Introduction: Race, Genetics, and Disease: Questions of Evidence, Matters of Consequence

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SPECIAL ISSUE ON RACE, GENOMICS, AND BIOMEDICINE

Introduction
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This special issue of *Studies of Science* highlights ongoing debates concerning race, genomics, and disease. Some of the papers examine the production of disease etiology research, pharmaceutical drug response, or DNA genealogy tests, while others analyze institutional consequences and challenges arising from contemporary biomedicine, such as medical education and recruiting subjects for clinical research. In this introduction, we outline major issues that provide background and foreground for the specific studies that follow, and end with a brief description of the papers. First, we briefly outline the debates around contemporary genetics research on race, ancestry, population, and disease. Second, we describe genomics and disease research projects on the genetics of populations that provide the ground on which the past debates have played, as well as introduce very recent projects that may change the tenor of future debates. We discuss why some scientists argue that their research does not biologize race, while others argue that their findings do demonstrate racial differences. Finally, we relate these complex genomic sciences and their biopolitical debates to relevant STS themes.

The Current Debate on the Use of Race Categories in Biomedical Genomics: Will the New Genomics Challenge or Reify Social Categories?

Many sociologists, anthropologists, and biologists have argued that race categories proposed by 18th-century anthropologists do not constitute

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biologically or genetically distinct populations (for example, Boas, 1913; Du Bois, 1940; Montagu, 1942; Lewontin, 1974; Gould, 1977, 1994).[1] Building on these earlier studies, later scholars viewed race categories as socio-historical constructs that change over time and differ by locale (for example, Stepan, 1986; Haraway, 1997; Duster, 2003a; Hacking, 2005). Sociologists have argued that race and ethnicity should be conceptualized in relational, processual, dynamic, and disaggregated terms (Blumer, 1958) and have studied race and ethnicity as cultural idioms, cognitive schemas, discursive frames, contingent practices, or political projects (Omi & Winant, 1994; López, 1996; Davis, 2001; Brubaker et al., 2004). Several studies have examined differences in race classification schemes between countries or cultures or within a particular nation over time (Telles, 2004; Loveman & Muniz, 2008). Within STS, for example, Bowker & Star (1999) have examined the many inconsistencies between official and practical interpretations of race classifications in apartheid South Africa. Despite occasional attempts in the late 20th century to make the case for racial differences in, for example, intelligence, the consensus of social and historical scholarship is that racial and ethnic category formation should be studied as political, social, cultural, and psychological processes.

However, the last 10 to 15 years of advances in molecular biology, genetics, and genomics have made it possible to investigate the genetics of difference. It is now faster and cheaper than ever before to detect genetic variation between individuals and populations. Research following the sequencing of 'the' human genome has used these new technologies to study the genetics of population differences, some in search of disease genes, others in search of human demographic and evolutionary history.

In the 1990s and early 2000s, a number of genetic projects concerned with the biological basis of population differences began to emerge, producing what appeared to be a resurfacing of the genetics of race. Although many of these projects were examining the genetics of *difference*, but not the genetics of *racial* difference, some geneticists framed their findings in terms of 'racial' differences. In the context of American race politics, folk-understandings of race, and the history of racist scientific investigations in the USA, it is not surprising that members of the media and other public groups read the genetics of difference as the genetics of race.[2]

The recent upsurge in race-related biomedical research has been both lauded and critiqued. Some researchers studying the genetics of difference have argued that there is significant biological variation between different racial and ethnic groups in disease susceptibility and drug response and that knowledge of these differences would be useful for medical diagnosis and treatment (Risch et al., 2002; Satel, 2002; Burchard et al., 2003). Using this reasoning, Burchard et al. (2003) argued that to ignore race in genetic studies would be a disservice to underserved populations. In reaction, critics of race-based research have argued that the search for genetic contributions to racially stratified health outcomes may distract clinicians and public health officials from more proximate social causes and more effective social interventions to redress these inequities (Cooper et al.,

2003, 2005; Ossorio & Duster, 2005). Others suggested that while race as a sociopolitical construct is appropriate for monitoring health disparities, some recent human genetic variation studies show that genetic ancestry, which is correlated with geographic ancestry, is a better tool for genetic studies of complex diseases (Shields et al., 2005; Feldman, 2006). Other critics warned that while race may be expedient as a proxy for anything from diet to ancestry, contemporary biomedical uses are often incorrect, misleading, or may cause more harm than good (Sankar & Cho, 2002). Their primary concern was that the conflation of race categories (especially in the USA) with biomedical research categories has the potential to reinstitute and reify these race categories as biological (Marks, 1995; Duster, 2003a; Kahn, 2006; Wailoo & Pemberton, 2006).

The debates reveal diverse and often conflicting interpretations of recent genomic studies that interweave notions of race, ethnicity, national origin, and ancestry. These debates pivot around the view that the new genomics has resurrected race in biomedicine. But historians argue that race as an organizing principle never actually disappeared from scientific imaginations, despite other efforts to demonstrate the biological emptiness of race categories. Here it is important to distinguish racism from race-based research. The 1950 and 1951 UNESCO statements on race are often cited as demonstrating that Euro-American scientists in the post-Second World War era were vigilant against biological notions of racial differences, in part as a reaction to Nazi atrocities. However, historians point out that subsequent UNESCO statements critiqued racial prejudice and racism but did not disown the biological race concept itself (Müller-Wille, 2005; Brattain, 2007). Indeed, sociologists have since demonstrated that race as a biological concept is still prevalent among many natural and social scientists (Lieberman, 1968; Morning, 2007). More recently, Gissis (2009) has comparatively traced the use of race by American, British, and Israeli authors in American and British journals in the fields of genetics, epidemiology, and medicine from 1946–2003 and found that 'there has been both continuity in and reconstruction of the roles of "race" within the genetic/medical discourse'.

Contemporary Post-Genomic Projects: The Genetics of Individual Difference Versus the Genetics of Population Difference

In the interest of setting the stage for some of the science being debated and critiqued in this special issue, we next discuss contemporary 'human genetic variation studies', which examine the genetics of difference, including differences between individuals and differences between populations.

In the 1990s, the Human Genome Project (HGP) sequenced a composite human genome under the assumption that individual genomes were very similar. At that time, scientists estimated that there was at least 0.1% difference between human genomes (Marks, 1995), and researchers sequencing Craig Venter's genome have since raised that estimate to 0.5% (Levy et al., 2007). Although this difference is small, researchers argued that

even a 0.1% difference could potentially translate into biomedically significant genetic variability. Thus, even before the HGP was completed, scientists and bioscience funding administrators began to lobby for a catalog of the common heritable variations in the human genome, such as single-nucleotide polymorphisms (SNPs, pronounced 'snips')[3], small deletions and insertions, and other structural differences in genomes (Collins et al., 1997, 2003). The assumption, hope, and justification underlying these efforts was that identification of genomic variations could shed light on the genetic bases of human disease and variations in drug response.

Heart disease, cancer, asthma, type 2 diabetes, and other such diseases have complicated etiologies that likely involve the small, combinatorial influences of many genes, interactions between genes, and interactions between genes and environments (Cooper et al., 2003). Behavioral, environmental, and stochastic factors also affect disease manifestation. While acknowledging these complex interactions, biomedical geneticists argued that genetic factors might help explain why individuals (and in some cases groups) vary in their susceptibility to various diseases and in their responses to various therapies. Moreover, many researchers contended that knowledge of how genotypic variations are distributed in populations, as well as their associated medical risks, could allow physicians to recommend specific precautions for individuals thought to be carrying susceptibility markers.

The characterization of this genetic variability has been the site of recent controversy. To be more precise, it is the notion of *genotypic variations between populations* that has produced discord. The idea that different groups might vary in genetic susceptibility to common complex diseases has been heavily critiqued. In contrast, genetic variation within populations, or *genetic differences between individuals*, has not generated controversy. Further, even the use of populations in the search for genetic markers that may be involved in causing disease has been criticized. In particular, researchers who investigate the genetic basis of common complex diseases use *populations* in their 'genetic epidemiology' approach. That is, in order to 'find' and characterize genetic differences across populations, some of these projects begin their studies by selecting groups from which to collect DNA samples. The problem they face is how to determine which groups to study, how those groups should be described, and how they should be constituted. Some studies have used notions of race in their sample collections, others have not.

To clarify, it is the genetics of population differences and not the genetics of individual differences that has caused so many to raise the red flag and warn that this strategy could easily lead down a dangerous road in clinical medicine – where individuals from certain sociocultural groups are mistakenly and uncritically categorized together in a presumed biomedically similar group.

The Haplotype Mapping Project

The post-HGP search for candidate genes involved in common complex diseases has involved the genome-wide study of associations between

genetic marker frequencies and disease incidence, across many individuals. A key question in these studies is how best to select research populations. Population geneticists claim that extant human populations vary in their frequencies of particular SNPs, due to the relative geographic isolation of their respective 'ancestral' populations during early human evolution. The idea that marker frequencies vary across populations was a motivating factor for the National Human Genome Research Institute (NHGRI)-initiated International Haplotype Mapping Project (HapMap), which is documenting genetic variation in different populations and serving as a resource for many kinds of human genetic variation projects, including studies of complex diseases. The original HapMap project included samples from four 'populations': Japanese people from Tokyo, Yoruba people from Ibadan in Nigeria, Han Chinese from Beijing, and residents of Utah believed to be of northern or western European descent. These samples were chosen in part for convenience, and in late 2007 additional samples were included.[4]

However, the original HapMap samples generated much critique because of their evident relationship to continental categories (African, Asian, and European). Members of the media and others read race-based selection in the categories, despite official HapMap statements to the contrary. Some critics have read the HapMap and disease SNP projects as indicative of the search for 'racial' differences in disease susceptibility, arguing that they could 'reinscribe' race through genetic technologies or produce genetic categories of race. Others were concerned that members of the public might read the projects as proof that there are genetic differences between 'races'.

Genome-Wide Association Studies (GWASs)

One method for detecting disease-related SNPs that has risen to prominence is known as the genome-wide association study (GWAS). The large-scale statistical analyses in such studies aim to identify SNPs located in or near genes that might be involved in complex diseases, by characterizing SNP differences between cases (those afflicted with a disease) and controls (those who do not have the disease phenotype) in various populations. *Science* magazine recently named human genetic variation studies, especially those studies focusing on the search for genetic markers that cause common complex diseases, as its 'breakthrough of the year' for 2007 (Pennisi, 2007).

GWAS studies have produced a number of SNPs of interest with respect to common complex disease (see Altshuler & Daly, 2007; Clark & Li, 2007; Couzin & Kaiser, 2007). However, the research on whether or not these SNPs influence disease is still in process. GWAS experiments may produce candidate genes whose role in disease causation could then be studied, most likely by molecular geneticists. Some GWAS researchers studying type 2 diabetes take care to state that, should such candidate genes be identified, they will likely account for at most 10% of the etiology

of that disease. They emphasize the multifactorial web of causation, including genetic, social, and environmental factors, that will continue to challenge researchers studying common complex diseases.

In GWAS studies, 'ancestry' and 'ancestral differences' come into play in complex practices of statistically calculated genomic differences. In order to avoid spurious SNP–disease correlations, medical geneticists have argued that underlying differences in population structure between cases and controls need to be accounted for. Several algorithmic approaches have been developed to 'stratify' populations in order to mask out those differences among samples that are not relevant to disease. In response to concerns about a potential re-inscription of race through disease genomics, some geneticists conducting GWAS and haplotype mapping argued that their projects were *not* about race. In particular, some of these biomedical researchers are innovating new algorithmic approaches to circumvent the explicit use of race variables while, as they put it, 'correctly' accounting for population substructure within their datasets. These researchers distinguish the genetics of populations from the genetics of race.[5]

Race, Genomics, and Commercialization

Several pharmaceutical companies have produced and marketed drugs aimed specifically at racial minority groups in the USA. As discussed by Jonathan Kahn (2008) in this issue, NitroMed's BiDil was approved by the Federal Drug Administration (FDA) as the first 'ethnic' specific drug based on clinical trials in African-American subjects, but its supposed race-specific efficacy has been called into question because it has not been established that it is ineffective in other ethnic or racial groups.[6] As Kahn (2008) argues, the use of self-reported race as a proxy for genetic similarity has become routinized because it is much less expensive than assaying genetic markers. But such race-based research and marketing runs the danger of being misinterpreted as evidence of a genetic basis underlying disease susceptibility and differential responses to drugs across socioculturally defined racial groups (Cooper et al., 2003; Duster, 2005; Kahn, 2006).

In contrast to such group-based pharmaceuticals, the recent commercialization of GWAS results seems to have ushered in what we call a new 'risk genomics' based on applying the genetics of populations to the genetics of the individual. Although GWAS generate SNPs of interest, molecular biologists insist that the function of those SNPs in producing disease has yet to be demonstrated through molecular ('wet lab') experiments. Nonetheless, GWAS results have sparked a new industry in consumer-tailored genetic products and services. Companies such as '23andMe', 'deCODEme', and 'navigenics' have begun to offer direct-to-consumer 'personal genome services' that will genotype customers' samples and generate a personal genetic readout of their levels of risk for specific conditions and diseases (Goetz, 2007).[7] 23andMe will even estimate genetic susceptibility for certain diseases by combining phenotypic information about ethnicity with genotype data. For common complex diseases, these

commercial ventures are marketing risk estimates based on uncharacterized SNPs, *before* geneticists understand if and how those SNPs are related to disease causation and long before any targeted therapies are likely to be available. If genomic risk for disease is still in the process of being constituted in biomedical research contexts, what are these companies selling? Such risk genomics ventures may have deep and complex social ramifications for individuals and the risk communities and groups that result, as we discuss next.

Implications for STS: Naturecultures, Different Kinds of Difference, and Risk

Will new kinds of social arrangements arise from new genetic technologies and genome-wide studies of disease causation, or will they help to reify older social categories? Some sociologists and anthropologists have argued that the genetics of difference is not reviving older biological notions of race, but instead is ushering in a new era of biological citizenship organized around individuals with differential genetic risks. Nicholas Rose (2007) and Paul Rabinow (1991), for example, argue that new genetic technologies may challenge many of the older socio-historical categories and generate new configurations in which support and activist groups form around particular disease histories or risk identities. Self-organized and activist associations of people with particular heritable diseases appear to confirm the idea of active public involvement in ensuring particular biosocial outcomes. Michel Callon and Vololona Rabeharisoa (2008) examine just such a biosocial group in their study of a French patient organization that has established an institute for research on 'their' particular 'genetic' disease and convinced scientists of the benefits of working outside the constraints of commercial profit-making and academic career-making, which can impede the pursuit of therapies. Taussig et al. (2003) provide another kind of example where some members of the Little People of America have lobbied against genetic interventions that would 'treat' – or in their minds, erase – those with their condition.

On the other hand, if genetic affinity groups happen to overlap with complex socio-historically produced categories such as race, these technologies may have enhanced potential to introduce eugenics 'through the backdoor' (Duster, 2003a). In the USA, unequal access to healthcare and to healthy environments has already exacerbated socioeconomic inequalities to initiate what we call 'sociomaterial engineering' (cf. Fujimura, 2006). This collapsing of socio-historical and biogenetic categories (Montoya, 2007) produces a situation where biological citizenship is organized not around *individuals* with perceived differential genetic risks, but instead around already stratified *groups* with perceived differential genetic and health risks.

These different kinds of difference came to matter in complex ways. For example, Duster (2003b: 262) describes variability in the relative density of blood antigens to show the interactive feedback loops between biology, culture, and social stratification; race, used as a stratifying practice, has produced what could be read as 'negative' health practices and 'biological outcomes that make it impossible to completely disentangle the

biological from the social'. More specifically, in the 2003 context where white Americans constituted approximately 80% of the US population, proportionally fewer African Americans and Asian Americans donated blood than did whites. Their actions mattered because it is believed that blood from Americans of 'European' ancestry tends to have a greater number of antigens than blood from Americans of 'African' or 'Asian' ancestry. Immune systems generally produce antibodies to antigens they lack, either before or during exposure to them, and of the more than 200 blood antigen groups, most clinics only test for the ABO and Rh groups due to practical and financial constraints. African Americans and Asian Americans who receive blood from 'white' donors are therefore at a greater risk for adverse immune reactions than are whites who receive blood from non-white groups. African Americans proportionally donate less blood partly from a mistrust of scientists and medical doctors in the wake of particular historical events, for example the Tuskegee experiments. Thus, the biological consequences of social forces giving rise to skewed representation in the blood banks are that less blood is available for blood transfusions to African Americans and Asian Americans, and that members of these groups who need transfusions run a higher risk of life-threatening outcomes or side effects.

Duster argues that in the USA, 'social' race/ethnic groups behave differently with respect to transfusion for a variety of historical reasons, which in turn generate biological and clinical repercussions.[8] However, race may produce different consequences in different situations. Race is a social concept that changes depending on where and when it is used. It does work in the world that must be examined in each situation.[9] That is the task taken on by the authors in this special issue who follow race as it performs in the worlds of science and medicine.

Papers in the Special Issue

We begin the special issue with a study of the use of race in clinical medical research by feminist theorist and biologist Anne Fausto-Sterling (2008). Recent biomedical studies have claimed that there are racial gradations in bone density, with African Americans supposedly having the densest bones. Fausto-Sterling argues that such research on osteoporosis uses obscure and contradictory notions of race and is ultimately unhelpful for understanding osteoporosis. Instead, her examination emphasizes the importance of environment, cultural practices, dietary differences, and labor patterns in the etiology, progression, and display of bone density problems. She demonstrates that osteoporosis research poorly conceptualizes how context and life history affect racial differences in outcomes, and proposes a theoretical framework for improving biomedical research.

The next paper by anthropologist Duana Fullwiley moves us methodologically to a laboratory ethnography. Fullwiley (2008) focuses on a medical genetics laboratory that attempts to identify biological differences in asthma susceptibility between 'racially admixed' minority groups. She describes how a group of collaborating scientists rely on traditional archetypes of Africans,

Asians, Europeans, and Native Americans as 'Old World' source populations to explain 'New World' genetic difference. She demonstrates that, despite—and perhaps because of—their dedication to reducing health disparities in asthma severity suffered by Puerto Ricans, these scientists sought to frame disease morbidity as linked to ancestral genetic background. Fullwiley suggests that we are now faced with a 'bio-logistical construction of race' where political motives and assumptions about racial difference inhere in the very biomarkers collected and ultimately put to work in models of continental ancestry.

Legal scholar Jonathan Kahn (2008) continues the examination of the use of race in biomedical research in his study of the development of BiDil, the first "ethnic" (read "racial")-specific drug approved by the U.S. Food and Drug Administration. He shows how BiDil's approval resulted from explicit efforts on the part of its developers to reorient a drug that had insignificant results for a general population to a drug for a specific population—African-Americans. In that process, BiDil makers obtained quick FDA approval and extended its patent period by 13 years. Kahn raises the concern that BiDil geneticizes race by using self-identified race to stand in for genetic markers as a research variable—a practice that has become standard in the new, rapidly expanding field of pharmacogenomics because it is much less expensive. Further, as Kahn points out, the 2001-2004 BiDil trials that led to FDA approval enrolled only self-identified African Americans. There were no comparison groups and thus no new evidence for race-specific responses to BiDil.

Sociologist Alondra Nelson (2008) tracks how members of the general public decide who and what to believe regarding their genetic ancestry. Bolnick et al. (2007) have raised concerns about the limitations of for-profit ancestry testing services. Nelson takes this concern in a new direction by asking whether and how African American and black British individuals who avail of commercial genetic genealogical testing services use such information to think about their racial/ethnic identities. She shows us that they accept the information provided by such services unless there is contradictory evidence available. In the latter case, users adjudicate between test results and other biographical information available through family oral histories, conventional genealogies, or other tests. Although not directly about medical health, Nelson's paper provides a framework for approaching the problem of public consumption of scientific knowledge, and suggests how social studies of science and technology may be made useful to the public at large. If, as she argues, people do not take science as the ultimate authority for determining their racial identities, might the public be open to the kinds of critiques of scientific authority and the articulations of scientific debate presented in the other papers in this issue?

Physician-historian Warwick Anderson (2008) was part of a team of anthropologists and historians of medicine who taught a course about race to medical students. This group of instructors understood race to be not a biological absolute, but instead a complex set of categories produced socially and historically. However, as Anderson argues, these medical

anthropologists and historians encountered difficulties when the medical students dismissed their views in favor of those geneticists and medical researchers who argued otherwise. Anderson shows how these reactions motivated self-criticism among the social scientists and historians about their own marginal status and lack of credibility in the American medical school setting. Given this institutional context, Anderson raises the question of how to translate the social and historical complexities of race to future medical doctors and researchers. Complementing studies which indicate that practicing medical doctors continue to have little knowledge of the complexities of genetics (Doksum, et al., 2003), Anderson's paper raises concern about the bleak future of medical caretakers who accept at face value the very kinds of genetics research criticized in the earlier papers in this special issue.

In the final paper, sociologist Steven Epstein (2008) examines how the institution of clinical trials contributes to new inscriptions of race. He follows a practice he calls "recruitmentology," which attempts to find new ways to convince people to participate in clinical trials. He examines how "recruitmentologists" re-conceptualize race in the process of trying to overcome mistrust and collective memory especially on the part of racial/ethnic minorities, and describes how recruitmentology further institutionalizes race as a variable in clinical and pharmaceutical research and participates in the production of racial identities.

Notes

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1. While some anthropologists in the post-war era were interested in differences between populations, they viewed this variability as a product of geographical clines and not as discrete races. A cline is a 'character gradient', which is a continuous gradation over space in the form or frequency of a trait (Livingstone, 1962: 133, 137). See also Kittles & Weiss (2003).
2. Although Nicholas Wade, science writer for the *New York Times*, has often mistaken 'race' for 'ancestry' (see Wade 2002), he is not the only one.
3. A SNP is a single base pair position in genomic DNA at which different sequence alternatives exist in a population. Within a population, the frequency of a SNP variant is its estimated occurrence in that population. This frequency can differ across human populations such that a SNP variant that is common in one geographical/clinal group may be rare in another. See Brookes (1999).
4. NHGRI, International HapMap Project (<www.HapMap.org/aboutHapMap.html>).
5. This discussion is based on a research project in which the authors of this introduction are currently engaged.
6. NitroMed announced in January 2008 that it was suspending its marketing and sales of BiDil, but will continue to make BiDil available for patients. It is also considering 'strategic alternatives' (Armstrong, 2008).

7. For recent papers about the limitations associated with the technology's ability to provide accurate assessments of risk, see Hunter et al. (2008) and Editorial in *Nature Genetics*, December 2007.
8. This frame of analysis is consistent with the STS theme of moving beyond the social/natural and human/nonhuman boundaries, which has produced concepts such as the material-semiotic (Haraway, 1997), intra-action (Barad, 1998), socio-materiality (Fujimura, 2006), and biocultural synthesis (Goodman & Leatherman, 1998).
9. This too is consistent with the STS theme of paying attention to the continually evolving ways in which scientists and technologists construct objects, knowledge, and society anew with each project. This approach is exemplified in ethnomethodological, symbolic interactionist, and actor-network theory methods of research in science studies.

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