Congress of the United States
House of Representatives
Washington, DC 20515

The Honorable Donna M. Christensen

Member of Congress

Chair of the Congressional Black Caucus Health Braintrust

Testimony

Cardiovascular and Renal Drugs Advisory Committee

BiDil drug application

Department of Health and Human Services

Food and Drug Administration

Good Morning:

I am here before you this afternoon as Chair of the Health Braintrust of the Congressional Black Caucus.

Today Ladies and Gentlemen, you have before you an unprecedented opportunity to significantly reduce one of the major health disparities in the African American community, and in doing so begin a process that will bring some degree of equity and justice to the American health care system.

Every day more than 200 African Americans die from premature causes. The leading cause of those deaths is heart disease, which we suffer more disproportionately from than any other racial group. Heart failure among African Americans is expected to increase from 725,000 to 900,000 in the next five years -- 50% of these patients survive less than five years after diagnosed.

Studies have suggested that deficiencies of nitric oxide play a role in the intransigence of Congestive Heart Failure in African Americans. The medication before you today, BiDil, widens blood vessels by increasing nitric oxide levels.

Through the A-HeFT clinical trials with its 1100 African-American men and women participants, it was found that the drug showed a remarkable "43% reduction in mortality, a 33% reduction in hospitalization from heart failure and an overall improvement in their quality of life."

It is important to note that the drugs which are included in BiDil are not new medicines. They have been standard treatment for heart disease and hypertension for decades. It is a specific combination of these drugs, known as BiDil, when used with other medicines which have proven by themselves ineffective in reducing mortality or improving quality of life that is before the panel today. So I think I can assume that it is not the safety of the medication which is in question today. In fact the American Heart Association lauded BiDil as one of the top 10 advances in 2004.

Neither could our concern be the A-HeFT trial itself because it could be considered a model trial for its methodology and the fact that unlike some recent cases of medication already approved, the trial was stopped after 18 months because of higher mortality in the placebo group.

So let me then focus the rest of my remarks on the issue of the approval of the indications -- the approval of BiDil in the treatment of congestive heart failure in patients of one race, African American.

When I spoke to the principal investigators last year, I applauded them, the Association of Black Cardiologists and Nitromed for being willing to take what everyone knew would be a controversial step. I did not say this then, but I also feel that to ignore the positive results in the few African Americans who were in the initial study would have been negligent.

Today in BiDil because they took that risk, having confidence in their product, and ensuring that every care was taken to protect the interests of the cohorts, we are here asking for your approval for a drug that will save countless lives of African Americans, a drug which we would not have had if they had ignored the findings.

So why are we hesitating. This drug would not likely be approved for the larger population, because it did not prove efficacious in Whites who made up the vast majority of the first trial. Further, approving it for Blacks today does not prohibit further studies from being done in other groups.

Neither does it cast any negative stigma on African Americans because it would be indicated specifically for us. We have long been stigmatized by any number of false assumptions and superficial traits, which stigmatization is perpetuated today and works to our disadvantage, denial of our rights and even death – beginning with the simple color of our skin. Would you deny us life now rather than do what the evidence shows can and should be done?

I have read some of the opponent's papers, and I think many of the points of concern they raise are legitimate and serve to offer protections for future drug investigations and trials.

We know that all of us no matter the color of our skin, or race or ethnic origin are 99% the same genetically. Approving BiDil as a drug for African Americans doesn't change that. Nowhere have I read in the study or subsequently heard that the choice of cohorts in A-HeFT was based on genetics or specific alleles.

The identification as "Black' was self described, and that term as we all agree, connotes not just the less than 1% difference, but it appears to override the far more genetic differences that exist among us, and "Black" as self described, would also include all of the "social forces and biological feedback loops" that Dr. Troy Duster admonishes us to understand.

The position of the CBC on the approval of BiDil is clear and unequivocal. It should be approved and indicated for use in African Americans.

We are not only cognizant of the many social, political and economic variants which define being an African American is in this country.

Addressing these and eliminating the disparities that exist in all aspects of our lives remains our highest priority until these gaps are closed.

Their continued existence despite our best efforts must not be used to deny treatment to those for whom treatment has been denied and deferred for 400 years. Today this panel is being asked to begin to reverse that.

Knowing that diseases are expressed differently in different racial and ethnic groups, the challenge is not to avoid research but to act appropriately when this research is conducted and reported and to commit to the continuous education of physicians and patients so that these drugs can be appropriately used. It is also critical that we continue the kind of research that was inherent in the promise of the decoding of the human genome, whereby we move closer and closer to identifying targeted treatments and more precise measures than race for determining the effectiveness of a treatment.

Finally it is our hope that the experience of A-HeFt and BiDil will encourage wider inclusion of minority patients and women in clinical trials, a position that the CBC has long encouraged and advocated.

The results of A-HeFT could not be clearer in demonstrating that BiDil can save thousands of lives, and reduce untold suffering for African American heart failure patients and their families.

I commend FDA for encouraging the inclusion of people of color in clinical trials. We encourage you to do more. We also applaud their role in helping to design the A-HeFT trial to assess the safety and effectiveness of BiDil to treat heart failure in African American patients.

I ask that you consider our perspective – the perspective of African American elected representatives --in your review and decision on BiDil