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science progress

The Color of Our Genes

Balancing the Promise and Risks of Racial Categories in Human Biotechnology

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A group of faculty members from Stanford University recently published a set of guidelines for using race in human genetics research. These guidelines, called the "Ten Commandments of Race and Genetics" by the New Scientist, provide both a descriptive account of the relevance of race to biomedical research and normative suggestions that call for using racial categories in a responsible manner.

These recommendations come at a time when the race and genetics conversation is at a fever pitch. Many hope that advances in human biotechnology will yield profound medical, scientific, and social advances. But what often goes unacknowledged is that if we are not extremely careful, commercial and forensic applications utilizing human biotechnology may resuscitate harmful ideas about the significance of genetics to understanding racial difference and the cause of racial disparities. To help mitigate such misunderstandings, policy tools such as race impact assessments should be adopted widely across several regulatory agencies. By facilitating greater engagement between public policy and human biotechnology, race impact assessments can provide a forum for multiple stakeholders to work with government to assess the effect race-specific biotechnologies might have on minority communities.

To understand why public policy must grapple with the impact human biotechnology might have on racial minorities, we must first take a close look at how race has informed these technologies' development and deployment.

Race and Genetics: From Research to Main Street

One of the Human Genome Project's most heralded findings was that all humans are over 99.9 percent similar at the molecular level, a discovery that supports the social rather than genetic character of racial categories. (Subsequent research has slightly raised the initial estimate of difference, to around 0.5 percent.[1]) At the time that the HGP's results became public in 2000, numerous scientists and other observers predicted that its finding of human genetic similarity would finally move society beyond biological theories of racial difference that have fueled centuries of racial strife.[2] The truths of science, some hoped, could promote racial healing. Yet almost as soon as researchers announced this result, several research projects began to focus on mapping the less than 1 percent of human genetic variation onto social categories of race.[3]

Since then, biomedical researchers and companies have become increasingly interested in developing treatments that use race and ancestry (both perceived and self-identified) as proxies for groups' genetic predispositions. Put differently, these efforts presume that social categories of race reflect medically relevant genetic differences, even when such differences have not been identified. This is better known as race-based medicine: drugs that are developed, approved, and marketed for specified racial groups. Only one of these drugs, BiDil (marketed to treat heart failure in African Americans), has received FDA approval. But others are in development.

Meanwhile, dozens of biotechnology companies are marketing genetic testing services directly to consumers, bypassing physicians and other health care profes-

sionals. Combined with the power and reach of the Internet, direct-to-consumer genetic testing offers people the ability to swab their cheeks at home, mail the sample (along with a fee ranging from $100 to $1,000), and receive information a few weeks later.

While much skepticism has accompanied the growth of DTC genetic testing, there has been less public discussion about the significant concerns stemming from genetic tests claiming to reveal information about consumers' ancestral origins, which are often interpreted as tests of racial purity and mixture. Genetic ancestry tests are gaining popularity, especially among African Americans who often have these tests pitched to them as a way to make an end run around the genealogical dead end produced by the slave trade. But in examining less than 1 percent of a person's genetic background, these tests often overstate their ability to say anything significant about a person's heritage, giving the impression that social categories of race and ethnicity are somehow genetically verifiable.

Biotechnology is also making an impact in forensics, a field that uses techniques such as ballistics, fingerprinting, and toxicology to investigate crimes. Two decades ago, the United Kingdom's Sir Alec Jeffrey's revolutionized forensics by developing genetic profiling. This capacity to extract unique identifying information from hair or body fluids left at crime scenes has given police a powerful tool to catch suspects.

A good part of DNA forensics' power now comes from massive databases storing large numbers of genetic profiles. Once a DNA sample is gathered from a crime scene, it can be checked against stored profiles for matches.

But whose DNA winds up in police databases? Typically, it is people who have had previous run-ins with law enforcement. And herein lies the risk for minority communities: given that Blacks and Latinos are disproportionately policed, arrested, and prosecuted, their profiles are likely to be over-represented. This means that the significant civil liberties concerns raised by DNA forensics will disproportionately burden these communities.

Will Human Biotechnology Revive Biological Theories of Race?

Like many scholars, the authors of the Stanford guidelines recognize that there is no scientific basis for the idea that human genetic variation reflects any sort of racial hierarchy and acknowledge that racial categories exist within social and political contexts that shift over time. They discourage researchers from using race as a proxy for biological similarity, and caution against what they term the "naïve leap" to genetic explanations of complex social phenomena such as IQ or propensity for violence. Their guidelines are an important contribution, and should be adopted widely so that research on race and human genetics can proceed responsibly.

But as I argue in my report, "Playing the Gene Card? A Report on Race and Human Biotechnology," concerns about race and human biotechnologies cannot be limited to individual research agendas or best practices in clinical settings. Instead, it is crucial to consider how these technologies, particularly when taken together, are likely to have a public impact. However laudatory, no set of voluntary guidelines or recommendations can obviate the need for greater public oversight of how racial categories are deployed—in research, in the marketing of the resulting products, and in the public understanding of the research findings.

This point is particularly relevant since the approval of regulatory bodies such as the Food and Drug Administration and the United States Patent and Trademark Office can allow the state to sanction potentially misguided claims about the relationship between race, genetics, and social and health outcomes. Regulatory bodies can play a powerful role in giving misplaced legitimacy to claims that correlate social categories of race with genetic variations when the evidence is not yet robust, effectively putting the cart before the horse.

There is some evidence that social categories of race may be genetically relevant to the extent that they may 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 today's applications in biomedicine, genealogy, and forensics have treated race in a somewhat circular fashion; unexamined ideas and assumptions about the genetic relevance of race, often reflecting lay perspectives, can shape research questions and methodologies. This is what Troy Duster and others have called the reification of race: transforming race as a social concept into a specific, definite, concrete, and now presumably genetic category that can feed back into preexisting assumptions about racial difference.

The potential of race-specific medicine, genetic ancestry tests, and DNA forensics to revive biological thinking about race is not necessarily due to any ill intent on the part of researchers working in the area of race and genetics. To the contrary, many scientists have devoted their careers to egalitarian and praiseworthy pursuits such as resolving health disparities and assisting law enforcement. For example, the use of racial categories in biomedical research has been proposed as a way to make biomedicine more inclusive. But even with the best of intentions, commercial and forensic applications of this research can unwittingly create the very difference they seek to find. As in other areas, racial injustice is best understood as a matter of systematic outcomes rather than a question of intentions.

The social, political, and economic dynamics surrounding research concerning race and genetics might allow less-than-robust scientific studies or weak correlations between genetic variations and social categories of race to be marketed as commercially viable genetic tests or biomedicines. Our society's continued stake in the idea that social

categories of race reflect inherent biological differences—even when faced with substantial evidence to the contrary—contributes to the acceptance of these products. And this process might work to reconstitute an inaccurate and unsubstantiated view of racial difference and disparities.

Why We Need Race Impact Assessments

Given the remarkably high stakes involved and the rapid development of biotech products and services that implicate racial categories, it is time for policymakers to take these matters under serious consideration. Responsible regulation and oversight can go a long way towards ensuring that these products and services are based on sound scientific research, and that they do not promote unfounded biological theories of racial difference. Regulators can help protect racial minorities from inappropriate commercial pressures, less than forthright marketing, and the often-unintentional re-articulation of folk notions of biological race. The goal is to create an environment in which research and scientific innovation can move forward while guarding against potentially harmful social outcomes.

How might this work? In order to encourage more forethought in regulatory decision-making and implementation, other fields have adopted the use of impact assessments. One relevant example is the health impact assessment,[4] which is a set of procedures, methods, and tools that, according to the World Health Organization,

> …provide a structured framework to map the full range of health consequences of any proposal, whether these are negative or positive. It helps clarify the expected health implications of a given action, and of any alternatives being considered, for the population groups affected by the proposal. It allows health to be considered early in the process of policy development and so helps ensure that health impacts are not overlooked.

Public health researcher John Kemm notes that despite different definitions, two essential characteristics of health impact assessments are that they "seek to predict the future consequences for health of possible decisions; and that [they] seek to inform decision-making." 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[5] could encourage shared responsibility among multiple actors—including regulators, researchers, internal 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 based on sound evidence. Just as health impact assessments aim "to enhance recognition of societal determinants of health and of intersectoral responsibility for health,"[6] 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, modifications to the traditional role of the Food and Drug Administration might allow it to convene advisory committees as part of its review process that look beyond safety and efficacy to evaluate whether medicines with race specific indications such as BiDil might reinforce biological understandings of race when no biological or genetic mechanisms have been identified.

The composition of such a committee would have to accurately reflect the demographic makeup of the stakeholders and constituent groups affected by the research. 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 and/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, the use of molecular photofitting, 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 in human biotechnology 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 though strategic planning that promotes the public good.

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Notes

[1] Samuel Levy et. al. write "Comparison with previous reference human genome sequences, which were composites comprising multiple humans, revealed that the majority of genomic alterations are the well-studied class of variants based on single nucleotides (SNPs). However, the results also reveal that lesser studied genomic variants, insertions and deletions, while comprising a minority (22%) of genomic variation events, actually account for almost 74% of variant nucleotides. Inclusion of insertion and deletion genetic variation into our estimates of interchromosomal difference reveals that only 99.5% similarity exists between the two chromosomal copies of an individual and that genetic variation between two individuals is as much as five times higher than previously estimated. … [Therefore] we can, for the first time, make a conservative estimate that a minimum of 0.5% variation exists between two haploid genomes." Samuel Levy, "The Diploid Genome Sequence of an Individual Human," PLoS Biology 5:10 2113–44. (Cited passages at 2114 and 2132).

[2] The New York Times' Amy Harmon writes that "When scientists first decoded the human genome in 2000, they were quick to portray it as proof of humankind's remarkable similarity. The DNA of any two people, they emphasized, is at least 99 percent identical. But new research is exploring the remaining fraction to explain differences between people of different continental origins." Amy Harmon, "In DNA Era, New Worries About Prejudice," New York Times, November 11, 2007, http://www.nytimes.com/2007/11/11/us/11dna.html?_r=1&hp&oref=slogin.

[3] Duana Fullwiley, "The Molecularization of Race: Institutionalizing Human Difference in Pharmacogenomic Practice," 16 Science As Culture 1 (2007).

[4] 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," J Epidemiol Community Health 2003;57:659–662.

[5] Racial impact statements or assessments have been proposed in other contexts such as mitigating sentencing disparities. See e.g., Marc Mauer, "Racial Impact Statements As a Means of Reducing Unwarranted Sentencing Disparities," 5 Ohio State Journal of Criminal Law 19 (2007).

[6] Nancy Krieger et. al., "Assessing Health Impact Assessment: Multidisciplinary and International Perspectives," J Epidemiol Community Health 2003;57:659–662.