NATIONAL Minority Health Month FOUNDATION

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TESTIMONY BEFORE THE
FDA CARDIOVASCULAR AND RENAL DRUGS ADVISORY COMMITTEE
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Good Afternoon. My name is Gary Puckrein. I am Executive Director of the National Minority Health Month Foundation. I am here to testify in support of NDA 20-727, the new drug application submitted by NitroMed, Inc. for BiDil®. The National Minority Health Month Foundation has received an unrestricted educational grant to undertake epidemiological research on chronic heart failure patients.

The efficacy of BiDil® has been researched over two decades, beginning with the Veterans Affairs Vasodilator-Heart Failure Trials (V-HeFT I and II), which were conducted in Veterans Administration hospitals from 1980 through 1990, and culminating with the African-American Heart Failure Trial, which ended in 2004. As evidenced by the A-HeFT results, approval of BiDil® will have an immediate and positive impact on the health and quality of life of many patients with heart failure. Further, the lessons learned from the A-HeFT protocol will contribute to the experiential database required to advance progress toward personalized medicine and improve the quality of health care for all Americans.

In supporting the approval of BiDil® based upon the A-HeFT results, I assert no absolute or implied correlation between "social race" or genotype, and the efficacy of BiDil®.

- I support BiDil® because it will *extend* the life of many Americans with heart failure.
- I support BiDil® because it will improve the *quality* of life for many Americans with heart failure.

I understand that for the purposes of A-HeFT, self-identified social race was used to define an African-American/Black patient population. An analysis of the A-HeFT results demonstrated that a subset of this patient cluster responded favorably to BiDil®. It is my understanding that the A-HeFT researchers do not assert that all African-American/Black heart failure patients will benefit from BiDil®, nor that A-HeFT demonstrates that BiDil® will not be effective in other population groups that can be categorized by "social race". The results of the trial cannot be read to mean that it works on all African-Americans/Blacks or that it will not work in Caucasians/Whites or other self-identified racial groups. Further, it is my understanding that A-HeFT also demonstrated that adverse clinical effects did not present in the patients in the clinical trial who did not respond to BiDil®.

Access to BiDil® will reduce mortality rates and improve the quality of life for some Americans with Health Failure, as well as lower the personal and societal costs of treating this condition. Conversely, lack of access to BiDil® has the potential to create avoidable human and fiscal resource demands on the health care delivery and financing system and, most importantly to unnecessarily compromised health status for thousands of Americans. To attain this goal, BiDil® must be a part of the standard armamentarium of treatment modalities available to physicians who treat patients with Heart Failure.

We all recognize that the race and ethnic categories that we are currently using are non-anthropologic (in other words, not scientifically based). They are categories that describe the socio-cultural construct of our

society. New science is compelling us all to delineate more precisely when and how these constructs can be invoked. For the purposes of the A-HeFT trial, the compromise was made to use these socio-cultural constructs to identify a patient population who will find benefit in this new medication. Some geneticists and social scientists denounce this accommodation as unscientific -- but they cannot offer us an immediate alternative to identify these patients. Others suggest that this medication should be withheld and, by that fact, would allow critically ill patients to die as we devise new nomenclature, or identify the specific physiological or biological markers, that will permit us to transcend disproved notions of race.

The more prudent decision is to accept A-HeFT and the benefits that it portends, while clearly stating the obvious – that "social race" provides us with an imperfect reflection of the physiological and biologic markers for one population in which BiDil® I is effective. My support, therefore, can and should in no way be construed as support for designation of BiDil® as a race drug.

In closing, we have an imperfect, sometimes inaccurate, often misused, frequently offensive taxonomy of "social race" which is, at best a proxy for a host of environmental, biological, cultural and socio-economic impactors on health. As a historian, I am fully cognizant that resolutions to the aforementioned issues that are acceptable and defensible will take time, research, resources and a sea change in this country's collective understanding and valuing of the intrinsic nature of humanity. I am also cognizant that genomic science is at a tipping point that must not be compromised by oversight or expedience. We all seek a more evolved answer.

But what are we to do in the interim?

I, for one, will not sacrifice one more life while we engage in that which is destined to be an extended, exhilarating, often exasperating investigation. I encourage the Department of Health and Human Services, the pharmaceutical industry, and other public and private sector partners to join us in that forward momentum.

In the interim, I request that you approve BiDil® with the most inclusive language possible.

The benefits are documented and the need is dire.

Thank you.