

**Is It a Black Drug If We Say It Is?  
Controversy Surrounding BiDil, the First “Race-Based” Drug  
by David Hutto**

**Talking About Health Care**

In discussions of health care in the United States, the most frequent topic at the moment is lack of health insurance for many Americans. A different issue, less talked about, is the inequity in health care based on race or ethnic groups. Although such disparities are not as frequently discussed, their existence is a clearly established fact (Satcher *et al.*). What we do about these inequities will partly depend on how we talk about the problem. In referring to lower life expectancy for black males, for instance, Senator Tom Coburn of Oklahoma has stated that black males have a genetic disposition to less life expectancy (cited in Kahn “From Disparity”). Such a statement could conceivably be followed by the idea that medical resources should therefore be best used for people who have a chance of living longer.

Recent advancements in scientific knowledge are also beginning to have a strong impact on the discussion of health care. With the deciphering of the human genome, it is said that we are now in a “post-genomic” age, in which attempts are increasingly being made to treat illness based on knowledge of the genetic code, as with the drug Herceptin, used to treat some breast cancers that have extra copies of the gene HER2 (Kingsland). On June 23, 2005, a new element entered the discussion, when the Federal Drug Administration (FDA) approved a drug called BiDil, to be used as a treatment for heart patients. What makes BiDil striking is that it is approved specifically, and only, for black patients, the first such “race-based” drug in U.S. history. As the FDA-approved label for Indications and Usage reads: “BiDil is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients” (“BiDil Package Insert”). Now that the first race-based medicine has been approved by the Federal government, a great deal of discussion has occurred as to how the approval came about and what it might mean. This article examines the discussions surrounding BiDil, beginning with the background that allowed approval to occur, then detailing the rhetoric involved in marketing the drug. The article ends

by looking at discussions of questions raised by the existence of this drug, including the interaction of race and medicine.

### A “New” Heart Medicine: BiDil

BiDil was created by combining two vasodilator drugs, hydralazine hydrochloride and isosorbide dinitrate, which are both approved to be used separately, and which both exist in generic form. When combined in the formulation making up BiDil, however, *and* when administered specifically to black patients, the FDA has declared that this is a new drug. The origin of BiDil began in 1980 when Dr. Jay Cohn from the University of Minnesota led a study of vasodilators (the Vasodilator Heart Failure Trial—“V-HeFT I”) in heart patients around the country, followed later by a second trial “V-HeFT II” (Kahn “From Disparity”). Neither of these trials was conducted with regard to the race of the patients, and both showed some positive effects from the combination of hydralazine hydrochloride and isosorbide dinitrate.

In 1989 Cohn took out a patent on combining the two vasodilators, in a combination that received the name BiDil. In the early 1990s, an application to the FDA for approval of BiDil for all patients was rejected, as the FDA said that the effect of the drug, although visible, did not reach a required level of statistical significance. Following this failure of approval, Cohn and Peter Carson, who had also worked on V-HeFT, went back to the original data and looked at it again. During this reexamination they discovered a presumed difference in black patients, and—at the recommendation of the FDA—a decision was made to conduct a new trial of BiDil only in black patients (Temple and Stockbridge). Cohn also acquired a second patent on BiDil, specifying that the drug is specifically for black patients. The new trial was known as the African American Heart Failure Trial (“A-HeFT”), and was supported by a company called NitroMed, of Lexington, Massachusetts. *Forbes Magazine* called the results of A-HeFT “astounding” (Herper), and the *Bay State Banner* said they were “staggering” (Devine “Cost”), with a 43% improvement in patients taking the drug. After the A-HeFT trial, NitroMed submitted an application to the FDA, this time stating that the drug was only for black patients. This time, based on unanimous recommendation from the advisory panel, the drug was approved.

## **Kairos and FDA Approval of BiDil**

No medicine in the United States, prior to BiDil, has been described as appropriate only for a particular race. Everyone involved in the approval in 2005 would have been aware that this decision was going into new territory and establishing a precedent that could lead in unknown directions. Why was a “race-based” drug approved at this time? To judge from the intensity of the discussion that has followed the decision, much more was involved in the approval of BiDil than a logical examination of scientific data. The kairos surrounding the decision involved not only medical knowledge, but also circumstances of social change and economic considerations.

*General background* One of the more obvious aspects of kairotic knowledge is attitudes toward race in America. In an article explaining the FDA view, two authors from the FDA mention, among other reasons for approving BiDil, “the need for heart failure treatments for black patients” (Temple and Stockbridge). For most of American history, separating people by race has been done for purposes of discrimination and oppression. Beginning in the 1960s, however, with the rise of the Civil Rights movement, society began to recognize racial distinctions as a way to acknowledge past discrimination and try to eliminate it. A belief in the positive benefits of distinguishing by race eventually combined with a recognition of racial inequities in health care, creating a kairotic moment in which a separate drug for blacks might be seen as a way to overcome previous health care neglect. A feeling of urgency to address the problem may have also arisen not only from a knowledge of health care disparities among minorities, but from the extent of the problem of heart failure in blacks. More than 700,000 blacks in the U.S. have heart failure (2005 statistic), they are less likely than whites to respond to treatment (Stein), and heart disease is the leading cause of death for blacks when all ages are combined (“CDC Wonder”).

Perhaps equally important in the kairos of BiDil approval has been a major advance in human knowledge, with the description of the complete genetic code for human beings. The Human Genome Project was completed in 2003, two years before BiDil approval, for the first time making it possible to investigate whether particular genes are related to various disease conditions. One of the early effects of decoding the genome has been to focus increasing attention on the genetic and molecular level in treating

disease. In these early days of trying to apply genome knowledge, biological variations have been considered not only among individuals, but among groups with similarities in their genetic code. Such an approach has led investigators to look at racial or ethnic groups as a potential way of gaining useful genetic information. The recognition of race at a genetic level has of course been disputed, but it is also happening against the social background of recognizing race for benign purposes, and the argument is made that there are medical benefits to studying the genetics of groups. The new interest in race and genes is illustrated by the fact that Howard University, for example, a historically black school, has created a gene bank for research containing only samples from black participants (Sankar). Additionally, the Association of Black Cardiologists supported the A-HeFT study focused only on black patients. Thus in 2005 even among some scientists and physicians there was an attitude that could support the logic of a drug to treat a single race.

*The background of BiDil prior to approval* Social attitudes and scientific knowledge helped to create circumstances in which the first race-based drug might be approved, but there are additional reasons as to why BiDil was the specific drug to achieve this status. In light of the desire to improve health care for blacks, and given the fact that heart disease is seen as a more serious problem for blacks than for whites, the A-HeFT study created the dramatic perception that a remarkably useful drug had been found. Results of the study showed that those who received the drug had a 43% reduced chance of dying and a 33% reduced chance of hospitalization (Taylor *et al.*). With such results, the benefits of BiDil were considered so obvious that the study was halted several months early to switch patients receiving a placebo onto the drug. The FDA had rejected BiDil in 1996, but in 2005, reconsidered for its usefulness only in black patients, it was approved. The drug itself had not changed, the mechanism of action had not changed, and the basic use of the drug had not changed. What had changed was the way the drug was described.

One of the most vocal critics of BiDil and NitroMed is Jonathan Kahn, a professor of law at Hamline University. Kahn claims that NitroMed tried to create a situation in which BiDil would be accepted as being effective just in blacks, rather than effective in anyone who takes it, because NitroMed

holds a patent on giving the drug to blacks rather than to all patients. This patent, Kahn says, even allows NitroMed to block anyone who tries to market the two generic drugs (which are combined to form BiDil) as treatment for heart failure. Therefore, “NitroMed has a vested interest in framing BiDil as a race-specific drug” (Kahn “Race”).

### **The Marketing Campaign**

*Background that had to be addressed* Many drugs are sold to very specific populations, but as the only drug ever marketed on a racial basis, BiDil was necessarily going to invoke some of the feelings and attitudes connected with the history of race in America. Stepping into this context, NitroMed needed to consider a number of elements specific to race if it was to successfully position the drug in the market, including the history of lower-quality health care for minorities. Not only did this inequity form a background to the marketing of BiDil, but references to the inequity became at least indirectly a part of the marketing appeals. Such a reference is evident, for instance, in Jay Cohn’s statement that BiDil should be available to blacks because we should not “deprive a population historically underserved by our medical system” (Cohn). The reference to inequity is also seen in the fact that NitroMed has a partnership with the NAACP called a “health justice campaign” (Devine “NAACP”).

Another factor that NitroMed needed to consider in marketing a drug only to black heart patients was in part a corollary to the history of unequal health care. Because of this disparity, there is a distrust of health care institutions by some of the people that NitroMed wanted to market to. As an example of such distrust, a Rand poll of American blacks in 2005 showed that 53% believe in a hidden cure for AIDS that is being withheld from poor people (Coats). NitroMed did address the problem of distrust early on by enlisting the support of black leaders. Part of black distrust of medical care also stems from the memory of the Tuskegee experiment. For most whites, if they know about Tuskegee at all, this experiment was an unfortunate aberration, but it is an incident that still affects attitudes in the black community. That effect was illustrated by the director of the Black AIDS Institute, Phil Wilson, who said, “The most common thing we hear with AIDS drugs is, ‘Oh, they’re going to experiment on you...The most cited example is

the Tuskegee trials, even though most of us don't even know what Tuskegee was" (Coats). NitroMed had to take this fear and distrust into account even before BiDil was approved, in trying to conduct an all-black study. When recruiting blacks to take part in the A-HeFT trial, for instance, Dr. Theodore Addai at Meharry Medical College in Nashville said, "We had to try to persuade them that this was not another Tuskegee" (Coats). It was probably of tremendous help in this regard that NitroMed had lined up the Association of Black Cardiologists as a co-sponsor of the study.

NitroMed also seems to have recognized and taken into account a third factor in marketing to the black community. In general, the authorities that are trusted by a white community and a black community are not the same. Thus NitroMed worked to actively inform and recruit black leadership, which would help to dispel the notion that here was yet another mostly white pharmaceutical company wanting to take advantage of the health needs of black patients. An article in *The Black Commentator* stated, "NitroMed, the pharmaceutical company that will produce BiDil, acted very shrewdly. The drug maker achieved this success by giving the heads up to black leadership, lest it be accused of recreating the infamous Tuskegee experiment" (Kimberly ).

***Specifics of the marketing*** The beginning of marketing BiDil might be thought of as taking place before BiDil was even approved for sale. With the recruitment of black cardiologists as co-sponsors of A-HeFT, a frame was being constructed that would later make it easier to market the drug. Once the drug had been approved, NitroMed moved to enlist support from even more black organizations, including the Congressional Black Caucus and in particular the NAACP, with which NitroMed formed a partnership. That partnership was announced as a "strategic alliance to implement measures to narrow health care disparities" and "to develop health advocacy initiatives" ("NAACP and NitroMed Announce"), including a \$1.5 million dollar donation from NitroMed to fund the initiatives. The language here indicates two rhetorical strategies. In referring to "health care disparities" NitroMed is trying to situate BiDil as a response to past inequities. Secondly, the announcement of "health advocacy initiatives" indicates a desire not merely to sell drugs, but to provide help to the black community. Both of these points would hopefully work to help build a positive ethos for NitroMed, which might in turn help sales.

NitroMed also benefitted from this partnership in a more practical way, as the NAACP helps NitroMed provide Medicare recipients with information about drug options, including BiDil. NitroMed company officials have even been invited to speak at NAACP meetings (Devine “NAACP”). This direct approach to potential consumers, focused on black groups, has also been used at black churches and health fairs, where people may be given information about heart disease and receive a free blood pressure screening, and where they can pick up a pamphlet about BiDil.

In a more traditional approach to marketing, ads have been placed in print and radio media, but because NitroMed is a small company with limited resources, the ads for the most part have not been given broad national coverage. Instead, the advertising has been focused on metropolitan areas with large black populations (Jewell “As Medications”). In September 2006 ads began running in Detroit, Houston, and Washington, D.C., and in October ads began to run in *Jet* magazine. The rhetorical strategy of these ads has been to take a fairly soft and friendly approach. A 60-second radio ad plays on family themes, with a grandfather and a granddaughter sitting at dinner, and the granddaughter asking her grandfather to play after dinner. One of the print ads has an image of a grandfather with a girl on his knee. The NitroMed VP of marketing said of the targeting of such images, “The dialogue around a family meal is something that resonates throughout the African-American community” (Jewell “Targeted”).

### **Is BiDil Really a “Black” Drug?**

Some drugs are marketed with little controversy, but it is probably no surprise that BiDil has not been one of those drugs. Because the A-HeFT study did not involve anyone but black patients, the question has been raised as to whether it is scientifically valid to consider BiDil as a medicine for blacks only. Although the benefits of BiDil to the study participants was obvious, critics say that the study provided no information as to whether the drug might also work for anyone else. The point seems valid if we apply the standards of a scientific study, but other considerations are at work in the public discourse besides a strictly scientific judgement. The recognition that blacks have been a medically deprived population has combined with a reaction to the benefits of this drug to generate emotional support for

BiDil, and that support advocates its use for black heart patients. The *Bay State Banner* provides an example of the kind of language sometimes used, saying, “it looked like help was on the horizon for hundreds of thousands of afflicted souls” (Devine “Cost”). The phrase “afflicted souls” indicates the underlying attitude about the suffering of this deprived group, an attitude that NitroMed spokespersons picked up on.

There have even been instances in which BiDil was considered *so much* to be a black drug that not providing it led to charges of racism. The fact that Medicare will not pay for BiDil provoked such a response from Juan M. Cofield, president of the NAACP’s New England council. He said the Medicare position “is so contrary to evidence-based medicine and so extraordinary that it arouses suspicions of institutional racism” (Winstein). Cofield went on to say that if BiDil “were not a medication for blacks, their response might be different.” Although Gary Puckrein, a NitroMed shareholder and executive director of the National Minority Health Month Foundation, does not regard BiDil as a race-based drug, he did see racism at work in some reactions to the drug. Speaking of calls to use the cheaper generic drugs, sometimes requiring patients to cut pills in half to get the same dose as BiDil, Puckrein said, “If that were white patients, nobody in America would tell them, [buy two different drugs], go home and cut them, and...take multiple pills a day” (Westphal).

There is also support for marketing BiDil to blacks based on a logical and practical point of view. Even if the drug would be effective in non-blacks, at least we know it works for black patients, so it should be available to them. The argument “at least it works” appeared in the magazine *Black Enterprise*, where Waine Kong, of the Association of Black Cardiologists, which co-sponsored the A-HeFT study, said, “I’m aware of the issues that BiDil has raised, but if a medication works, what’s wrong with that? It doesn’t mean we stop monitoring the drug to see its effects on the black community” (“Are Race-Specific Drugs Unethical”). The same argument was made by the inventor of BiDil, Jay Cohn, who said that the benefit of BiDil “was so profound that it would be irresponsible to deny the favorable effect...” Cohn then goes on in the same sentence to make the argument that we should not “deprive a population historically underserved by our medical system” (Cohn), thus appealing to both logic and emotion. Much

of the support for BiDil, from the popular press, from medical professionals, and from black leaders, has used combinations of logos and pathos, similar to Cohn.

Another approach to arguing in favor of BiDil generally, and specifically as a medicine for black heart patients, has been to appeal to authorities. NitroMed has made enormous use of such appeals, even basing part of its marketing strategy on this approach, in the partnership with the NAACP. In addition, the NitroMed webpage for BiDil says that the drug was recognized by the American Heart Association as a major advancement in treatment. The same NitroMed page also says that BiDil is co-sponsored by the Association of Black Cardiologists, and that it is supported by the National Medical Association (an association of black doctors) and by the Congressional Black Caucus.

In addition to the efforts of NitroMed, many credible authorities have come out in support of BiDil and the study that led to it. Charles L. Curry, president of the International Society on Hypertension in Blacks, said, “This is the most important advance in the treatment of black people that I have seen in my lifetime” (Stein). Dr. Augustus Grant, past president of the Association of Black Cardiologists, wrote, “It’s a delight to see a trial that clearly shows a benefit of therapy in a particular racial group” (“Heart Drug for Blacks”), and another past president of the same organization, Dr. Paul Underwood, supported the BiDil study when he said, “The significance of the study is that in the past we had to assume that medicines that were good for the majority were good for African Americans” (Holloway). Clearly, with so much support from authorities like this—who, after all, would know better than black heart doctors?—the implication is that it must be valid to consider BiDil a black drug.

In spite of strong support for BiDil as a race-based drug, using appeals to logic, emotion, and authority, there have also been strong arguments against BiDil as a black drug. The arguments begin with the A-HeFT study that led to FDA approval. In a brief commentary in the British medical journal *The Lancet*, Troy Duster condemns the classification of BiDil as a race-based drug, and writing about the re-examination of data from the earlier V-HeFT I and II trials (in which researchers decided they had found evidence of separate reactions in blacks), Duster writes, “The reinterpretation of already obtained data sets by racial categories thereby conveniently circumnavigates the problem of having to define what is

meant by race” (Duster). This criticism touches on a general social/linguistic dilemma—what do we mean by this word “race”? More specifically, if race is a scientific category, sufficient for medical testing, how is it defined? The problem is illustrated by an article in the *Journal of the American College of Cardiology*. That discussion looked at the problem of prescribing a drug based on self identification of race (as with BiDil), citing a U.S. Census Bureau study that within a two-year period, people in 34% of households changed their reported ethnic identity (Haga and Ginsburg). The Census Bureau also found in 2000 that with the possibility to give more than one response to race, almost 7 million people identified themselves as members of more than one race (Schwartz 1392).

Other comments about BiDil show tremendous cynicism about the entire process of marketing the drug, possibly part of a general distrust of pharmaceutical companies, and perhaps part of the kairos of any drug discussion. These criticisms all work from a commonplace assuming that BiDil has definitely not been shown to actually be a black drug. Since this is true—in the thinking of such critics—BiDil is therefore being marketed to black heart patients only as a way to make money off them. Jonathan Kahn claims that “race has been exploited” to market BiDil, writing “The medical evidence from A-HeFT supports no claims regarding racial variation in response” (Kahn “Race”). The same view can also be found in *The Black Commentator*, an online magazine: “NitroMed is using black people to get a drug approved that it couldn't get approved otherwise and in the process maintaining a patent” (Kimberly). Another example comes from an editorial in the magazine *Colorlines*, where Tram Nguyen says that BiDil is part of a broader context of treating racial problems in ways that do not benefit the people who need help. In the editorial, Nguyen refers to “a socking profit to drug manufacturers,” implying that BiDil is more about economics than science (Nguyen).

The question of BiDil as a black drug has also been raised from the point of view of whether such a classification might deprive other races of its benefits. Perhaps this is not a “black” drug because it would also help other people. Ironically, even NitroMed seems to support this idea, with a statement on their website: “Ongoing analysis of the genetic data from A-HeFT may help researchers identify other patient populations in whom BiDil can be studied, potentially leading to a new generation of personalized

medicine” (“Genomic Analysis”). As Troy Duster states the criticism, “The problem is, when you racialise [a medicine], there are going to be many white people who could have benefited from the drug not being prescribed it, and many black people who have a different kind of response to the drug being given it” (Kingsland). Everyone involved with researching BiDil acknowledges that the reason it works is not known, which means that belief in BiDil as a specifically black drug is based on circumstantial evidence.

### **Broader Questions Connected With BiDil Approval**

*Is race a valid consideration in medicine?* The approval of BiDil has brought into sharper focus a discussion that existed before anyone ever thought of BiDil, the question of whether it is reasonable to consider a variable concept like race in medical care. As Jay Cohn, the inventor of BiDil, writes, “The practice of using race or ethnic origin as a distinguishing feature of populations... is a universal and well-accepted custom in medicine” (Cohn). This argument in favor of looking at race is based on custom, which may be persuasive, but custom does not necessarily make a valid scientific argument. In an editorial in *The New England Journal of Medicine*, Robert Schwartz denies the usefulness of race, writing “I maintain that attributing differences in a biologic end point to race is not only imprecise but also of no proven value in treating an individual patient” (Schwartz 1392). Cohn, however, justifies the practice with a practical appeal, writing that racial distinction in medicine “has nearly always revealed differences in mechanisms of disease” (Cohn). Of course Cohn’s argument begs the question, raised previously, as to how to define race.

There appears to be scientific support for Cohn’s view of race as a useful method for discovering probabilities or underlying mechanisms of disease in different groups of people. In his *New England Journal of Medicine* article, Schwartz predicted (in 2001) that the Human Genome Project would “force an end to medical research that is arbitrarily based on race,” but instead, the opposite seems to be occurring. A search of the national medical database PubMed using the search terms “genetic disease and race” brings up 4,659 hits. Some diseases have long been known to be associated with particular groups,

such as sickle cell anemia in blacks or Tay-Sachs disease in Ashkenazi Jews. Schwartz argues, however, that such cases are due to geographic isolation, not to race as such.

There is also more indirect evidence supporting the use of race in the form of information showing that racial or ethnic groups differ in metabolic processes, with the concomitant possibility of differences in disease mechanisms. The *Journal of the American Medical Association* reported a study looking at models for predicting breast cancer risk and found that the “spectrum of mutations that occur in African Americans is ‘vastly different’” (cited in “Access to genetic counseling”). Ethnic differences are also cited in a report put out by the National Alliance for Hispanic Health, which describes four differences in drug reactions by Hispanics compared to the general population or to whites (“Report on Hispanics and genes”). The kind of indirect evidence that could be related to a disease process comes from a study showing racial differences between “Caucasian girls [and] African American girls” in the body’s reaction to a high-salt diet. As the researchers from Purdue University summarized the study, “This proves that salt is processed differently in the races...” (“Races react differently”). In spite of evidence of possible racial or ethnic difference, Craig Venter, who worked on one of the programs mapping the human genome, said, “It is disturbing to see reputable scientists and physicians even categorizing things in terms of race... There is no basis in the genetic code for race” (Brody and Hunt).

Of course public discussion of anything having to do with race (and probably of anything to do with medicine) is not simply a question of what seems to be scientifically valid. As already mentioned, considerations of history, of justice, of financial gain, and other factors will become part of the discussion, and these non-scientific factors may even become more important than science in shaping the conversation. Research based on race may be done because it is felt to be “about time” someone properly paid attention to a particular group. The many articles appearing on the PubMed database indicate an active interest in the interaction between race (however it might be defined) and medicine. Further evidence of that interest can be seen in reports of drugs being tested (like BiDil) for differences in effect among racial or ethnic groups. One argument given in support of such testing is to balance previous inequity. In discussing BiDil, an article in *Forbes* magazine says, “Part of the problem is that clinical

trials have too often focused on white men” (Herper). Thus Keith Ferdinand at Xavier University tested Crestor (cholesterol drug from AstraZeneca), and Patrick Griffin at Morehouse School of Medicine tested Aricept (Alzheimer drug from Pfizer), in black patients (Herper). Other studies have also been done looking at the effects of drugs in racial or ethnic groups.

The growing number of reports of racially differentiated drug reactions has been challenged by an article in the journal *Nature Genetics*, which discussed 29 drugs that the article said were claimed to have racial differences in safety or efficacy. The authors of the article concluded, however, that only 4 of the 29 showed possible evidence of genetic differences (cited in Kahn “From Disparity”). In spite of the authors’ negative conclusion, some popular media began talking about the 29 drugs, citing them as “proven” to have different racial reactions. This false information even took on political overtones, as when John Entine, of the conservative American Enterprise Institute, cited the *Nature Genetics* article as showing 29 drugs “known” to affect racial groups differently (Kahn “From Diversity”).

***Is race-based medicine good social policy?*** For the first time in the history of American medical care, the Federal government has said that a drug is meant only for one race. The obvious question of how to define a race was simply skipped, so that the drug is intended for “self identified” blacks. Since the mechanism of this drug, although unknown, is assumed to operate at the molecular level differently in blacks than in whites due to differences in genetic code, the U.S. government has implicitly supported the idea that race is a matter of genes. Two questions arise that may affect science and medicine, but they are not scientific questions. They are, rather, based on what our society considers to be socially good. (1) What does it mean if we decide to investigate race as a factor in medicine? (2) What does it mean that the government has made a decision based on race as a genetic category?

As already noted from some of the people quoted above, there are those who feel that considering race in health care is a very positive step. The benefit most commonly cited, the entire heart of the matter, in fact, is that attention to race should result in better health care for minorities. This point operates from the understanding that minorities have often received inferior health care to what most of the white population receives. Supported with examples based on frequency of genetic variation, an article in *The*

*New England Journal of Medicine* advocated medical research based on racial or ethnic groups. The authors do recognize potential problems from focusing on genetic causes of disease, writing “Excessive focus on racial or ethnic groups runs the risk of undervaluing the great diversity that exists among persons within groups,” but the authors go on to say that avoiding research based on racial genetics will “retard progress in biomedical research and limit the effectiveness of clinical decision making” (Burchard *et al.*). Race-based medicine is also supported—very cautiously—by M. Gregg Bloche in an article from *Race and Ethnicity*. Bloche refers to the BiDil example, with the obvious benefits of the drug, to say “To try to argue that the trial shouldn’t have been conducted, or that the FDA shouldn’t have approved BiDil based on this data, is to put opposition to race-based categories ahead of extension of life” (Bloche).

The ultimate goal of genetic research is to treat each individual based on their personal DNA. At the moment, however, our technology does not allow this, although genetic testing is already a part of the treatment regimen in some cases. For now, those who advocate considering race as part of medical care argue that although race is undefined, and although it may be socially awkward to talk about it, we are moving in the right direction by beginning to focus on genetic differences among people.

And of course there is a counter argument. Only rarely is a disease caused entirely by genes, with no relationship to the environment an individual lives in, including diet, exercise, health care, exposure to harmful substances, and so on. A person can inherit a genetic tendency for a disease but never get it, or the severity of the disease can vary according to circumstances. These nongenetic factors involve the social environment, and some of the factors that influence health care can be woven into complicated social webs, such as sources of pollution, cost of fresh fruit, or affordability of health insurance. One of the arguments against paying attention to race in medical care is that such attention could distract us from dealing with problems in the social structure that affect health. Treating diseases at the molecular and even genetic level is amazing and exciting. This technology can be so enticing that there are those who fear we may get so caught up in trying to develop exactly the right drug and method of delivery that our attention will be deflected from the social and economic causes of disease. There is also a concern that BiDil may set a precedent so that the search for new drugs becomes too focused on narrow populations

where companies might make a profit, without regard to the broader social good of researching needed drugs that will not be as profitable.

Another concern raised by BiDil involves the Federal government appearing to support the idea that race is a genetic category. There have been times in recent history when race was commonly considered an absolute biological category, with related beliefs that a race could be biologically superior or inferior. In most of the scientific world, at least, these beliefs have eventually been dispelled, and race has come to be more and more regarded as a social creation based on fairly superficial differences. With the racial approval of BiDil, there is concern among some critics that this decision gives greater authority to a belief in the genetic basis of race. A common response to this concern is that race is merely a temporary stand-in for still unknown genetic factors, but in the meantime, attention to race can improve the health of individuals. Nevertheless, there is a fear that if race is recognized as a biological category by the government for medical reasons, a legal precedent is established that may have unforeseen consequences. Once race is considered a definite biological category—legally established—even for a beneficial reason such as medical care, that legal recognition may then be used for detrimental reasons.

## **Conclusion**

BiDil appears at the intersection of three topics that often generate more heat than light in the intensity of debate: race, access to health care, and cost of prescription medication. Some of this intensity can be seen in statements that not using BiDil is malpractice, while selling it is exploitation, or that not paying for BiDil is racism, while approving it is a step toward institutional racism.

What can be learned from looking at the rhetoric surrounding BiDil? A number of interesting observations can be made after taking a close look at this case. (1) Although BiDil may be unusual in being the first raced-based drug, the discussions surrounding BiDil also serve as a good illustration of the fact that social discourse about medicine is definitely not limited to scientific knowledge. In some cases, scientific knowledge may not even be the most important part of the conversation. (2) Even the scientists may be influenced by that broader conversation. In the BiDil case we see that the FDA decision to

approve the drug appears to have taken place with an awareness of the social situation, with a sense that something needed to be done to address health inequities for minorities. (3) The testing, approval, and marketing of BiDil very clearly illustrate an unpleasant reality about medicine, at least that part of medicine involving drugs. Drugs are developed and sold by money-making businesses, and the businesses would not exist if they didn't pay attention to profit. Looking at what has happened with BiDil, we can see that this small pharmaceutical company did what they could to shape the debate, and to position their drug in the social, medical, and political circumstances that existed. Companies are going to use the resources they can to sell their products, even if other people feel that products that save lives should somehow be exempt from the usual commercial process. (4) One of the things that makes BiDil an interesting case is that trying to sell the product in this case means trying to market to a racial group. When we look at that process, we see that the circumstances involving race have affected the direct rhetoric being used, as well as having an effect on bringing in respected authorities and trying to shape the ethos of the company. (5) The case of BiDil also shows us a 21<sup>st</sup> century version of an enduring American question—updated with talk of the human genome—what are we going to do about race? And what is the role of race in medicine?

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