

Misreading race and genomics after BiDil

To the editor:

On June 16, a Food and Drug Administration (FDA) advisory committee will decide whether to approve a drug to treat heart failure in African Americans, and only African Americans. This race-specific drug is called BiDil. BiDil is not a new drug. It is merely a combination into a single pill of two existing generic drugs that have been used to treat heart failure irrespective of race for more than a decade.

BiDil is noteworthy because it may become the first race-specific drug ever approved by the FDA. The good news is that BiDil does seem to help many people suffering from heart failure, a debilitating and ultimately fatal disease afflicting several million Americans. Less fortunate is the way race has been exploited to bring this drug to market.

The FDA approval of BiDil for only African Americans would give the federal government's stamp of approval to using race, in effect, as a genetic category. But race is not genetic, as even the BiDil researchers admit. Once we sanction such talk, it is a short step to talking about races as inferior and superior. Given our nation's troubled history of racial oppression, this should not be taken lightly.

In fact, the data from the clinical trial of BiDil (called A-HeFT, for African American Heart Failure Trial) says nothing about whether BiDil works differently or better in African Americans than anyone else. This is because A-HeFT enrolled only "self-identified" African Americans; there was no comparison population^{1,2}.

Why then did NitroMed, the corporate sponsor of the A-HeFT trials and holder to the rights to BiDil, seek race-specific approval for its drug? Perhaps the answer lies not in medicine but in commerce. NitroMed holds a patent for a non-race-specific use of BiDil, which expires in 2007; it also holds a race-specific patent that lasts until 2020. This extra 13 years of patent protection may present a compelling commercial reason for seeking to cast BiDil as a racial drug, even though to do so is not supported by the medical evidence³.

The dynamic relation between markets and the skewed interpretation of clinical trial data has recently moved beyond BiDil to support larger claims about the legitimacy of developing race-specific drugs, including misrepresentation of results published in this journal⁴ (Box 1). Garbled reports of these results were almost invariably paired with a discussion of the nearly contemporaneous formal announcement of the A-HeFT results for BiDil. The linking of BiDil to the "29 medicines" is not accidental. They are paired to give the impression that there is some 'real' difference underlying racial response to these drugs.

In fact, of the 29 medicines identified, Tate and Goldstein considered only 4 to provide evidence of a genetic cause for the differential drug response and only an additional 9 to provide evidence that "the association has a reasonable underlying physiological basis." For the remaining 16 medicines, Tate and Goldstein found either no demonstration of a physiological basis to any observed difference or possibly false positive claims. Moreover, of the 13 medicines with some supporting evidence of racial difference, three were ACE inhibitors, whose claims of racial difference have been hotly contested in the professional literature⁴, and one was BiDil⁴. All 13 dealt with hypertension, and the International Society on Hypertension in Blacks has issued guidelines arguing against race-specific treatment of hypertension⁵.

One might dismiss the distortion of the paper by Tate and Goldstein as mere sloppy journalism. But the use, or misuse, of the "29 medicines" statistic has been embraced in more expert and often more conservative circles. Prominent here are John Entine and Sally Satel, both fellows at the American Enterprise Institute. Both have gained a good deal of notoriety for their popular works of race and genetics: Entine for his book *Taboo: Why Black Athletes Dominate Sports and Why We are Afraid to Talk About It*⁶, and Satel for, among other writings, a prominent article titled "I am a racially profiling doctor"⁷. Not only do Entine and Satel omit any reference

to Tate and Goldstein's qualifying analysis, but they also extend the purported connection between race and drug response into the realm of genetics. BiDil provides the starting point for this move toward identifying race with genetic difference, a difference that the A-HeFT investigators themselves do not make.

This marks a critical moment of reification of race as genetic⁸. By connecting BiDil to the manipulated "29 medicines" statistic, Satel and Entine cast BiDil as the poster drug for the future of addressing racial difference in medicine. Entine's and Satel's message is that race and genetics correlate closely enough to provide the basis not only for general medical practice but also for addressing specific health disparities; remember that these discussions are also indirectly being framed by the misleading assumption that A-HeFT proved that BiDil worked differently in African-Americans. The related message is that the correlation also provides the basis for market-driven pharmaceutical development to produce new drugs such as BiDil to address these differences.

This is where reification in the context of medical practice intersects with broader strategies regarding commerce and the politics of difference. At work here is an appropriation of race as reified in the BiDil story to serve larger political agendas aimed at transmuting health disparities, rooted in social and economic inequality, into mere health differences, rooted in biology and genetics. Attempts to address social disparity generally implicate the power of the state or other nonmarket institutions consciously to intervene both in the allocation of resources and the sanctioning of racist practices. In contrast, attempts to address genetic difference may be located at the level of the molecule and targeted by pharmaceuticals developed and dispensed through the purportedly impersonal forces of the market. Implicit in the logic of conservatives such as Satel and Entine, who use BiDil to characterize disparate health outcomes in terms of genetics, is an argument for privatizing efforts to address what are currently characterized as health disparities.

The story of BiDil raises concerns over the dangers of reifying race in a manner that could lead to new forms of discrimination. BiDil, however, is part of a much larger dynamic of reification in which the purported reality of race as genetic is used to obscure the social reality of racism. For all the legitimate concerns that the genomics revolution might lead to new forms of discrimination, we must also be alert to the potential appropriation of genetics to obscure or justify existing inequalities.

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BOX 1 HOW BLACK BECOMES WHITE AS THE MEDIA 'SIMPLIFY' RESEARCH.

Misquotation of a *Nature Genetics* Perspective, with emphasis (in bold) added.

*Nature Genetics*⁴

"29 medicines (or combinations of medicines) have been **claimed**, in peer-reviewed scientific or medical journals, to have differences in either safety or, more commonly, efficacy among racial or ethnic groups. But these claims are universally controversial, and there is **no consensus** on how important race or ethnicity is in determining drug response."

*Los Angeles Times*⁹

"[A] report in the journal *Nature Genetics* last month [that] listed 29 drugs that are **known** to have different efficacies in the two races."

*Times of London*¹⁰

"[O]nly last week, *Nature Genetics* revealed research from University College London **showing** that 29 medicines have safety or efficacy profiles that vary between ethnic or racial groups."

*New York Times*¹¹

"By one count, some 29 medicines **show evidence** of being safer or more effective in one racial group or another, suggesting that more targeted medicines may be coming."

*USA Today*¹²

"At least 29 drugs are known to work differently in blacks than in whites, according to a recent report in *Nature Genetics*. Blood pressure medicines that are standard for whites have decreased responsiveness in blacks. The FDA requires that information to be included in drug labeling."

John Entine (http://www.aei.org/include/event_print.asp?eventID=937)

"Only last month, the prestigious journal *Nature Genetics* reported that at least 29 medicines have so far been identified that are either safer or more effective in certain populations because of **genetic differences** between those population groups."

Sally Satel

"[G]enerally, when we're talking about BiDil and things like that, its skin color as a marker for genetic heritage." (http://www.aei.org/include/event_print.asp?eventID=937)

"Last month, the prestigious journal *Nature Genetics* reported that at least 29 medicines have been shown to be either safer or more effective in certain populations because of genetic differences."¹³