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# “Special Treatment”: BiDil, Tuskegee, and the Logic of Race

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The presence of the Tuskegee Syphilis Study was palpable at the June 16, 2005, Food and Drug Administration’s (FDA) Advisory Committee meeting on BiDil, a heart medication from the pharmaceutical company NitroMed that sought approval as the first race-specific drug. So ubiquitous is the restless and unsettled spirit of Tuskegee that it continues to hover over the African American public and the biomedical research/health care provider communities more than three and a half decades after the actual study “died.” No one invoked the word “Tuskegee” in that dimly lit meeting room as BiDil gained the Advisory Committee’s approval. Yet its power was exerted even when it was not named. The FDA Committee’s chairman, Cleveland Clinic cardiology chief Steven Nissen, acknowledged this after the committee met: “We were putting [Tuskegee]...to rest.”<sup>1</sup>

The Tuskegee Study has the prominent place in the racialized lexicon of American health care politics. It was the longest running (1932-1972) non-therapeutic experiment in American history, involving the U.S. Public Health Service’s (PHS) intended failure to treat hundreds of African American men with late stage syphilis in and around Tuskegee, Alabama, while the men thought they were being treated. It is a powerful incantation, a continued condensed symbol of distrust, refusal of treatment, deceit, and blatant racism that is often called out to testify.<sup>2</sup>

Tuskegee’s presence was at the BiDil approval meeting, however, in two differing forms because of what ethicist Sandra Soo-Jin Lee calls the BiDil “paradox”: the need to justify the drug because of health disparities between black and white populations in the United States, by using race, and the need to promise that race is only the “best available proxy” on the way to genetic individualized care, where race will not be used.<sup>3</sup> Tuskegee was invoked in spirit to remember the disparities as well as the failures and betrayals in American medicine for African Americans. If Tuskegee was the worst example of doing nothing and racism in medicine, then BiDil was meant to be at least the current best example of doing something and attacking that racism.

Beyond the invocation of Tuskegee’s failures as a way to justify a race-specific drug, BiDil and Tuskegee demonstrate the problems of ignoring individuals by using race as a proxy and of remembering Tuskegee

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only in terms of racism. It is the “logic” of race, not just acts of racism that undergirded Tuskegee and is central to BiDil’s approval, which demands recognition. It is far easier to decry the racism that led to the efforts to deny treatment and enact deceit in Tuskegee, and that could presumably be appeased with providing BiDil as “special treatment,” than to be critical of the assumptions about race that link them.<sup>4</sup>

and other statistical concerns. Its approval was based on assumptions that nitric oxide uptake is different in blacks than whites, and this drug, when added to other heart medications, would mean improved life chances for African American patients. It was at the much shorter public comment section of the meeting that the more-often emotional, overtly political, and evocative testimony was heard.<sup>6</sup>

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This does not mean that BiDil is another Tuskegee, that the black patients who participated in the trials for the drug were misused, or that the black physicians who supported BiDil are racial sell-outs.<sup>5</sup> Nor would an historian argue that the racial logic of the 1930s-1970s is the same as that in the 21st century. The meanings we make of race in medicine are too dependent on historical context, the professional sub-groups that invoke it, the science that is used to explain biological phenomenon, and the political and economic demands it answers to remain stable. A 40-year prospective study done in the mid-20th century to watch what happened when a disease was untreated before the “gold standard” of randomized control trials is not the same as the study set up to pass approval with the FDA for a drug made from two widely available generics.

Tuskegee’s importance for understanding BiDil is thus not a question of equivalencies of racial horror tales. However, the availability of Tuskegee as a visible and invisible racial symbol, and as a link in the use of racial logic that made both Tuskegee and BiDil possible, is worth considering.

#### Disparities and Denial of Care

An FDA committee hearing is meant to be a public event, where a jury of scientific peers from outside the FDA ponders the statistical and clinical evidence, explains their logic, and votes on whether to advise a drug’s approval. The discussion about BiDil did this, focusing on surrogate and composite endpoints, p values, hazard ratios, last observation carried forward,

Representative Donna Christian-Christensen of the Black Congressional Caucus, the first public speaker, raised the link of BiDil to health disparities and hinted at Tuskegee through the language of history and denial. Providing the Caucus’s “clear and unequivocal” imprimatur for approval, she argued the committee “must reverse the history” that had been “used to deny treatment to those for whom treatment has been denied and deferred for 400 years.” In her strongly worded comments, she acknowledged political concerns with BiDil’s racial links but then asked rhetorically, “Would you deny a life now to us rather than do what the evidence shows can and should be done?” Gary Puckrein of the National Minority Health Foundation followed and also used the dangers of refusing to treat to sup-

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port BiDil by declaring, “We cannot allow people not to have their medications.”<sup>7</sup> Both speakers made it seem that approving BiDil acknowledged the racism that led to the past denials of treatment and provided an immediate sign of the American government’s reparations for racial wrongs. Others argued that the approval of BiDil would serve as an encouragement for African Americans to participate, not fear, research trials.

Tuskegee was not specifically named at the meeting. It did not have to be. In a rhetorical tradition of being signified, it could be called upon without direct referencing, thereby increasing its power. Shared concern over health disparities and past failures to treat prop-

erly could be acknowledged as a way to erase the worries that BiDil was based on a biological population claim, thus providing a strengthened “moral imperative” for acceptance.<sup>8</sup> By avoiding direct mention of Tuskegee through oblique language, its negative connotations could be avoided.

NitroMed, the drug’s maker, was aware of the dangers of linking BiDil and Tuskegee directly and reminding the public of the history of race-specific research. The company’s vice president for marketing, William

had more meanings than statistics when it serviced racial presuppositions, and that race could be made to both matter and not matter.<sup>12</sup> It was this kind of racial logic that resonated with BiDil.

BiDil’s approval rested on results from a clinical trial called A-HeFT (for African-American Heart Failure Trial) that enrolled only black men and women and showed significant improvement when BiDil was added to other medications and use of a statistically limited “post-hoc retrospective sub-group analysis” of a “20 year old study.”<sup>13</sup> The evidence appeared to make congestive heart failure seem almost a “different disease” in “self-identified” African-Americans at the level of population as “self-identified” race became the surrogate marker for some other interactive, but unknown, biological and environmental process. However, there was no real discussion

about what affects nitric oxide uptake or possible gene expression in individuals.<sup>14</sup>

It was the willingness to allow for an unknown factor (assumed to be biological) to explain what is claimed as racial difference that rhetorically links Tuskegee and BiDil. Jay Cohn, the inventor of BiDil, in his FDA testimony agreed: “It does appear that black people, for reasons which we certainly do not know, exhibit on average a less robust response to this released nitric oxide.” Despite his own statement that the reasons for its “working” were unclear, two sentences later Cohn would claim, “So, there are very good biological underpinning to this differential response.”<sup>15</sup>

The Tuskegee researchers made claims about the basis for the presumed racial differences in syphilis within a similar rhetoric. In 1932, leading syphilologist Dr. Joseph Earle Moore of Johns Hopkins reminded a Tuskegee Study physician that “[s]yphilis in the negro [*sic*] is in many respects almost a different disease from syphilis in the white” when it was assumed that there were differences between the cardiovascular and neurological complications of the disease.<sup>16</sup> Theories ranged from those who claimed that “rural negroes,” as one PHS Study in 1930 argued on the basis of two community studies, have a “sex appetite [that] is enormous” to assertions that there were “racial variations in immunity” to syphilis in differing, seemingly visually and geographically defined human racial groups.<sup>17</sup>

Dr. O. C. Wenger, who was the PHS’s leading expert on race and syphilis in this period, was concerned with what he called “the eternal question — the possibility of some unknown factors being responsible for this tremendously high rate of positives in the negro [*sic*]

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“B. J.” Jones, told a reporter that BiDil was “the antithesis of Tuskegee” but that the company “has no plans to address the topic head-on. ‘We don’t want to create an issue where there isn’t one.’”<sup>9</sup> It was, however, already there. A Meharry Medical School physician who recruited subjects for the BiDil trials in 2001 told *Time* magazine, “We had to try to persuade them that this was not another Tuskegee.” Other newspaper and blog accounts after the FDA meeting raised similar worries and reached for Tuskegee as the metaphor to explain fears about BiDil’s racial targeting.<sup>10</sup>

Few of these accounts considered that in 1932 when Dr. Eugene H. Dibble, Medical Director of the John A. Andrew Hospital at the Tuskegee Institute, agreed to the study he, too, hoped it would bring more resources into his severely underserved population that had been ignored. Perceived need in dire circumstances can become part of the rationale for agreeing to what seems to be an interim measure. The untoward consequences of acceptance are often not considered.

### The Links of Racial Logic

As a condensed symbol, the Tuskegee Study can be “used and abused” in multiple ways even if the myriad details are lost or mis-remembered.<sup>11</sup> The facts that it was a government study that only targeted African American men, that led patients to believe they were being treated when the PHS sought to deny them treatment, and that resulted in a long-lasting manipulation of trust are keys to Tuskegee’s cultural power in memory and fears. There was, however, a racial logic within the Tuskegee Study that syphilis was a different disease in blacks and whites, that only the highest prevalence rates had meaning, that clinical judgment

group.”<sup>18</sup> This “high rate,” Wenger reminded his fellow PHS Tuskegee researcher Raymond Vonderlehr nearly six years into the Tuskegee study, “cannot be explained to anyone’s satisfaction.”<sup>19</sup>

Even if there was the admission that no clear explanation existed, race was assumed to be a biological answer. Other physicians countered these claims and debated the reality of racial differences in syphilis, but such concerns never shaped the theoretical underpinnings at Tuskegee.<sup>20</sup>

With BiDil, members of the FDA Advisory Committee tried to raise questions to undermine the race-based argument and its assumption that a genetic and racially marked difference existed. Dr. Jonathan Sackner-Bernstein, a New York cardiologist on the committee, suggested that diabetes, alcohol consumption, or even gender differences, might be affecting the outcomes, rather than some vaguely defined notion of race. BiDil’s acceptance was based on a study only on African Americans without any understanding of what the “very good biological underpinnings” were for the differences and assumptions a priori that lower nitric oxide levels are somehow specific to all African Americans as a biologically distinct racial grouping. To make this work, support was found in the sub-group analysis of older studies, even when, as committee statistician Thomas Fleming noted at the FDA meeting, “[T]he real post hoc aspect of [the older studies] was race.”<sup>21</sup>

Race as a construct allows for the assumption of what Steven Nissen called “biological plausibility.” Nissen dismissed the worries over how race was used to gain BiDil’s approval as “political, not scientific” since the “data was solid.”<sup>22</sup> Because Nissen chaired the meeting and kept control over what questions would be answered, his views mattered.<sup>23</sup> “Respecting biological differences, based on selective evolution,” he stated, “is not racial bias.” Nissen explained historical selective genetic pressures by connecting recent studies that link salt retention to platelets and the body’s ability to coagulate the blood. While these studies do not say anything about race, Nissen argued there could have been selective survival in an African past.<sup>24</sup> His views reflect how the lingering assumptions, despite the efforts to debunk the slavery/Africa/salt hypotheses, can be reorganized into another form when race is already the answer.<sup>25</sup>

The need for a race-specific drug rests in part on statistics that are used to show a much higher mortality rate among African Americans than whites. Historian and lawyer Jonathan Kahn argued during his allowable ten minutes of public testimony, however, that CDC data shows this claim is accurate only for those in the “45-64 age group” (comprising “6% of the mortality group”), but not for those above 65 “where

92% of mortality occurs.” Both at the FDA meeting and in an interview, Nissen dismissed Kahn’s review of the data as wrong. At the conclusion of the meeting he stated, “I did not agree with the speaker who argued that there isn’t a disproportionate burden. I am convinced that there is. That is important.” Regrettably, there was no extended discussion of who was right.<sup>26</sup>

Similarly, part of the justification for the Tuskegee Study was the finding in 1930 in Macon County (where Tuskegee is the county seat) of a prevalence rate for syphilis of an astounding 39.5%. But the same prevalence survey of African Americans in five other counties also found a figure as low as 8.9%, less than “in many white groups” as Surgeon General Thomas Parran wrote, which raised questions about the assumption that African Americans were, as one physician noted, a “syphilis-soaked race.” Two years later, in the original data for what became the Tuskegee Study and in a different part of Macon County and only with men over 18 with presumed late latent disease, the positives had dropped to 22.5%.<sup>27</sup>

Prevalence surveys of course are dependent on many differing variables, but in this case, the highest numbers were used to back up biological assumptions about the need for a race-based study. Other contradictory and flawed data were allowed to protect the “a priori assumptions about difference,” and the clinical experiences of the PHS researchers as experts on race and syphilis continued. What they knew from their clinical experiences in the urban clinics, not just the research and the numbers they had before them, shaped their thinking.<sup>28</sup>

With questions swirling at the BiDil hearing about the “good enough” data, the clinicians on the panel, as often the case, relied upon their sense of clinical judgment. While much of the meeting focused on verbal dueling and flashing of mathematical prowess over the statistics of the NitroMed studies, it was the importance of clinical judgment that won out. In voting “yes” for BiDil, Nissen argued, “Compelling doesn’t necessarily mean statistical. Compelling to me means also clinical.”<sup>29</sup>

In the management of medical uncertainty, and especially when there is complex and competing statistical evidence, physicians often must, understandably, rely on their own clinical judgment. The PHS doctor/researchers at Tuskegee dismissed concerns of an American Heart Association committee that their data on the cardiovascular damage from syphilis was faulty and that differing exposures to malaria would affect the course of neurosyphilis and could explain differences.<sup>30</sup> With BiDil, clinical judgment and experiences with patients filtered the statistical data. Given the sense that it was imperative to “do some-

thing” that would require accepting “adjustments” to the data, that enough black people in the public part of the FDA meeting had approved the dismissal of charges of “racism,” and that NitroMed’s data was “good enough” — added to the chance to make history — the push in the end was for approval.<sup>31</sup>

### Thinking about Race

Part of the difficulty goes as well to the nature of the FDA hearing process. Discussion of scientific evidence takes the majority of hearing time and questioning. The public comment is given a much shorter shrift and often provides emotional testifying from consumers as much as additional scientific data. Advisory committees are aware that they are seen as dithering away on academic niceties of statistical data while at some point a leap of faith, buttressed by their best scientific understanding, is needed to save lives.

tique the linking of group identity with narrow definitions of ancestry. Many of those who opposed the drug’s approval thought it should be approved if not race specific. However, their points were balanced by the testimonies of black patients and physicians who claimed BiDil would allow African Americans with heart disease to live long enough to now “know their grandchildren” and how the pharmaceutical/medical research community was finally doing the right thing for black communities.<sup>35</sup> In the face of such emotional claims to fix racism, a discussion of the biological complexities of the use of race as a category never really happened.<sup>36</sup>

Only in the closing hour, and quite near to the actual committee vote, did the committee return to the questions of race. In summing up the discussions, Nissen argued that there were enough differences in self-identified African Americans responses to this and other

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Broader discussions of how we might think about race and genetic evidence appear as theoretical intrusions on such a discussion, where they are assumed to be already known or are shunted to the margins of the debate. For example, on the committee itself, geneticist and behavioral scientist Vivian Ota-Wang, now on the staff of the ELSI (Ethical, Legal and Social Implications) Program of the National Human Genome Research Institute at NIH, attempted to interject an alternative explanation for the data findings and to question the ways race was being left undefined.<sup>32</sup> A quarter of the way through the hearing she argued, “[T]here is a presumption here that somehow this self-identified social identifier is somewhat equivalent or representative of a biological process, and I am not sure it really is.”<sup>33</sup> But Nissen moved immediately on to other members of the committee, and this point was ignored. An hour later it was brought up again this time by the FDA’s Robert Temple, but Nissen shunted the discussion off to the need to do something for underserved populations.<sup>34</sup>

Race was raised by a number of speakers in the public commentary portion of the hearing to cri-

drugs to satisfy what he called “biological plausibility,” and until genomic medicine could produce a “gene chip” that would show individual differences, then race would have to do. While Ota-Wang tried again to make her points, it was a too little discussion too late in the process.<sup>37</sup> BiDil was approved, and the labeling would go out that it was a drug for self-identified African Americans even though, as the label says, “the mechanism of action underlying the beneficial effects of BiDil in heart failure has not been established.”<sup>38</sup>

Ota-Wang was partially right about how the approval would be read as biological and race specific. In a *Boston Globe* story on NitroMed, the reporter wrote, “African Americans lack enough nitric oxide, a chemical that helps the heart work effortlessly.”<sup>39</sup> A national survey of physicians done after the BiDil decision showed “81% believe that race should be used as a biological basis for determining ailments or diseases.”<sup>40</sup>

Ironically, BiDil may fade off the medical horizon if its high price means that physicians will reach for the generics instead, as appears to be the case since the drug was approved. Patients might take the supposedly “all natural Perfusia-SR,” a time-released ver-

sion of a L-arginine, an amino acid that theoretically increases nitric oxide and is being promoted as a BiDil equivalent in the pages of *Jet*, the popular magazine targeted to black readers.<sup>41</sup> Realizing the limits of their racial profile, NitroMed asserted its media campaign will “focus on quality of life rather than race.”<sup>42</sup> As with many other drug companies after receiving the approval for one purpose, the pharmaceutical company will try and expand the market for what has been called “off-label” usage. This time, however, the label of “African American” may actually just stick. And BiDil’s societal impact will be felt no matter what actually happens to the drug as pharmaceutical companies prepare to produce more presumably race-specific drugs.<sup>43</sup>

Both Tuskegee and BiDil remind us of why we must critique, very specifically, how and why race is used as a variable in medical research.<sup>44</sup> Tuskegee could happen in part because racism left a population underfed, undereducated, ill, and in critical need of treatment, and clinical certainty about race — both behavioral and physiological — could be used to explain these conditions. A “natural” study could be constructed to prove what was already assumed, even when contradictory data on purported racial differences and alternative explanations to prevalence rates existed. Statistical manipulations and questionable research at Tuskegee, even in an era when clinical trials were badly organized, protected racialized assumptions about disease. In the face of clinical and autopsy evidence that might undermine that certainty, race and some unknown biological process in the “bad blood” would shore up clinical experience of racial differences — except when race was allowed to disappear to make a larger medical and public health need apparent.

With BiDil, clinical certainty about race-based population differences and the desire and demand to do something out of need underscored the basis for FDA approval. The racism that led to the denial of care, deceit, and questionable ethics at Tuskegee is remembered to shore up this demand and dismiss racism charges when a drug is approved for only African Americans, while the logic of race that made Tuskegee happen is forgotten or ignored. “Biological plausibility,” focused on genetic expressions yet to be determined, allows race to become the real surrogate endpoint in a clinical study, and this meta-language, once again, overwhelms other variables — except when race is supposed to disappear to make a larger group of potential uses of the drug appear.

There may never need to be a federal apology for BiDil, as there was for Tuskegee, for its harm is less apparent. Governmental support, however, for the

substitution of race as a population category for the needs of individuals can have its own deadly effects. “Special treatment” can be exceedingly dangerous.<sup>45</sup>

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5. I was accused of making the BiDil=Tuskegee claim when I gave this paper at an MIT conference in April 2006. But I never made this simple phrase an equation.
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7. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, “Cardiovascular and Renal Drugs Advisory Committee,” Transcript, vol. II, June 16, 2005, at 207-208 and 214 [hereinafter cited as BiDil Transcript]. Both the Caucus and the Foundation received donations from NitroMed, but only Puckrein acknowledged this. I also attended the committee meeting.
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  28. On the a priori use of race, see B. Roy, "The Tuskegee Syphilis Experiment: Biotechnology and the Administrative State," in Reverby, ed., *supra* note 2, at 299-317.
  29. See BiDil Transcript, *supra* note 7, at 396.
  30. J. H. Jones, *Bad Blood* (New York: Free Press, 1992): at 139-140. The criticism of the cardiologists is one of the factors that led to the push for autopsies on the men in the Tuskegee Study. The X-ray diagnosis that Dr. Raymond Vonderlehr (one of the key PHS physicians in the Study) was using was considered "arbitrary," which even he admitted. An analysis of the patient record data of the Tuskegee Study participants makes clear, as well, that the labeling of those with cardiovascular syphilis (as opposed to hypertension) was often arbitrary, and not even decided clearly at autopsy. See Reverby, *supra* note 12.
  31. See BiDil Transcript, *supra* note 7, at 302.
  32. *Id.* Author telephone interview with Vivian Ota-Wang, February 1, 2006.
  33. See BiDil Transcript, *supra* note 7, at 99.
  34. *Id.*, at 187.
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Self identified African American status, some people think, may be a proxy for some genetic marker. I'm not willing to go that far.... So the physiology may be related to blood pressure, socioeconomic status, stress, socioeconomic disadvantages. We don't know what it is.

"Controversial Heart Drug," PBS NewsHour, June 17, 2005, available at <[http://www.pbs.org/newshour/bb/health/jan-june05/heart\\_6-17.html](http://www.pbs.org/newshour/bb/health/jan-june05/heart_6-17.html)> (last visited May 21, 2008).
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  42. J. W. Payne, "The Race to Market; Heart Supplement Targets Blacks, Echoing Race-Based Drug," *The Washington Post*, December 13, 2005, at F01; Associated Press, "NitroMed Plans Ads for Heart Drug OK'd for Blacks," *Boston Globe*, September 1, 2006, available at <[http://www.boston.com/business/globe/articles/2006/09/01/nitromed\\_plans\\_ads\\_for\\_heart\\_drug\\_okd\\_for\\_blacks](http://www.boston.com/business/globe/articles/2006/09/01/nitromed_plans_ads_for_heart_drug_okd_for_blacks)> (last visited May 28, 2008).
  43. "Hundreds of New Medicines Now in Development for Diseases that Affect Hispanic Americans," September 17, 2006, available at <<http://www.medicalnewstoday.com/medical-news.php?newsid=52031>> (last visited May 22, 2008).
  44. Troy Duster argues that sociologists ought not just be deconstructing the social construction of race, but look specifically at the architecture of this deployment. See T. Duster, "Comparative Perspectives and Competing Explanations: Taking on the Newly Configured Reductionist Challenge to Sociology," *American Sociological Review* 71, no. 1 (February 2006): 1-15.
  45. On the problems of "inclusion," see S. Epstein, *Inclusion: The Politics of Difference in Medical Research* (Chicago: University of Chicago Press, 2007) and S. M. Reverby, "Inclusion and Exclusion: The Politics of History, Difference, and Medical Research," *Journal of the History of Medicine* 63, no. 1 (January 2008): 103-113.

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