
PETITION

of

WASHINGTON LEGAL FOUNDATION

to the

**CENTERS FOR MEDICARE AND MEDICAID SERVICES
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Concerning

**COVERAGE FOR BIDIL
UNDER FEDERAL HEALTH CARE PROGRAMS**

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August 7, 2008

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Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
Room 413G
200 Independence Avenue
Washington, DC 20201

Re: Petition to Revise CMS Reimbursement Policies Regarding BiDil®

Dear Mr. Weems:

The Washington Legal Foundation (WLF) is writing to express its unhappiness over reimbursement policies adopted by the Centers for Medicare and Medicaid Services (CMS) regarding the drug BiDil®. BiDil is a drug approved by the Food and Drug Administration for treating heart failure among African-American patients. CMS has never suggested that BiDil is not effective, or that the Food and Drug Administration (FDA) has approved an alternative drug with equivalent approved indications. CMS nevertheless has engaged in a course of conduct that discourages doctors from prescribing BiDil for their patients and makes it difficult for those who do so to obtain reimbursement.

The predictable results: BiDil sales have lagged and, more importantly, undertreatment of heart failure among blacks continues to be a major health care problem. Fewer than 2% of all black Medicare beneficiaries suffering from heart failure are being treated with BiDil. Given that blacks suffer from heart failure at rates more than twice that of whites, the undertreatment problem is not only a health care issue but also one raising concerns regarding racial equality. WLF respectfully suggests that under these circumstances, CMS's conduct opens the agency up to allegations of racial insensitivity.

WLF hereby petitions CMS to reverse its policies that have discouraged reimbursement for use of BiDil. WLF does not believe that those policies are based on sound science, sound legal analysis, or sound public policy. WLF urges CMS to adopt as a goal the use of BiDil by a significant percentage of the African-American population suffering from heart failure.

I. Interests of the Washington Legal Foundation

WLF is a public interest law and policy center based in Washington, D.C., with supporters in all 50 States. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government. In particular, WLF devotes a substantial portion of its resources to promoting patients' rights and improved health care. For example, WLF has worked to improve patient access to developmental drugs. *See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (*en banc*), *cert. denied*, 128 S. Ct. 1069 (2008). WLF successfully challenged FDA restrictions on patient access to speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). WLF is currently involved in litigation with CMS over CMS's restrictions on patient access to truthful information about insurance benefits available under Medicare Part D. *Fox v. Leavitt*, No. 06-1490(RMC) (D.D.C.). WLF regularly submits formal comments to CMS in regulatory proceedings, in support of increased patient access to medical care. For example, WLF submitted comments to CMS on February 10, 2004, and June 25, 2004, concerning Medicare coverage of off-label uses of FDA-approved cancer drugs under Part B, Part D, and the Section 641 demonstration program. WLF also submitted comments to CMS on June 6, 2005, concerning the agency's draft guidance entitled, "Factors CMS considers in Making a Determination of Coverage with Evidence Development." On June 13, 2007, WLF submitted comments to CMS concerning the agency's "Proposed Decision Memorandum for Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Disease Indications." Most recently, WLF filed comments with CMS on July 28, 2008, regarding the treatment of physician-owned implant companies and other medical device companies under the Physician Self-referral Law (the "Stark Law").

WLF's interest in CMS's policies toward BiDil is based solely on its interests in improved patient care and ensuring that government policymakers are sensitive to the manner in which their policies are perceived by members of various racial and ethnic groups. WLF has no financial interest in the matters raised herein. In particular, WLF has no financial ties to the manufacturer of BiDil.

II. Background.

Chronic heart failure is the term often used to describe a condition in which the heart loses its ability to meet the demands of the body due to an inadequate output. More than five million Americans suffer from heart failure, with more than 500,000 new cases being diagnosed each year. Because heart failure results in nearly one million hospitalizations each year, treatment costs are huge; the most recent American Heart Association study estimated annual treatment costs at \$34.8 billion.

Pharmacological advances in recent decades have greatly improved the medical profession's ability to treat heart failure; administering drugs is now by far the most widely used method of treating the condition. Moreover, increased use of drugs is associated with decreased hospitalization, thereby reducing treatment costs. The most effective drugs have been angiotensin-converting enzyme (ACE) inhibitors. Numerous studies have shown that use of ACE inhibitors decreases hospitalizations, improves symptoms, delays disease progression, and prolongs life expectancy.

However, for reasons not well understood, ACE inhibitors have proven to be less effective in treatment of heart failure within one well-defined segment of the population: African-Americans. That reduced effectiveness is particularly troubling because, as noted above, black Americans suffer from heart failure at rates more than twice as high as those for other Americans. The reduced effectiveness of existing drugs among African-Americans led to a search for new drugs and, ultimately, the development of BiDil.

NitroMed, a Massachusetts-based pharmaceutical company, has conducted a series of clinical trials to test the efficacy of using a combination of two unpatented compounds – isosorbide dinitrate (ISDN) and hydralazine hydrochloride (HYD) to treat heart failure. Two trials, the Vasodilator-Heart Failure Trial I and II (“V-HeFT I” and “V-HeFT II”), were conducted in the 1990s. Those trials demonstrated that a combination of ISDN and HYD outperformed a placebo in treating heart failure, but FDA declined to approve NitroMed's proposed drug because it did not outperform enalapril, an ACE inhibitor that served as the basis of comparison in V-HeFT II.¹

Subsequent medical evidence indicated that African-Americans heart failure patients did not respond nearly as well as did white patients to ACE inhibitors. That led to a retrospective analysis of the data from V-HeFT I and V-HeFT II; the analysis revealed that patients who identified themselves as black responded much better to the ISDN/HYD combination than did those who identified themselves as white. The analysis prompted FDA to encourage NitroMed to undertake a new clinical trial beginning in 2001 (the African-American Heart Failure Trial, or “A-HeFT”) among self-identified African-Americans suffering from heart failure. The results of that trial were dramatic. Those receiving standard therapy plus a fixed-dose combination of ISDN and HYD showed a 43% improvement in survival and a 33% reduction in the rate of first

¹ See Salma Lemtouni, *Clinical Review: NDA 20-727*, FDA (June 7, 2006) at 45 (available at http://www.fda.gov/phrms/dockets/ac/05/briefing/2005-4145B2_01_02-FDA-Medical-Review.pdf (last visited August 4, 2008)).

hospitalizations for heart failure, over those who received standard therapy plus a placebo.² The death rate fell so dramatically for those receiving ISDN/HYD that the board monitoring the trial recommended its early termination so that those on placebo would not continue to be denied access to the drug.

Based on that trial data, FDA in 2005 approved BiDil®, the brand name given by NitroMed to the fixed-dose combination of 20 mg of ISDN and 37.5 mg of HYD, as a new drug for the treatment of heart failure among African-Americans. The approval decision was somewhat controversial; critics suggested that race-based drug approvals could have adverse impacts on a society that at times has difficulty accepting that humans of all skin colors are largely similar to one another. But FDA officials explained that those critics “d[id] not appreciate the urgency of strong scientific evidence of a survival benefit in black patients”; delay in approval, for the purpose of identifying a subset of the white population that might experience similar benefit from BiDil, would result in numerous unnecessary deaths among African-Americans.³

Medical experts outside FDA concur regarding the importance of BiDil in the treatment of heart failure among blacks. The American Heart Association (AHA) ranked the development of BiDil as #2 among “the top ten research advances in heart disease and stroke” for 2004. In 2006, the Heart Failure Society of America included the use of the fixed-dose combination of ISDN and HYD as the standard of care in the treatment of heart failure in blacks and issued a “strong recommendation” for its use. The Task Force on Practice Guidelines of the American College of Cardiology (ACC) and the AHA deems the use of the ISDN/HYD combination to be “reasonable” and states that it “can be effective in blacks” suffering from heart failure. The recently released guidelines of the AHA’s Council for High Blood Pressure Research state that “the addition of hydralazine/isosorbide dinitrate (BiDil) should be considered” in managing hypertension among black patients with or at risk of coronary artery disease.⁴

Unfortunately, despite the fanfare that accompanied BiDil’s launch in July 2005, and the endorsement of its use by numerous medical authorities, African-American heart failure patients

² Ann L. Taylor, *et al.*, “Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure,” 351 N. ENGL. J. MED. 2049-2057 (Nov. 11, 2004).

³ Robert Temple, *et al.*, “BiDil for Heart Failure in Black Patients: The U.S. Food and Drug Administration Perspective,” 146(1) ANNALS OF INT. MED. 57-62 (Jan. 2, 2007).

⁴ Amber Huntzinger, “AHA Releases Guidelines for Hypertension Management in Adults with or at Risk of CAD,” 78 AM. FAM. PHYS. 271 (July 15, 2008). *See also*, Laura Smoot, “Caring for the Failing Heart,” 152 CONTIN. EDUC. 44 (June 16, 2008).

are not being prescribed the drug in any significant numbers. By some estimates, no more than 2% of blacks who could benefit from the drug are receiving it. For the final quarter of 2007, NitroMed reported that doctors wrote fewer than 31,000 prescriptions for BiDil.

The tepid sales have been disastrous for NitroMed, whose sole product is BiDil. Total revenues have barely exceeded \$3 million per quarter for BiDil, a product for which analysts initially estimated annual sales of \$625 million based on BiDil's use by 750,000 black heart failure patients. As a result, NitroMed announced in January 2008 that it was laying off its *entire* sales force. Thus, although BiDil sales continue, the lack of any active marketing makes it unlikely that the undertreatment of black heart failure patients will be rectified any time soon. As explained below, WLF respectfully suggests that much of the undertreatment is the product of misguided CMS coverage policies.

III. Generic Alternatives.

CMS's sole objection to the widespread use of BiDil appears to be cost-based. As we understand CMS's position, it does not question BiDil's effectiveness in treating heart failure among African-American patients. CMS argues that a combination of less expensive generic drugs provides the same therapeutic benefits as BiDil. But there is no scientific evidence to support that conclusion; more importantly, the supposed benefits of the generic combination are purely theoretical at this point. Very few doctors are prescribing the combination – an unsurprising result given the absence of any labeling for such prescriptions. Moreover, the likelihood that the pharmaceutical industry will make future investments leading to breakthrough discoveries equivalent to those uncovered in the A-HeFT study is greatly diminished if CMS continues to act in a manner so likely to undermine the patent system established by Congress.

The issue of generic substitution arises because BiDil consists of the combination of two compounds – ISDN and HYD – that have been approved for marketing by FDA for many years and are not protected by patents (and thus are relatively inexpensive). But neither product has ever been approved for treatment of heart failure, nor is there medical evidence suggesting that either compound is effective by itself in treating heart failure among black patients. HYD is approved by FDA for treating hypertension, either alone or as an adjunct. ISDN is indicated for the prevention of angina pectoris due to coronary artery disease.

Medical researchers have developed a number of theories regarding why ISDN and HYD in a fixed-dose combination are effective in treating heart failure among black patients while neither drug by itself is effective. It is known that ISDN is a vasodilator with effects on both arteries and veins; the dilation properties of nitrates result from the release of nitric oxide that leads to the relaxation of vascular smooth muscle. African-Americans are thought to be less able to produce nitric oxide than are other segments of the population. HYD is thought to enhance

the effects of ISDN by enhancing the bioavailability of nitric oxide.

There is no clinical evidence demonstrating that the same medical benefits are obtained when ISDN and HYD are prescribed separately. CMS nonetheless has taken steps designed to encourage Medicare Part D insurers not to include BiDil on their formularies and instead to encourage generic substitution. Those steps in turn have encouraged state Medicaid programs and private insurers to impose similar limitations on reimbursement for BiDil. WLF respectfully suggests that such steps are badly misguided and petitions CMS to reverse course and to adopt a policy of encouraging coverage for BiDil among black heart failure patients.

IV. Lack of FDA Approval and Other Practical Obstacles to Generic Substitution

Whatever else one can say about CMS's efforts, it is largely uncontested that they have been a practical failure: very few physicians are prescribing a combination of generic ISDN and HYD to their black patients suffering from heart failure. The combination of that failure with CMS's efforts to block coverage for BiDil has had catastrophic consequences: heart failure continues to be severely undertreated among African Americans despite the ready availability for the past three years of a breakthrough treatment.

The paucity of generic substitution is hardly surprising. FDA has not approved either ISDN or HYD for treatment of heart failure, and thus neither product contains any labeling to guide physicians in how to administer them for that purpose. Moreover, FDA has stated explicitly that the combination of ISDN and HYD, prescribed separately, is not bioequivalent to the fixed-dose combination provided by BiDil.

Moreover, neither generic ISDN nor generic HYD is approved for sale in a dosage that allows patients to obtain the same combination of the drugs provided by BiDil. BiDil is a fixed-dose combination of 20 mg of ISDN and 37.5 mg of HYD. While generic ISDN is available in a 20 mg dose, HYD is available only in 10, 25, 50, and 100 mg doses. Thus, doctors prescribing a "generic substitute" would need to ask their patients to divide their HYD pills and take a significantly increased number of pills. Any such request significantly increases the risk that patients will not comply with the drug regimen. When one considers that BiDil itself is a three-times-a-day medication and is generally administered in combination with other medications (such as ACE inhibitors), the risk of noncompliance with the multi-pill "generic substitute" – and the resultant loss of health benefits for African-Americans – becomes intolerably high. In light of those risks, there should be little wonder why doctors do not prescribe CMS's recommended "generic substitute."

Alternatively, doctors could prescribe ISDN and HYD in dosages that do not precisely mimic BiDil's fixed dose combination. But there is *no* medical evidence to support the efficacy of such prescriptions. The only relevant clinical study performed to date regarding treating black

heart failure patients is the A-HeFT; the only combination proven effective by that study was the fixed-dose combination contained in BiDil: 20 mg of ISDN and 37.5 mg of HYD. FDA has approved that fixed-dose combination as safe and effective in treating black heart failure patients. CMS should not be placing itself in the position of second-guessing FDA's scientific judgments by recommending other combinations of ISDN and HYD, particularly where it lacks any clinical evidence as a basis for doing so. And it is unsurprising that doctors have not been going along with such recommendations.

IV. Cost Effectiveness.

CMS undoubtedly has opposed coverage for BiDil because it believes that doing so reduces federal Medicare and Medicaid expenses. If CMS can convince doctors to prescribe a "generic substitute" in place of BiDil, the thinking apparently goes, then federal expenditures will decrease – because the price of BiDil is significantly higher than the price of generic ISDN and generic HYD.

But even if CMS were correct that its proposed generic substitute were just as effective as BiDil in treating heart failure among blacks – a proposition for which there is no medical evidence – CMS's thinking is flawed because its initial premise is unsound. For the reasons explained above, CMS has not been able to convince more than a negligible number of doctors to prescribe CMS's proposed generic substitute. Thus, any evaluation of CMS cost savings necessarily entails comparing the costs of BiDil to the costs of confining the treatment of black heart failure patients to standard therapies.

According to a pharmacoeconomic analysis published in December 2005, the issue is not even close: prescribing BiDil to black heart failure patients as an adjunct to standard therapies results in far fewer medical expenditures than if BiDil is not prescribed.⁵ The analysis examined health care costs incurred by patients who participated in the A-HeFT clinical trial. The analysis concluded that patients who were given BiDil incurred significantly fewer costs than those given a placebo, due primarily to substantial reductions in both the number and length of heart failure-related hospitalizations. Use of BiDil versus placebo during the follow-up period resulted in per-patient savings of \$533 for heart failure-related costs and savings of \$1,730 for total direct healthcare costs. The analysis also projected the cost per life-year saved by comparing the cost of BiDil based on the duration of time the therapy prolonged life on average to the overall cost of treatment for heart failure patients not given BiDil. Those per-year costs were determined to be

⁵ Derek C. Angus, *et al.*, "Cost Effectiveness of Fixed-Dose Combination of Isosorbide Dinitrate and Hydralazine Therapy for Blacks with Heart Failure," 112 *Circulation: Journal of the American Heart Assoc.* 3745-3753 (Dec. 2005).

well below \$50,000 at one, two, and five years as well as over the course of the life of the average patient.⁶ Moreover, the reported cost savings do not take into account the value that African-American patients place on their improved quality of life (*e.g.*, a reduction in the time spent in the hospital).

In sum, CMS is being penny-wise and pound-foolish in opposing coverage for BiDil. Expanding coverage for BiDil will lead to reduced Medicare and Medicaid expenses (by reducing hospitalization and other healthcare costs), in addition to providing significantly improved healthcare for African-Americans.

V. The Department of Veterans Affairs Review.

In responding to critics of its policies regarding BiDil, CMS has pointed to a review conducted by the U.S. Department of Veterans Affairs regarding the drug's cost-effectiveness (hereinafter, the "VA Review").⁷ But the VA Review did little more than state the obvious: BiDil costs more than generic ISDN and HYD. It made virtually no effort to determine whether administering generic ISDN and HYD to black heart failure patients is as effective as administering fixed-dose BiDil to those same patients. Accordingly, CMS is not on solid scientific ground in citing the VA Review in support of its opposition to providing coverage for BiDil.

The VA Review is a cursory, 10-page discussion of BiDil and the three clinical studies that preceded its approval as a new drug by FDA. It apparently concluded (although it did not say so explicitly) that the "generic substitute" is just as effective as BiDil in treating black heart failure patients. It apparently reached that conclusion based on the results of V-HeFT I and V-HeFT II; it noted that those two studies had entailed separate administration of ISDN and HYD (at varying dosages), rather than BiDil's fixed-dose combination (20 mg of ISDN and 37.5 mg of HYD) in a single pill. The VA Review concluded that because V-HeFT I & II had shown that the separate administration of ISDN and HYD was more effective in reducing mortality among heart failure patients than was a placebo, the separate administration of the generic drugs at

⁶Health economists generally deem a drug therapy to be cost-effective if it extends life by a year at a cost of under \$50,000.

⁷ See Veterans Health Administration Pharmacy Benefits Management Strategic Health Care Group and the Medical Advisory Panel, *National Formulary Review: Combination Isosorbide Dinitrate/Hydralazine (Bidil®)* (April 2006) (available at <http://www.pbm.va.gov/monograph/ISDNHydralazineFormularyReview.pdf> (last visited August 6, 2008)).

varying dosages must be as effective as BiDil in treating heart failure among African-American.

That (unstated) conclusion is an example of junk science at its worst. What the VA Review fails to mention is that following V-HeFT I & II, FDA *refused* NitroMed's application to market a combination ISDN/HYD product. In other words, FDA deemed those two studies insufficient to demonstrate the product's effectiveness, even within specific sub-populations such as African-Americans. Only after NitroMed completed A-HeFT (which focused on the effectiveness of the fixed-dose product among African-Americans) did FDA approve NitroMed's NDA. Moreover, to point out merely the more obvious deficiencies in the VA Review's conclusion, V-HeFT I & II were not confined to black patients, were not confined to patients who were also receiving standard therapy, and did not compare the effectiveness of administering ISDN and HYD at various relative doses.

The VA Review also stated that its review of VA records showed that 12,626 VA patients who had been prescribed HYD had also been prescribed a nitrate (either ISDN or ISMN, which the VA Review assumed, without explanation, was interchangeable with ISDN). *Id.* at 7. But the VA Review failed to explain the relevance of that showing, other than to state the obvious fact that generic HYD and generic ISDN/ISMN cost less than BiDil (and thus that switching those 12,626 patients to BiDil would entail increased costs). For example, the VA Review made no effort to trace the effectiveness of the treatment of those patients with HYD and ISDN/ISMN. The reason for that failure is obvious: the VA Review admitted that it had no idea how many of those patients were African-Americans or whether doctors had administered the combination of drugs to treat the same condition (*i.e.*, the VA knew only that the patients had received both sets of drugs but not whether that combination was more than a coincidence). Indeed, the VA Review admitted that it did not know whether the patients were even suffering from heart failure (after all, HYD, ISDN, and ISMN are not labeled for treatment of heart failure). In the absence of any evidence regarding why the drugs were being administered, to whom they were administered, and whether they were effective, the VA Review's citation to those 12,626 patients was wildly out of place in a study that was supposed to be measuring the cost-effectiveness of different drugs in treating a medical condition within a specified sub-population of veterans.⁸

⁸ The VA Review ultimately concluded, “[T]he fixed-dose combination [*i.e.*, BiDil] should be reserved for those patients with advanced HF where the clinician has determined that the patient is having difficulty adhering to the medication regimen due to the number of pills per day, and that switching to the fixed-dose combination would decrease the pill burden and significantly improve adherence.” *Id.* at 8. Thus, even the VA Review recognized that the increased number of pills required by the “generic substitute” has the potential to generate significant healthcare problems.

No clinical studies have ever been performed on the effectiveness of the “generic substitute” in treating heart failure among African American patients. In the absence of such studies or any other reliable scientific evidence indicating that the “generic substitute” is as effective as BiDil, CMS has no defensible basis for actively blocking African-American Medicare and Medicaid patients from gaining access to BiDil.

VI. CMS Is Undermining the Patent System.

As a result of NitroMed’s pioneering studies, the medical community now has available to it important new information regarding the treatment of heart failure among African Americans. NitroMed was rewarded for its efforts with a patent on BiDil’s use for treatment of heart failure, as well as FDA-enforced exclusivity for the marketing of its drug. Those benefits would not have been conferred if the Patent Office and FDA had not determined that what NitroMed developed not only was safe and effective but also new and non-obvious. Congress adopted the patent system and the FDA exclusivity system as a means of rewarding companies that risk the vast sums of money necessary to discover and develop new therapies. By discouraging coverage for BiDil, CMS is second-guessing the determinations of the Patent Office and FDA that BiDil is a real advance in medical treatment.

WLF respectfully submits that CMS’s actions not only are contrary to Congress’s intent in establishing the patent and drug exclusivity system, but also are jeopardizing our nation’s ability to continue as a leader in pharmaceutical discoveries. CMS no doubt owes an obligation to American taxpayers to avoid unnecessary medical expenses. But reliance on pseudo-science like the VA Review suggests that CMS seeks at all costs to avoid paying the premium prices that Congress endorsed for innovative drugs as a means of encouraging continued research and development expenditures.

Price controls on prescription drugs – no matter how they may be disguised – stifle pharmaceutical research, with the inevitable result that fewer life-saving drugs will be developed. Moreover, the experience in Canada and elsewhere is that price controls inevitably lead to shortages both in drugs and medical services – without having any significant effect on costs. *See* “Prescription Drug Costs: Has Canada Found the Answer?,” National Center for Policy Analysis, Brief Analysis No. 323 (May 19, 2000). That study found:

The Canadian government purposely restricts the overall availability of prescription drugs through a combination of lengthy drug approval process and oppressive price controls. The result is that patients are often harmed. [¶] . . . Through limiting the availability of prescription drugs and controlling prices of those that are available, Canada has succeeded only in preventing Canadians from obtaining drugs that might have reduced hospital stays and expensive medical procedures. Despite prices on some

individual drugs that are lower than in the United States, Canada has been unable to hold down the overall cost of either prescription drugs or other health care. The result is a lower standard of health care at a higher cost than Canadian patients and taxpayers have a right to expect.

Id. Many economists believe that Europe's low rate of drug innovation in recent years vis a vis the United States is similarly attributable to the prescription drug price controls that are prevalent throughout Europe. See, e.g., Mary T. Griffin, *AIDS Drugs & The Pharmaceutical Industry: A Need for Reform*, 17 AM. J. L. AND MED. 363, 407 (1991).

On average, it costs anywhere from \$800 million to \$1.7 billion in research and development costs to get a drug approved for use in the United States. See, e.g., Robert P. Crouner, "Beware Price Controls in Name of Health," *The Detroit News* (Feb. 22, 2002) (citing Tufts University study indicating average cost of developing a new drug is \$802 million and that average time to bring a new drug to market is 10-12 years).⁹ Moreover, "only 10% of potential drug candidates reach the human trial phase and only a small portion of these actually reach the market." Wendy H. Schacht, *Patent Reform: Issues in the Biomedical and Software Industries* (Congressional Research Service, April 7, 2006) at 6. NitroMed had good reason to believe that it was among the lucky few when FDA approved BiDil for marketing. But thanks to CMS's willingness to second-guess FDA's determination, NitroMed is unlikely ever to recoup its investment. Innovator pharmaceutical companies will be far less willing to invest funds in development of promising new drugs if they come to believe that even when they successfully navigate the FDA bureaucracy and win FDA approval as the only company authorized to sell a drug for treatment of a well-defined medical condition, they will be denied Medicaid and Medicare coverage for that drug. Such a development would be a death sentence for the numerous patients who suffer from illnesses for which effective drug treatments have not yet been developed.

⁹ More recent estimates have increased that figure to as high as \$1.7 billion. See Pharmacy Times, "Drug Development" (Dec. 2005) (available at <http://www.pharmacytimes.com/Article.cfm?Menu=1&ID=2865>). Tufts University pegs the average cost of developing a new biotechnology product at \$1.2 billion. Tufts Center for the Study of Drug Development, *Average Cost to Develop a New Biotechnology Product Is \$1.2 Billion* (Nov. 9, 2006) (available at <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69>).

VII. CMS Policy Toward BiDil Suggests Racial Insensitivity.

CMS does not need to be reminded about the particular healthcare problems encountered in this country by African-Americans. Blacks have significantly shorter life expectancies than do white Americans. That discrepancy is at least partially attributable to the long history of discrimination encountered by blacks seeking adequate healthcare. Of particular relevance to the BiDil issue, blacks suffer from heart failure at rates nearly twice that of whites.

In light of the history of racial discrimination in the healthcare field, CMS's policy toward BiDil is particularly disturbing. BiDil is the first drug ever approved by FDA in the absence of evidence that it is effective within the general American population, but rather based solely on evidence that it is safe and effective when administered to African-Americans. FDA would not have taken that controversial step in the absence of solid evidence that BiDil provided a significant benefit to African-Americans suffering from heart failure. Yet in large measure as a result of CMS policies, the vast majority of black heart failure patients are not receiving that benefit, nor are they even receiving the combination of products that, according to CMS, constitutes the generic equivalent of BiDil. It is small wonder that prominent members of the African-American community – including many leading black physicians, the Association of Black Cardiologists, Members of Congress, and the NAACP – have seriously questioned CMS's policy. CMS's unwillingness to support coverage for the one drug approved solely for African-Americans, an unwillingness that undoubtedly is contributing to the woeful undertreatment of black heart failure patients, suggests insensitivity to the need for the federal government to lead the way in promoting racial equality in healthcare delivery.

WLF respectfully requests that CMS reconsider that policy. Creating the appearance of racial equality in healthcare delivery is at least as important a goal for CMS as is taking steps to eliminate unnecessary expenditures.

Mr. Kerry Weems
August 7, 2008
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Conclusion

The Washington Legal Foundation respectfully request that CMS adopt a policy of providing coverage for BiDil under Medicare, Medicaid, and all other federal healthcare programs, when prescribed to African Americans for treatment of functional Class III or IV heart failure.

Sincerely,

/s/ Daniel J. Popeo
Daniel J. Popeo
Chairman and General Counsel

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel