

"reforms in the 1970s to counter researchers' excessive reliance on 'vulnerable populations' such as women and prisoners" (Hartigan 2013, 9–10). One notorious example was African Americans' past participation in the Tuskegee Study of Untreated Syphilis in the Negro Male, conducted between 1932 and 1972. According to the website for the Centers for Disease Control and Prevention (<http://www.cdc.gov/tuskegee/timeline.htm>), a review panel set up in 1972 found that participants in this study

had agreed freely to be examined and treated. However, there was no evidence that researchers had informed them of the study or its real purpose. In fact, the men had been misled and had not been given all the facts required to provide informed consent.

The men were never given adequate treatment for their disease. Even when penicillin became the drug of choice for syphilis in 1947, researchers did not offer it to the subjects. The advisory panel found nothing to show that subjects were ever given the choice of quitting the study, even when this new, highly effective treatment became widely used.

All these matters come together in the contentious and much-analyzed example of BiDil, a medication designed to treat African Americans suffering from heart disease. On its website (which has since been taken down), NitroMed, the original manufacturer of BiDil, described this drug as "a fixed-dose combination medicine consisting of isosorbide dinitrate and hydralazine hydrochloride. It is approved by the FDA for the treatment of heart failure in self-identified African American patients when added to standard heart failure medicines" (<http://www.bidil.com/pnt/questions.php#1>). FDA approval, the site reported, was based on the results of the African-American Heart Failure Trial (or A-HeFT), which "studied 10,050 self-identified African American patients with heart failure: It is the largest number of African American patients ever studied in a major heart failure trial. . . . A-HeFT was started on May 29, 2001, and the study was halted early in July 2004 due to a significant survival benefit seen with BiDil as compared to standard therapy alone" (<http://www.bidil.com/pnt/questions.php#2>).

The original BiDil website also listed a series of "common questions" people ask about BiDil, including the following: "What about claims that BiDil is a 'race drug'?" The site's answer included the following excerpt from a 2007 article by the FDA doctors who approved the drug:

Only African American patients were studied in A-HeFT, so the FDA approval for BiDil is for "self-identified African American patients with heart failure" only. There is insufficient clinical trial data to draw any conclusions about the effects of BiDil in other populations. . . .

Not understanding the reasons for the difference in treatment effect by race did not justify withholding the treatment from those who could benefit from it. . . . Race or ethnicity is clearly a highly imperfect description of the genomic and other physiological characteristics that cause people to differ, but it can be a useful proxy for those characteristics until the pathophysiological bases for observed racial differences are better understood. (<http://www.bidil.com/pnt/questions.php#9>)

As these excerpts show, neither NitroMed nor the FDA endorsed nineteenth-century American racial categories. They emphasized that the drug trial showing the effectiveness of BiDil involved only "self-identified" African American subjects, which the FDA agrees is a "highly imperfect" but "useful proxy" for whatever factors are responsible for the observed "racial differences." However, BiDil quickly became the center of a controversy that ended in commercial failure for NitroMed in 2008. In 2011 BiDil was purchased by Arbor Pharmaceuticals, which was still marketing the drug in March 2014 (<http://bidil.com/coupon/>).

Ann Pollock, who provides a detailed analysis of the BiDil controversy, points out that none of those involved disputed BiDil's efficacy: it worked. Rather, the challenge was to bring the drug to market in a way that would simultaneously address the needs of different stakeholders with an interest in African American heart failure. That is, the FDA, NitroMed, and the Association of Black Cardiologists (ABC) (who carried out the original A-HeFT trials) shared "an interest in health disparities, the deluge of data around African American responses to ACE inhibitors, and the increasing capacity of African American cardiologists to do clinical trials" (Pollock 2012, 162). In Pollock's view,

In the lead-up to BiDil, there was alignment of interests by NitroMed and ABC, but they were not necessarily seeing BiDil as a solution to the same problem. For NitroMed, the principal problem was how to get approval for the drug combination in a way that would be profitable. . . . For ABC, the problem was and is more diffuse: how to get the funding to run trials and thus participate in the production of evidence-based medicine, and how to find solutions for black morbidity and mortality from heart failure. (2012, 162–63)

The current situation is perplexing, to say the least: such notions as race and "genetics" and "biology" are still with us, but their meanings appear to have changed, producing consequences that seem to be both positive and negative. Some observers suspect that this kind of research will only give the older racial classifications a new lease on life (see *In Their Own Words*, page 153). John Hartigan (2013) argues,