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Special Section: Open Forum

Race-Based Medicine and Justice as Recognition: Exploring the Phenomenon of BiDil

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Introduction

In the United States, health disparities have been framed by categories of race. Racial health disparities have been documented for cardiovascular disease, cancer, diabetes, HIV/AIDS, and numerous other diseases and measures of health status.[1] Although such disparities can be read as symptoms of disparities in healthcare access,[2] pervasive social and economic inequities, and discrimination,[3] some have suggested that the disparities might be due, at least in part, to biological differences based on race.[4] Or, to be more precise, if race itself has no determined biological meaning, race may nonetheless be a proxy that collects a group of individuals who share certain physiological or genotypic features that affect health.[5] Thus, self-identified race might serve as a rough guide for what sort of treatment will best work for an individual. This disagreement over the meaning of race and its place in medical science has been widely analyzed,[6] but with little settled policy guidance for clinical or research practice.

Yet if we look to recent developments in the pharmaceutical industry, particularly the 2005 Food and Drug Administration (FDA) approval of BiDil as a heart failure drug for African Americans, it appears that the model of racial biological difference has carried the day. BiDil was the FDA's first approval of a racially targeted drug. Approval was granted after a clinical study with an African American cohort showed significantly reduced risk of mortality, increased time to first hospitalization for heart failure, and improved quality of life.[7] In combination with a growing consensus on the importance of population differences in the distribution of genetic variants that control drug metabolism[8] and fears regarding the failure of the blockbuster drug model,[9] the pharmaceutical industry appears to be looking increasingly at drug development and marketing that is racially targeted.[10]

BiDil's approval has been widely critiqued in academic circles on numerous grounds. Nevertheless, many advocates for African American health concerns have argued that BiDil is an important step toward reducing disparities in healthcare by creating medical therapies that are responsive to African American needs.[11] Many of these advocates also publicly rejected the notion that BiDil is a *race-specific* drug, arguing that social race is a poor surrogate for the biological differences that underlie BiDil's efficacy.[12] Thus, competing commitments to reducing health disparities while rejecting a biologically deterministic view of race have placed African American community leaders and health advocates in

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a state of conflict, both among themselves and with academic scholars of race, with respect to the desirability of BiDil.[13]

In this paper, we offer a sympathetic reading of this response to BiDil by some African American community leaders and aim to show how many of the academic critiques have failed to adequately account for the competing commitments of community stakeholders. We argue that justice involves not only the fair distribution of benefits but also an element of recognition, such that socially marginalized groups have the opportunity to be heard and to participate in decisionmaking. In the case of BiDil, we believe that African American community leaders capitalized on an opportunity to bring attention to African American health issues, even as they risked complicity with an inaccurate portrayal of race as biological. Using Nancy Fraser's bivalent theory of justice (involving both recognition and redistribution),[14] we argue that community leaders can be viewed as strategically affirming the use of race in hopes of ultimately transforming the process of drug development and garnering more careful attention to the problem of health disparities. Given the context of health disparities and statements made by community advocates that explicitly link BiDil to remedying such disparities, we believe this strategy is best understood not simply as a calculated risk assumed for the sake of some consequentialist benefit but rather as a means of asserting a demand for justice.

To make this argument, we first offer a short history of BiDil's approval and the resulting academic criticisms. By showing how these criticisms fail to acknowledge stakeholder perspectives (even as they are convincing in other respects), we move to a Fraserian analysis of the African American community response. This response shows that the process of achieving recognition sometimes requires strategically affirming racial labels in the short term. As such, seeking recognition can allow for questionable, even potentially dangerous, partnerships in the name of promoting future justice.

The Troubled History of BiDil

In the early 1980s, studies showed that the combination of hydralazine and isosorbide dinitrate (H/I), the two drugs that would subsequently be marketed as BiDil, reduced mortality due to heart failure.[15] By the late 1980s, enalapril, an angiotensin converting enzyme inhibitor (ACE-inhibitor), became standard therapy for heart failure.[16] Although H/I remained a viable alternative therapy, efforts to gain approval for H/I as a supplemental therapy were not successful. In the early 1990s, evidence began to suggest that ACE-inhibitors may be less effective in people of African descent.[17] These findings led H/I investigators to reanalyze their data by racial subgroups,[18] and ultimately to sponsor a clinical trial limited to self-identified African Americans.[19] In this second trial, patients received standard therapy or standard therapy plus H/I. With compelling data showing significant improvement with H/I, the investigators sought FDA approval for "BiDil" with racially targeted labeling. This request was approved in 2005,[20] extending owner Nitromed's patent on H/I therapy by 13 years.

A wide variety of African American community leaders and health advocates enthusiastically supported the approval of BiDil on the grounds that the drug would directly improve the health and quality of life of African Americans suffering from congestive heart failure and hence serve as an important vehicle

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for justice in healthcare. Some claimed that BiDil had begun to break the cycle of health disparities by showing responsiveness to the healthcare needs of African Americans and garnering trust in that community.[21] All were aware of the potentially politically charged nature of the approval but held different takes on its significance. One representative at the FDA advisory hearing argued that "the study's results should not be obscured by invalid ethical concerns of perceived political objections."[22] Another voiced clear opposition to scientific and academic criticisms.[23] Yet many of the African American leaders qualified their endorsement, noting that although BiDil should be approved, doing so should not support what one representative called an "absolute or implied correlation between social race, genetic type and the efficacy of BiDil. I support BiDil because it will extend the life of many Americans with heart failure. I support it because it will improve the quality of life of these patients."[24]

Academic critiques, in contrast, warned that the BiDil approval process might increase healthcare inequities for African Americans. These critiques fell into two general categories: (1) concern that the pharmaceutical industry has exploited the African American community and its interest in health disparities for corporate profit and (2) concern that BiDil reifies the biological category of race and sets a problematic precedent for future drug development.

Many critics worried that the African American community, already vulnerable in the face of existing health disparities, was exploited by Nitromed for the sake of corporate profit.[25] Critics argued that the clinical trial that led to approval of BiDil for African Americans was enabled by a form of "statistical mischief"[26] that overestimated racial heart failure disparities yet never considered BiDil's effectiveness in other racial or ethnic populations. The resultant race-specific labeling extended patent protection even as BiDil's discoverer recommended treating heart failure patients with BiDil regardless of race.[27] Thus, to the extent that such off-label prescribing becomes widespread, the relative health benefits to the African American community may be small compared to the profit gained by NitroMed.

The charge of exploitation was further bolstered by the specifics of the pricing regimen adopted by NitroMed in the wake of the FDA approval: When taken independently, equivalent generic versions of hydralazine (H) and isosorbide dinitrate (I) would cost $1.50–$3.00 per day, whereas H/I combined into BiDil was priced at $5.40–$10.80 per day.[28] Such pricing may place BiDil beyond the means of those most at risk of heart failure in the African American community.[29] Critics have noted that the pricing policy is thus at odds with the apparent objective to reduce health disparities that motivated the drug's development.

This class of critique, while compelling, does not wholly account for the fact that community advocates played a significant role in securing BiDil's FDA approval. Some critics have suggested that the support of key African American advocates was "bought" by drawing attention to NitroMed's financial support of several organizations that testified during the FDA approval process (especially the NAACP and the NMHMF).[30] In other cases, the emphasis on statistical mischief appears to imply that the African American community may have lacked the scientific savvy to appropriately judge the evidentiary relevance of a race-specific clinical trial. However, these analyses miss the possibility that community leaders came to support BiDil strategically, willing to risk potential exploitation for the sake of gaining greater public awareness of the problem of African American health and healthcare disparities.

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A second, related concern voiced by critics was that BiDil's race-specific label promotes an unwarranted biological understanding of race and sets a problematic precedent for future drug development. Although scientists involved in BiDil's development agree that self-identified race is, at best, a rough proxy measure for other factors that affect the treatment of heart failure, critics worry that scientists presume those other factors to be individual genetic or physiological features. The concern is that scientists will increasingly pursue biological explanations of racial difference rather than social and cultural explanations.[31] Further, when medical studies and FDA labeling make use of racial categories without careful attention and explicit qualifications about their nature, drug development and treatment decisions will be based increasingly on racial identity.[32] In these ways, BiDil may contribute to a growing infrastructure of racialization.[33]

We find the criticisms about precedent setting and reification of race as a biological category troubling and important to keep in mind. Yet, community advocates took great pains to deny the biological salience of race while supporting BiDil. If, as critics suggest, healthcare justice is not achieved by the adoption of the sort of racially targeted drug development epitomized by BiDil, then why has this model been embraced by key thought leaders and advocates in the African American community? To more fully explore this apparent contradiction, we draw on the bivalent justice theory of philosopher Nancy Fraser.

Fraserian Justice: Redistribution, Recognition, and the Transformation of Race

Philosophical theories of justice tend to focus on the fair distribution of benefits and burdens among members of society. Though such members are understood to occupy different social positions and to hold varying amounts of the goods to be (re)distributed (e.g., resources, income, wealth), the former is often assumed to be a consequence of the latter. Doing justice, then, may be reduced to ensuring some baseline or proportionate share of societal opportunities and goods. Yet sometimes marginalized social positions result not from a lack of material goods, but rather (or also) from a history of oppression that misconstrues the meaning and significance of difference. Furthermore, distributive justice paradigms that emphasize allocation schemes may fail to attend to how institutional structures that provide the background for distribution may themselves need to be analyzed through the lens of justice.

Philosopher Nancy Fraser has articulated a growing consensus that justice requires not only the fair (re)distribution of benefits and burdens but also *recognition*, a form of mutual respect that identifies and addresses the dynamics of power that reinforce differences in social status among individuals and groups.[34] Justice as recognition involves the acknowledgment of difference, respectful engagement with nondominant views, and full participation for all in the design and functioning of social institutions and practices. Thus, to treat people fairly, one ought to take account of the impact of social discrimination (misrecognition) that results from institutionalized patterns of cultural value that regard some people as inferior or invisible and others as superior.

One key challenge to more standard theories of distributive justice is that in emphasizing common needs (in seeing difference as an "unjust differential" (p. 15)),[15] they tend to minimize or reduce identity differences that matter to those suffering from injustice, often those most vulnerable and situated at the margins. Fraser

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refers to this as the "dedifferentiating" quality of redistribution. On the other hand, strategies solely formulated from a recognition-based understanding of justice tend to assume that group differences are benign and given, but have been "maliciously transformed into a value hierarchy."[35] Recognition theorists argue that "a difference-blind politics of redistribution can reinforce injustice by falsely universalizing dominant group norms, requiring subordinate groups to assimilate to them, and misrecognizing the latter's distinctiveness."[36]

In an attempt to reconcile this tension, Fraser proposes that distribution and recognition are meaningful only in the context of participation in social life and that justice can only be achieved in a society where individuals and groups are able to interact as full partners or, in her words, have "parity of participation."[37] The project of justice is thus not only to (re)distribute the material goods of society but also to dismantle institutionalized cultural value patterns that prevent participatory parity and replace them with cultural value patterns that support participatory parity. Gaining participatory parity may well require significant redistribution of goods, enough to provide the material support necessary to ensure independence and voice.[38] But to make the case for this redistribution, groups that have been unfairly marginalized must be included in social policy discussions. Recognition is required for fair redistribution, and redistribution helps to promote recognition through providing the means of securing participatory parity.[39]

Fraser suggests that remedies for injustice can be evaluated along an axis of affirmative and transformative strategies. "Affirmative strategies" attempt to remedy injustice within existing social and political structures (e.g., mainstream multiculturalism and the celebration of racial differences) and, in contrast to transformative strategies, do not attempt to change the underlying structures that cause injustice (e.g., the social construction of racial categories). From this perspective, affirmative strategies, in response to misrecognition, tend to reify collective identities, resulting in stereotypes and a backlash of misrecognition where the disadvantaged are marked as inferior and needy.[40] In contrast, "transformative approaches" may be regarded as "dereifying" in that they deconstruct identity categories (e.g., race) and, when applied to maldistribution, promote solidarity by seeking entitlements on a common basis for all. Yet, because transformative approaches are far from the realities of people's experiences of maldistribution and misrecognition, they are impractical for most. Faced with these options, Fraser turns to a mode of covert strategies she calls "non-reformist reform." These are strategies with "a double face: on the one hand, they engage people's identities and satisfy some of the needs [for recognizing group differences]; . . . on the other hand, they set in motion a trajectory of change in which more radical reforms become practical over time."[41]

Race and the problem of racism lend themselves to such an expanded consideration of justice.[42] The focus on the individual as the unit by which a fair distribution of goods (in the case of healthcare justice, health and well-being) should be achieved is often criticized as an inadequate paradigm for achieving the goals of justice in the face of institutional and systemic racism.[43] In the case of racism, maldistribution refers to society's economic structures that generate economic disparities such as unemployment and poverty along racial lines. Misrecognition refers to historical dominance of Euro-American-centric cultural values that privilege the symbolic value of whiteness and that result in the

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subordinate social status of people who are not "white." Furthermore, this dual nature of racism requires that both efforts to reapportion resources (redistribution) and recognize different cultural value patterns (recognition) be used to combat racism and its pernicious effects. The hope is that by utilizing recognition and redistribution, one may avoid remedies that are paternalistic or require social, political, or cultural homogeneity.

Given this dualistic perspective on racial injustice, the challenge is how to evaluate and choose among possible remedies. Fraser suggests that we should evaluate claims of injustice and possible remedies following a norm of fair participation. In other words, a claim of injustice should articulate how a maldistribution and/or misrecognition has hindered participation and remedies should be evaluated for their ability to improve participatory parity. We follow Fraser's lead here because the legacy of racism seems unlikely to be sufficiently addressed through redistributive means alone and because our concerns over the constitution of racial groups recommend a certain distancing from more traditional identity politics.

A Fraserian Reading of BiDil

Returning to the case of race-targeted medicine, how does an understanding of justice grounded in recognition as participatory parity inform our view of BiDil and the competing commitments to reducing health disparities and rejecting a biologically deterministic view of race that confront African American community leaders and community members?

Support for BiDil invoked claims of misrecognition in that African Americans bear the burden of health disparities and yet have not historically been fully included in research. African Americans clearly have a strong case of misrecognition to be made in terms of their treatment by and participation in the U.S. healthcare system. *Unequal Treatment* and the other reports on racial disparities in health and healthcare show unequivocally that African Americans have been stereotyped, offered inferior treatment, and treated with a lack of respect (historically, through abuses such as the Tuskegee syphilis study,[44] as well as in the present, through more insidious forms of institutionalized racism). This misrecognition has led to a distrust of biomedical research and the healthcare system that has contributed to low levels of African American involvement in clinical trials and a lack of efficacious treatment options.[45] The injustice of unequal participation in research was raised by African American organizations in the public commentary during the FDA advisory review of BiDil as a justification both for BiDil's approval as well as the strategy of developing and marketing race-targeted medicine.

BiDil can be understood as a first step toward remedying the above claims of misrecognition through an affirmative strategy. BiDil is a drug that attempts to reduce the healthcare disparity in efficacious drugs for heart failure by recognizing the particular health needs of African Americans. Using the standard of participatory parity, it is conceivable that improving health of African Americans through such recognition will allow African Americans to participate more fully in social interaction.

If African American health needs are recognized as significant by pharmaceutical companies like NitroMed, then the hope is that related partnerships may

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form to facilitate research that addresses pressing health concerns in the African American community. In this way, by endorsing BiDil, African American community leaders can be seen as positioning themselves to carry out a Fraserian nonreformist reform strategy. They appear to endorse differentiating racialized categories in a way that reifies the existence of biological race categories, but solely in the name of capitalizing on NitroMed's interest in health disparities and with the clear insistence that the difference they acknowledge is *social* not biological. By developing partnerships, they aim to transform the targets of research (toward health issues of community interest) as well as the way research is done (by emphasizing community collaborations). Although such a move is a gamble in that it risks reifying racial categories in medicine, it may help improve parity of participation and ultimately reduce racial health disparities if done carefully, with clear and consistent qualifications about the meaning of race.

Of course, we acknowledge that the participatory benefits of reducing congestive heart failure among African Americans and initiating African American community partnerships with the pharmaceutical industry may be offset by new forms of maldistribution. In short, dollars spent on BiDil take away resources for other healthcare or civic priorities that promote participation in social life, and unnecessarily so, given the existence of generic equivalents. Such concerns may be somewhat allayed by evidence that many hospital formularies are not responding positively to BiDil but rely instead on generics. Nonetheless, NitroMed's targeted outreach campaign and the inclusion of BiDil in some Medicare plans suggest that this problem still looms.[46]

More importantly, even if BiDil can be made affordable, its success and that of other race-targeted drugs may shift material resources away from research on other causes of health disparities. Indeed many of the clinical researchers involved with BiDil are now conducting other African American-specific clinical drug trials in partnerships with the pharmaceutical industry.[47] Such research may aim to meet the needs of the African American community regardless of the mechanism of the benefit, or perhaps it rests on a promise of personalized medicine that ideally would render racialized categories obsolete. But such partnerships do, at least in the near term, take society's focus off the social and environmental causes of health disparities.

At a symbolic level, BiDil potentially does serve as a positive signal that society values African American health to the point of marketing drugs specifically for their use. Given African American leaders' explicit refusal to understand race as biologically determined, we imagine that their partnerships, if developed fully and implemented justly (at the earliest stages of drug development and problem identification), may serve to transform the use of race in medical research. Indeed, they may move us toward a future of race-targeted medicines that use race as a proxy for either individual *or* social and environmental factors that will ultimately serve to deconstruct race. Though race is not biologically meaningful, there is reason to believe that some degree of racial targeting of drugs could be acceptable[48] because of the potential to accrue benefits, the lack of alternative therapies, the symbolic significance of gaining attention to address health inequalities, and the promise that medicine will eventually move beyond race.

Determining what constitutes adequate participation in drug research and development is also needed. In the BiDil case, it appears that the decision to pursue the development of a race-targeted drug occurred prior to the involvement of

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African American clinicians and community leaders.[49] Given the current consensus against labeling BiDil a drug for African Americans and rejection of a race-based interpretation of BiDil's efficacy, earlier community participation would have likely resulted in a very different story. Furthermore, thousands of other African American and other racial and ethnic minority organizations working to improve the health of their constituents were not solicited nor heard. Additional voices may have clarified the political significance of BiDil for the African American community or at least highlighted the tensions within the community raised by BiDil.

Finally, who is responsible for ensuring participation? In the context of genetics research in Native American communities and health justice, the authors of a model of ''responsive justice'' draw upon Fraser to argue that distributive justice is insufficient for achieving health justice and that justice requires those with power to recognize and share power with those who constitute the marginalized and disenfranchised minority.[50] They argue that Fraser's model of justice requires a further dimension of responsibility (in addition to distribution and recognition) to ensure that those with greater power, in their case scientists, conduct research in partnership with marginalized communities. Translating this element of responsibility to the case at hand might require not only NitroMed and the FDA but also academics to ensure community participation beyond that of mere representation in deliberations over BiDil, race-targeted drugs, justice, and health disparities.

Our analysis leaves us somewhat ambivalent about the transformative potential of the partnerships built in the unfolding of BiDil. We take seriously the concern that using race in this way risks rebiologizing the concept of race, but also recognize the desire of some in the African American community to take that risk, not just as a calculation of likely overall benefit, but rather as a step toward achieving justice. Although we doubt that more race-targeted drugs, in themselves, will eliminate the pervasive, structurally determined, racial health inequities that plague the United States, we hope that the partnerships begun in the context of BiDil may be further developed and used to effectively transform drug development practices. The truly transformative move would be away from drugs targeted to racial groups and toward drugs developed to address the needs of marginalized communities, whatever their racial category.

Conclusion

This Fraserian reading of BiDil begins to explain why some who denounce biological race support BiDil. BiDil might help some people survive heart failure but, given the availability of cheaper generics, ''off-label'' prescribing for other racial groups, and the relatively small disparities involved, its impact on population-based health outcomes will likely be marginal. More importantly, BiDil recognizes African Americans as a social group that has suffered from unjust research practices and continues to feel the effects of health disparities. This recognition and its reliance on racial distinctiveness are meaningful because dominant cultural value patterns ignore qualities that are important for ensuring social recognition and interaction. In the current moment, African Americans may have little choice but to draw on race as the dominant mode of framing health. Rather than framing BiDil as an either-or choice between the potential

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medical benefits of race-targeted drugs and social harms of reifying a biological notion of race, some African Americans have strategically claimed this racially based recognition in the name of transforming future health disparities research.

Notes

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34. See note 14, Fraser, Honneth 2003:3. Fraser refers to this dualistic formulation of justice as a "perspectival dualist" understanding. Charles Taylor, Iris Marion Young, and Axel Honneth have articulated similar concepts of recognition.
35. See note 14, Fraser, Honneth 2003:15.
36. See note 14, Fraser, Honneth 2003:15.
37. See note 14, Fraser, Honneth 2003:15.
38. See note 14, Fraser, Honneth 2003:36.
39. For more on this iterative process, which Fraser argues involves some circularity but not vicious circularity, see note 14, Fraser, Honneth 2003:44.
40. See note 14, Fraser, Honneth 2003:76.
41. See note 14, Fraser, Honneth 2003:93.
42. See note 14, Fraser, Honneth 2003:22–3.
43. See McGary H. *Race and Social Justice*. Malden, MA: Blackwell; 1999.
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48. Not "targeted" in the sense that a drug is developed with the expectation that it will only work in a single racial group, but rather that drug design would prioritize the defined therapeutic needs of specific, underserved, racial identities.
49. See note 30, Saul 2005. In an interview with the *New York Times*, Waine Kong, executive director of the Association of Black Cardiologists, stated that the drug company was "aware of the political fallout if they did not have African American participation."
50. Goering S, Holland S, Fryer-Edwards K. Transforming genetic research practices with marginalized communities: A case for responsive justice. *Hastings Center Report* 2008;38(2):43–53.

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