Debate over the proper use of racial and ethnic categories in biomedical research has raged in recent years. With the Human Genome Project showing that human beings are overwhelmingly alike genetically, exhibiting more genetic variation within supposed “races” than between them, many have come to doubt the scientific utility of such categories. Yet federal authorities use Directive 15 from the Office of Management and Budget (OMB) to mandate the continued use of such categories in research. Moreover, researchers studying health disparities argue that data collection using racial and ethnic categories is necessary to determine whether conditions and care vary by race and ethnicity. Epidemiologists also defend the use of racial and ethnic categories to understand contributors to disease such as the stress of experiencing racial prejudice and reduced access to care because of bias. A number of conflicting proposals have been offered, some to discipline and improve the use of racial and ethnic categories, and some to eliminate such categories. This is a debate affecting researchers, funders, journal editors, research participants, and the broader community.

To make progress in this debate, the University of Minnesota’s Consortium on Law and Values in Health, Environment & the Life Sciences with the University’s Center for Bioethics convened a conference on April 18, 2005 to consider “Proposals for the Responsible Use of Racial and Ethnic Categories in Biomedical Research: Where Do We Go From Here?” The conference was co-sponsored by the Office of Minority Health and Multicultural Affairs at the Minnesota Department of Health. The articles that follow offer symposium participants’ views on the proper role of racial and ethnic categories.

The University of Minnesota was a natural home for this conference, as University professor Jay Cohn, M.D., was lead investigator and inventor on a patent for BiDil (combining isosorbide dinitrate and hydralazine), the first drug approved by the Food and Drug Administration (FDA) for patients of a particular racial or ethnic group – in this case, African-American patients with heart failure. Substantial controversy surrounds the drug and the FDA’s action. Beyond that, researchers at any major university must meet federal research requirements, while addressing the concerns of research participants and generating solid data. Yet using OMB Directive 15 categories may violate community expectations and generate data sorted by categories with questionable scientific validity.

Professor Troy Duster, Ph.D., of New York University and the University of California, Berkeley begins the symposium with “Lessons from History: Why Race and Ethnicity Have Played a Major Role in Biomedical Research.” He argues that while scientists and physicians can easily see that their fields were affected by social forces in the past (for example, slavery biasing mid-19th century science and racism compromising early and mid-20th century science), it is harder to recognize social forces at work now. Yet Duster finds continuing assumptions that blacks are biologically different from whites in flawed analyses of the biological underpinnings of violence, among other areas.

Susan M. Wolf, J.D., is McKnight Presidential Professor of Law, Medicine & Public Policy; Faegre & Benson Professor of Law; Professor of Medicine; and Chair of the Consortium on Law and Values in Health, Environment & the Life Sciences at the University of Minnesota. Much of her work relating to genetics and genomics is funded by the National Human Genome Research Institute at the National Institutes of Health, most recently a project on “Managing Incidental Findings in Humans Subjects Research.”
Duster predicts that “the next decade will witness an outburst of behavioral genetics research, buttressed by the molecular reinscription of race tying crime to biological processes, and then correlating those biological processes to race.” He thus sounds a warning to all studying race, ethnicity, and biology.

Professor Mildred Cho, Ph.D., of Stanford University has taken that warning seriously and offered important recommendations in the past for the responsible use of racial and ethnic categories in research. In “Racial and Ethnic Categories in Biomedical Research: There is no Baby in the Bathwater,” she argues against the use of racial and ethnic classifications in most medical research. Cho points out that we have no agreed set of racial and ethnic categories and cannot even agree on what “race” and “ethnicity” mean. There are categories far more reliable and relevant to research and clinical care such as categories based on environmental factors or more precise distinctions in ancestral origins. She cites data suggesting that neither relying on research participants’ self-report nor replacing racial categories with ethnic ones increases precision. “Race is real,” she argues, but not as “a measure of an individual.” Instead, race functions as “an interactive measure of a perception of an individual by another.” Thus, racial categories can be useful in studying whether the perceived race of patients correlates with health disparities. Beyond such research, however, there is “no clinical or scientific utility to racial and ethnic categories.”

Professor Raj Bhopal, M.D., M.P.H., of Edinburgh University defends the importance of racial and ethnic categories in epidemiology and public health. In “Race and Ethnicity: Responsible Use from Epidemiological and Public Health Perspectives” he begins by conceding that the concepts of race and ethnicity have long been abused. He argues, however, that they are essential to public health research and have potential for great good. Bhopal approaches these concepts with a historical eye to patterns of immigration into a multi-ethnic society. Non-white immigrants, in particular, may be marginalized and shoulder heavy health burdens. Epidemiological and public health research can identify health problems facing minority populations and suggest effective interventions. Abandoning racial and ethnic classifications would be a setback to public health efforts. However, existing classifications suffer from numerous weaknesses, including a lack of agreement on concepts and categories as well as continued racism and ethnocentrism. Bhopal urges improvement of racial and ethnic categories, recommending creation of an international glossary on ethnicity and race, the contextual use of racial and ethnic classifications, and using the healthiest population – rather than the white population – as the norm in studying particular public health problems. The overall goal should be “improving the health and well-being of minority groups and therefore the population as a whole.”

Professor Morris Foster, Ph.D., of the University of Oklahoma takes this debate into the field in “Analyzing the Use of Race and Ethnicity in Biomedical Research from a Local Community Perspective.” His article reports and analyzes an ethnographic study of health practices in three predominantly African-American

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she maintains, scientific racism continues to this day. Against this backdrop, the use of race in genetics, particularly haplotype mapping, threatens to revive “racialized ideas of biology” and a “reversion to biology to explain African-American inequality.” Brewer argues that resistance is crucial. African-Americans should resist being treated as “the other” and instead should assert that only they can define the experience of being African-American. The scientific community should address the relationship of race and genetics and train researchers in the meaning and history of race. Finally, the groups affected should be part of the dialogue.

Margaret Winker, M.D., Deputy Editor of JAMA, takes up the challenge of reexamining the use of race and ethnicity in research from the standpoint of a leading medical journal. In “Race and Ethnicity in Medical Research: Requirements Meet Reality” she notes that researchers routinely report their results by race or ethnicity, regardless of the relevance of these categories and their explanatory value. Further, the racial and ethnic classifications used are often inappropriate. Winker concedes that assessing race or ethnicity can be important. It can indicate whether the sample population is representative of a broader population, suggest whether randomization has succeeded, shed light on health disparities, and reveal drug response differences that invite more precise genetic analysis. However, researchers should explicitly address how they have assessed and analyzed race and ethnicity. Journals and editors have been among those issuing guidelines for over a decade in an effort to shift researcher practice. JAMA articulated policy in late 2004 and instituted changes in editing practice. Winker analyzes the effects of those changes and suggests further directions for improvement.

As journal editors have begun to consider what guidelines should govern the use of racial and ethnic categories in published research, legal scholars have started to analyze what legal limits should apply to researchers’ use of these categories. Professor Dorothy Roberts, J.D., of Northwestern University breaks new ground in medical research. In “The Use of Race and Ethnicity in Medical Research: Lessons from the African-American Heart Failure Trial” she begins with the focal dilemma: “using race as a biological category…can…reinforce racial stratifications as well as racist notions of inherent human differences. However...using race as a social category to study the impact of racism on health...is critical to eliminating health inequities.” Roberts then explores what law brings to this debate – how law encourages the use of racial and ethnic categories (for example, by mandating inclusion of certain categories of people in research and by having researchers use OMB Directive 15 race/ethnicity categories) and how law constrains that use (for example, through civil rights statutes and the Constitution’s Equal Protection Clause). Roberts proposes a normative framework to govern the application of law to biomedical research. Her “social justice approach holds that race is a socially constructed category without scientific basis that continues to produce health inequities, that these inequities require race-conscious legal remedies, and that biomedical research should be subject to legal regulation that promotes racial justice.” She spells out what this would mean in practice, what research would survive legal scrutiny and what research would not.

Professors Erik Lillquist, J.D., and Charles Sullivan, LL.B., LL.M., of Seton Hall Law School offer their own intriguing legal analysis in “Legal Regulations on the Use of Race in Medical Research.” They find no federal statutes directly governing the use of race and ethnicity in medical research. However, those laws that do protect against racial discrimination (specifically the Constitution’s Equal Protection Clause, Title VI of the Civil Rights Act of 1964, and 42 U.S. Code section 1981) may restrict the use of race in certain kinds of research. Lillquist and Sullivan find the use of race in clinical, genetic, and biomedical and biochemical research more problematic than in epidemiological studies. They argue that the recently completed clinical trial of BiDil, resulting in the FDA’s approval of the drug to treat African-Americans, is an especially problematic example of a clinical trial. “[R]ace-based clinical trials may lead to denial of potentially life-saving treatment to individuals on the basis of race.” The authors find this a violation of the Equal Protection Clause, Title VI, and section 1981. Like Roberts, they go on to consider what the law should bar. They argue that “law should be least restrictive of the use of race in epidemiological studies, and most restrictive in clinical trials.” Genetic research is an intermediate case, in which the government should refrain from funding research using race, but with some exceptions. Ultimately, they recommend that data on ancestry and social environment be collected directly, using race as a proxy only in certain cases. “We would bar both government authorization of race-based clinical trials and government funding of studies in which race is the variable of interest, except when a compelling interest can be identified...and researchers can show why they need to use race instead of using genetic markers.”

Finally, we focus on the BiDil controversy itself. Professor Jay Cohn, M.D., of the University of Minnesota defends the use of racial classifications in medical research. In “The Use of Race and Ethnicity in Medicine: Lessons from the African-American Heart Failure Trial” Cohn argues that there are “important differences in disease and therapeutic response among
populations defined by race.” Whether observed differences are genetically or environmentally determined, health care providers appropriately use knowledge of those differences in choosing what treatment to recommend. “We should be working toward better approaches in dealing with the differences, not raising legal and moral arguments...claiming that any effort at distinction is wrong.” To support this position, Cohn points to the results of the African-American Heart Failure Trial (A-HeFT), which found a “remarkably favorable and life-saving response to the drug BiDil” in a population self-identifying as African-American. Cohn defends the decision to conduct A-HeFT only in this population, on the basis of prior data showing differential response. He asserts that medical “[p]rogress requires that everyone accept the fact that subpopulations may and do differ in disease mechanism, prevalence, and therapeutic response.”

Professor Gregg Bloche, M.D., J.D., of Georgetown University takes a different view of the desirability of developing race-specific therapeutics, such as BiDil, in “Race, Money and Medicines.” He starts by advocating “[a]voidance of racial categories unless there is a good scientific reason for using them,” but he also urges that “we shouldn’t sacrifice lives or health merely to avoid classifying patients by race.” He finds the BiDil trial an acceptable departure from the presumption against using racial categories. The trial showed “stunning” therapeutic benefit among the African-American participants and conducting a larger multi-racial, multi-ethnic trial was not feasible for the start-up company providing funding. “Race-specific use meant extension of BiDil’s patent protection from 2007 to 2020, enabling the firm to raise funds...to support a trial in African-Americans only.” Yet Bloche urges that “[w]hen researchers use race...as a surrogate for poorly understood environmental or genetic factors, reporting of results should be accompanied by clear explanation.” Follow-up research to reveal the reasons for race-correlated differences is essential. Funding such research is a challenge, as pharmaceutical companies will have incentives to maintain established race-based markets. Bloche offers proposals for countering these incentives in order to fund needed research. “Use of racial categories should be understood as an interim step; follow-up inquiry...is important both to improve the efficacy of clinical care and to prevent race itself from being misunderstood as a biological determinant.”

This symposium advances the debate on the responsible use of racial and ethnic categories in biomedical research. This multidisciplinary group of authors, many of them already prominent participants in the debate, look across a range of research methodologies to query the utility, social impact, ethics, and legality of using these categories in research. These authors agree that historically racial and ethnic categories have been abused in science. They also largely agree that defining “race” and “ethnicity” and identifying appropriate racial and ethnic categories are problematic and challenging tasks. However, they disagree on what kinds of research warrant use of racial and ethnic categories and what safeguards should apply. Together, the articles in this symposium offer a rich set of substantive and procedural proposals for moving forward. These authors offer new tools for making progress in this critically important debate.

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