal of race impact assessments would be the same as its counterparts in public health and other realms: to increase dialogue between stakeholders and policymakers so as to balance competing interests through strategic planning that promotes the public good. Race impact assessments have the potential to play a key role in ensuring that human biotechnologies develop in a manner that benefits society without unduly burdening racial minorities.

NOTES

This chapter is excerpted from Osagie K. Obasogie, *Playing the Gene Card? A Report on Race and Human Biotechnology*, Center for Genetics and Society (2009). The full report is available at www.thegenecard.org.

1. "BiDil African-American Subset Is Surrogate For Genomics, Cmte. Chair Says," *The Pink Sheet* 67, no. 25 (June 20, 2005): 3.

2. See Jonathan Kahn, "Getting the Numbers Right: Statistical Mischief and Racial Profiling in Heart Failure Research," *Perspectives in Biology and Medicine* 46, no. 4 (autumn 2003): 475–78.
3. "Cohn . . . says he believes it probably will be effective in patients who aren't black. In fact, he says, he prescribes the generic drugs that make up BiDil for the 25 percent of his white patients who don't do well on other drugs. 'I actually think everybody should be using it,' Cohn said." Denise Gellene, "Heart Pill Intended Only for Blacks Sparks Debate," *Los Angeles Times*, June 16, 2005, http://articles.latimes.com/2005/jun/16/business/fi-bidil16.
4. Jonathan Kahn, "From Difference to Disparity: How Race Specific Medicines May Undermine Policies To Address Inequalities in Health Care," *Southern California Interdisciplinary Law Journal* 15 (2006): 106.
5. See Tara Bannow, "Race-related Controversy Causes Drug Flop," *Minnesota Daily*, March 9, 2010, www.mndaily.com/2010/03/09/race-related-controversy-causes-drug-flop.
6. Sarah K. Tate and David B. Goldstein, "Will Tomorrow's Medicines Work for Everyone?" *Nature Genetics Supplement* 36 (November 2004): S34. They go on to note that "these claims are universally controversial and there is no consensus on how important race or ethnicity is in determining drug response."
7. PhRMA, "Nearly 700 Medicines in the Pipeline Offer Hope for Closing the Health Gap for African Americans," December 2007, www.phrma.org/news_room/press_releases/new_report_offers_hope_for_african_americans,_shows_nearly_700_medicines_in_pipeline/ (accessed June 25, 2008).
8. D. Bolnick, D. Fullwiley, T. Duster et al, "Science and Business of Genetic Ancestry Testing," *Science* 318 (2007): 399–400.
9. See, for example, the Genetic Identity Ancestry Testing webpage, www.genetic-identity.com/Ancestry_Testing/ancestry_testing.html (accessed Mar. 25, 2008).
10. Tony N. Frudakis, *Molecular Photofitting: Predicting Ancestry and Phenotype Using DNA* (Burlington MA: Elsevier, 2008), 44
11. Deborah Bolnick, "Individual Ancestry Inference and the Reification of Race as a Biological Phenomenon," in *Revisiting Race in a Genomic Age*, ed. B. Koenig et al. (New Brunswick, NJ: Rutgers University Press, 2008).
12. Deborah A. Bolnick et al., "The Science and Business of Genetic Ancestry Testing," *Science* 318 (October 19, 2007): 399.
13. "For example, genetic ancestry testing can identify some of the groups and locations around the world where a test-taker's haplotypes or autosomal markers are found, but it is unlikely to identify all of them. Such inferences depend on the samples in a company's database, and even databases with 10,000 to 20,000 samples may fail to capture the full array of human genetic diversity in a particular population or region." Deborah A. Bolnick et al., "The Science and Business of Genetic Ancestry Testing," *Science* 318 (October 19, 2007): 399.
14. Ron Nixon, "DNA Tests Find Branches But Few Roots," *New York Times*, November 25, 2007, www.nytimes.com/2007/11/25/business/25dna.html (accessed March 25, 2008).

15. "Consumers often purchase these tests to learn about their race or ethnicity, but there is no clear-cut connection between an individual's DNA and his or her racial or ethnic affiliation. Worldwide patterns of human genetic diversity are weakly correlated with racial and ethnic categories because both are partially correlated with geography." Deborah A. Bolnick et al., "The Science and Business of Genetic Ancestry Testing," 399, 400.
16. Innocence Project, Special Report: *200 Exonerated, Too Many Wrongfully Convicted*, www.innocenceproject.org/Images/751/ip_200.pdf.
17. Frudakis, *Molecular Photofitting*, 16.
18. See Special Issue on the Impact of Behavioral Genetics on the Criminal Law, Law, and Contemporary Problems, 69 (2006): 1–2 (Nina A. Farahany and James E. Coleman, Jr., were the editors of the issue.)
19. See, for example, Kristina Staley, "The Police National DNA Database: Balancing Crime Detection, Human Rights and Privacy," Genewatch UK 22 (January 2005), www.genewatch.org/pub-492774 (accessed Mar. 25, 2008); Tania Simoncelli, "Retreating Justice: Proposed Expansion of Federal DNA Database Threatens Civil Liberties," *GeneWatch* 17 (April 2004): 3, www.gene-watch.org/genewatch/articles/17–2Simoncelli.html (accessed March 25, 2008).
20. "A partial match at 9 loci, for instance, would be a pair of individual who match at 9 CODIS loci out of the 13." Laurence D. Mueller, "Can Simple Population Genetic Models Reconcile Partial Match Frequencies Observed in Large Forensic Databases?" *Journal of Genetics* 87 (July 8, 2008): 2, 100–8.
21. Jon Jefferson, "Cold Hits Meet Cold Facts: Are DNA Matches Infallible?" *Transcript* 40 (2008): 29–33. Barlow's efforts to shed light on this issue have been repeatedly hindered. See, generally, A. C. Thompson, *Weird Science: Why is S. F.'s Crime Lab Resisting Scrutiny by Defense Attorneys?*
22. UC Irvine's Bill Thompson explains: "The risk of obtaining a match by coincidence is far higher when authorities search through thousands or millions of profiles for a match than when they compare the evidentiary profile to the profile of a single individual who has been identified as a suspect for other reasons. As an illustration, suppose that a partial DNA profile from a crime scene occurs with a frequency of 1 in 10 million in the general population. If this profile is compared to a single innocent suspect, the probability of a coincidental match is only 1 in 10 million. Consequently, if one finds such a match in a single-suspect case it seems safe to assume the match was no coincidence. By contrast, when searching through a database as large as the FBI's National DNA Index System (NDIS), which reportedly contains nearly 6 million profiles, there are literally millions of opportunities to find a match by coincidence. Even if everyone in the database is innocent, there is a substantial probability that one (or more) will have the 1-in-10 million profile. Hence, a match obtained in a database search might very well be coincidental." William C. Thompson, "The Potential for Error in Forensic DNA Testing (and How That Complicates the Use of DNA Databases for Criminal Investigation)," www.councilforresponsiblegenetics.org/pageDocuments/H4T5EOYUZI.pdf.

23. Karen Norrgard, "Forensics, DNA Fingerprinting, and CODIS," *Nature Education* 1, no. 1 (2008), www.nature.com/scitable/topicpage/Forensics-DNA-Fingerprinting-and-CODIS-736.
24. Frudakis, *Molecular Photofitting*, 16.
25. While an examination of health impact assessments is most relevant for the purposes of this discussion, it is important to acknowledge that health impact assessments have "much in common with and builds on "environmental impact assessment" and also has less recognized but salient links with the field of "health and human rights" and the concept of "human rights impact assessment." Nancy Krieger et al., "Assessing Health Impact Assessment: Multidisciplinary and International Perspectives," *Journal Epidemiology Community Health* 57 (2003): 659–62.
26. Racial impact statements or assessments have been proposed in other contexts such as mitigating sentencing disparities. See, for example, Marc Mauer, "Racial Impact Statements As a Means of Reducing Unwarranted Sentencing Disparities," *Ohio State Journal of Criminal Law* 5 (2007): 19.
27. Nancy Krieger et al., "Assessing Health Impact Assessment: Multidisciplinary and International Perspectives," *Journal Epidemiology Community Health* 57 (2003): 659–62.