Symposium Articles

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Introduction: Facts and Fictions: BiDil and the Resurgence of Racial Medicine  
Gregory M. Dorr and David S. Jones

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Flaws in the U.S. Food and Drug Administration’s Rationale for Supporting the Development and Approval of BiDil as a Treatment for Heart Failure Only in Black Patients  
George T. H. Ellison, Jay S. Kaufman, Rosemary F. Head, Paul A. Martin, and Jonathan D. Kahn

The U.S. Food and Drug Administration’s (FDA) rationale for supporting the development and approval of BiDil (a combination of hydralazine hydrochloride and isosorbide dinitrate; H-I) for heart failure specifically in black patients was based on under-powered, post hoc subgroup analyses of two relatively old trials (V-HeFT I and II), which were further complicated by substantial covariate imbalances between racial groups. Indeed, the only statistically significant difference observed between black and white patients was found without any adjustment for potential confounders in samples that were unlikely to have been adequately randomized. Meanwhile, because the accepted baseline therapy for heart failure has substantially improved since these trials took place, their results cannot be combined with data from the more recent trial (A-HeFT) amongst black patients alone. There is therefore little scientific evidence to support the approval of BiDil only for use in black patients, and the FDA’s rationale fails to consider the ethical consequences of recognizing racial categories as valid markers of innate biological difference, and permitting the development of group-specific therapies that are subject to commercial incentives rather than scientific evidence or therapeutic imperatives. This paper reviews the limitations in the scientific evidence used to support the approval of BiDil only for use in black patients; calls for further analysis of the V-HeFT I and II data which might clarify whether responses to H-I vary by race; and evaluates the consequences of commercial incentives to develop racialized medicines. We recommend that the FDA revise the procedures they use to examine applications for race-based therapies to ensure that these are based on robust scientific claims and do not undermine the aims of the 1992 Revitalization Act.

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Fixed-Dose Isosorbide Dinitrate-Hydralazine: Race-Based Cardiovascular Medicine Benefit or Mirage?  
Keith C. Ferdinand

Race is not a scientific category, but African Americans have increased prevalence and severity of heart failure. The African American Heart Failure trial showed the benefit of a combination of isosorbide dinitrate (a nitric oxide donor) and hydralazine (an antioxidant). Future research may unmask the reason for cardiovascular differences in therapy.

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Genotyping the Future: Scientists’ Expectations about Race/Ethnicity after BiDil  
Richard Tutton, Andrew Smart, Paul A. Martin, Richard Ashcroft, and George T. H. Ellison

The ongoing debate about the FDA approval of BiDil in 2005 demonstrates how the first racially/ethnically licensed drug is entangled in both utopian and dystopian future visions about the continued saliency of race/ethnicity in science and medicine. Drawing on the sociology of expectations, this paper analyzes how scientists in the field of pharmacogenetics are constructing certain visions of the future with respect to the use of social categories of race/ethnicity and the impact of high-throughput genotyping technologies that promise to transform scientific practices.

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Revitalizing Difference in the HapMap: Race and Contemporary Human Genetic Variation Research  
Jennifer A. Hamilton

Through an examination of the International Haplotype Map (HapMap), this paper explores some of the ways in which relationships among categories of race and genetic variation are being reconfigured in contemporary genetic research.
478
“Special Treatment”: BiDil, Tuskegee, and the Logic of Race
Susan M. Reverby
BiDil, a drug approved in 2005 by the FDA only for African Americans, was seen by many as almost reparations for the horrors of the Tuskegee Syphilis Study (1932-72) where treatment for black men was denied. The logic of race, however, rather than racism, links BiDil to the past many thought it was escaping.

485
Popular Representations of Race: The News Coverage of BiDil
Timothy Caulfield and Simrat Harry
The BiDil story offers an ideal opportunity to explore the nature and tone of media representations of race and genetics. For example, was a biological view of race emphasized? Or was the notion of race presented in a critical fashion?

491
Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines
Osagie K. Obasogie
A resounding debate has ensued over the utility of race in biomedical research, particularly as new drugs claiming to serve particular racial populations attempt to enter the marketplace. This creates a number of challenges for the Food and Drug Administration over how best to regulate new drugs seeking race specific indications. This article suggests that it may be beneficial for the FDA to turn to an area with experience negotiating such dilemmas – Constitutional Law – and its approach – strict scrutiny – to help guide when and under what circumstances Government should give effect to racial categories in biomedicine.

498
Understanding Race at the Frontier of Pharmaceutical Regulation: An Analysis of the Racial Difference Debate at the ICH
Wen-Hua Kuo
Looking closely into how the differences among populations are debated at the ICH, this paper aims to provide a comprehensive account on what actually occurs when states with different cultural backgrounds encounter one another at the frontier of pharmaceutical regulation, where neither West nor East shall exist.

506
Imperialism, Race, and Therapeutics: The Legacy of Medicalizing the “Colonial Body”
Patricia Barton
The era of high colonialism in South Asia coincided with the period when eugenics came to dominate much of the scientific discourse in Europe and America. Such attitudes were naturally transplanted into the colonial world where medical researchers helped to establish a pathological “difference” between Europeans in India and the colonial “Other,” thus creating a medical discourse dominated by racial segregated treatment regimes. With the growth of trans-national transfer of scientific knowledge, this colonial “research” began to underpin racially constructed medical practices wherever they occurred.

517
Mustard Gas and American Race-Based Human Experimentation in World War II
Susan L. Smith
This essay examines the risks of racialized science as revealed in the American mustard gas experiments of World War II. In a climate of contested beliefs over the existence and meanings of racial differences, medical researchers examined the bodies of Japanese American, African American, and Puerto Rican soldiers for evidence of how they differed from whites.

522
Nadav Davidovitch and Avital Margalit
In this essay, we analyze the case study of mass ringworm irradiation conducted in Israel during its first years of existence and its consequences. We analyzed the case study of ringworm irradiation in the framework of racial construction of illness and its treatment, showing the elasticity of race and ethnicity as medical and social categories.

530
Pharmaceutical Meaning-Making Beyond Marketing: Racialized Subjects of Generic Thiazide
Anne Pollock
In contrast to discussions of BiDil, this paper explores racial meaning-making processes around an old generic hypertension drug. By unpacking a vignette about race and thiazide outside marketing or medicine, it shows that racialization of drugs exceeds those spheres and moves in unpredictable ways.
Is Race-Based Medicine Good for Us?: African American Approaches to Race, Biomedicine, and Equality
Dorothy E. Roberts

This article presents a preliminary framework for exploring the intersection of science and racial politics in the public debate about race-based pharmaceuticals, especially among African Americans. It examines the influence of three political approaches to race consciousness on evaluations of racial medicine and offers an alternative critique.

Independent Articles

Human Subjects Protections in Biomedical Enhancement Research: Assessing Risk and Benefit and Obtaining Informed Consent
Maxwell J. Mehlman and Jessica W. Berg

The protection of human subjects in biomedical research relies on two principal mechanisms: assessing and comparing the risks and potential benefits of proposed research, and obtaining potential subjects' informed consent. While these have been discussed extensively in the literature, no attention has been paid to whether the processes should be different when the objective of an experimental biomedical intervention is to improve individual appearance, performance, or capability ("enhancement research") rather than to prevent, cure, or mitigate disease ("health-oriented research"). This essay examines this question in order to ensure that subjects in biomedical enhancement research receive adequate protection.

Research on Medical Records Without Informed Consent
Franklin G. Miller

Observational research involving access to personally identifiable data in medical records has often been conducted without informed consent, owing to practical barriers to soliciting consent and concerns about selection bias. Nevertheless, medical records research without informed consent appears to conflict with basic ethical norms relating to clinical research and personal privacy. This article analyzes the scope of these norms and provides an ethical justification for research using personally identifiable medical information without consent.

Rethinking Risk in Pediatric Research
Kathleen Cranley Glass and Ariella Binik

This article reviews four areas of pediatric research in which we have identified questionable levels of allowable risk, exceeding those foreseen by the Commission. They are the following: (1) the categorization of increasingly risky interventions as minimal risk in a variety of protocols; (2) the increasing number of applications for federal panel review of research not otherwise approvable because of higher projected risk levels; (3) research on asymptomatic at risk children; and (4) the inclusion of children and adolescents in placebo-controlled trials for participants of all ages without performing subgroup analysis. While embracing the imperative to include children in research is an encouraging step towards providing the pediatric population with effective medical care and finally eradicating the therapeutic orphan, we must ensure that this research does not become overly permissive.

Preventing HIV Transmission via HIV Exposure Laws: Applying Logic and Mathematical Modeling to Compare Statutory Approaches to Penalizing Undisclosed Exposure to HIV
Carol L. Galletly and Steven D. Pinkerton

Twenty-four U.S. states have enacted HIV exposure laws that prohibit HIV-positive persons from engaging in sexual activities with partners to whom they have not disclosed their HIV status. There is little standardization among existing HIV exposure laws, which vary substantially with respect to the sexual activities that are prohibited without prior serostatus disclosure. Logical analysis and mathematical modeling were used to explore the HIV prevention effectiveness of two types of HIV exposure laws: "strict" laws that require HIV-positive persons to disclose their serostatus to prospective partners prior to any sexual activity and "flexible" laws that require seropositive status disclosure only prior to high-risk sex (e.g., unprotected anal or vaginal intercourse). These laws were compared relative to each other and to a no-law alternative. The results of these analyses indicate that, under most (though not necessarily all) circumstances, both strict and flexible exposure laws can be expected to reduce HIV transmission risk relative to the no-law alternative, with flexible exposure laws producing the greater reduction in risk. This study demonstrates how logical analysis and mathematical modeling techniques can make an important contribution to the construction of a rational basis for decisions about a highly contested public health policy issue.
Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of JLME.

Next Issue:

National Health Care Reform
A Symposium
Guest Edited by Sara Rosenbaum and Jeanne Lambrew

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