National Medical Association

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National Medical Association
Statement Before the Food and Drug Administration (FDA)
Cardiovascular and Renal Drugs Advisory Committee
Review of NitroMed's New Drug Application (NDA)
Re: BiDil (and the AHeFT Study)
Gaithersburg, MD.
16 June 2005

Ladies and Gentlemen of the Cardiovascular and Renal Drugs Advisory Committee, thank you for the privilege of contributing to this process. I am Dr. Lucy Perez, a Past President of the National Medical Association, the organization for which I speak this afternoon.

On behalf of over 30,000 African American physicians, and hundreds of thousands of African Americans burdened with heart disease all over our nation, I would like to thank you for your open-mindedness in considering this most promising therapy.

The NDA in question, (NDA) 20-727, quotes official FDA correspondence to NitroMed in 2001 wherein it states:

"given the subset finding and the overall trend toward a survival effect in V-HeFT I, we believe a single, clearly positive study in a black CHF population would be a basis for approval of BiDil for the treatment of heart failure in Blacks".

Per the FDA's suggestion, such a trial has been conducted and the results are now a matter of public record. As you have already heard, patients receiving BiDil in addition to current standard therapies compared to patients receiving current therapies and placebo experienced a:

- **43 percent reduction in mortality (10.2 percent vs. 6.2 percent; P=0.012)**
- **39 percent reduction in first hospitalization for heart failure (16.4 percent vs. 24.4 percent; P<0.001)**
- **Improvement in quality of life (P=0.02).**

Given that all of the above 'p' values are less than 0.05, statistical significance can be established without question.

And given that this trial meets the standard set by the FDA of "a single, clearly positive study in a black CHF population," this study's incontrovertible results should not be obscured by invalid ethical concerns or perceived political objections.

We are convinced that given the disproportionate impact of cardiovascular disease on African Americans, anything short of approval of BiDil for use in this population cannot be justified, and would be tantamount to FDA disavowing its written and totally sound commitment in 2001.

The NMA would therefore urge this Committee to recommend to the FDA, without qualification, that BiDil be approved. We join several organizations in this request, including the International Society on Hypertension in Blacks; the Association of Black Cardiologists; National Association for the Advancement of Colored People; Alliance of Minority Medical Associations; and the National Minority Health Month Foundation. Several additional partners are aligned with us in supporting the approval of BiDil.

African Americans continue to die from heart disease at the alarming rate of about 78,000 a year. This number could be significantly reduced if BiDil is brought to market as soon as possible.

Thank you, ladies and gentlemen, for your attention.