News Release

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FOR IMMEDIATE RELEASE **August 7, 2008**

WLF PETITIONS CMS TO REVISE REIMBURSEMENT POLICIES FOR BIDIL

The Washington Legal Foundation (WLF) today petitioned the Centers for Medicare and Medicaid Services (CMS) to revise its reimbursement policies regarding BiDil, a drug approved by FDA for treating heart failure among African-Americans.

WLF charged that CMS policy is aggravating a serious healthcare problem among blacks: the undertreatment of heart failure. 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 not only is a healthcare issue but also raises concerns regarding racial equality, WLF charged. WLF said that CMS is inappropriately denying insurance coverage for BiDil and instead promoting a less-expensive "generic substitute" -- even though FDA has determined that there is no generic substitute for BiDil.

"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," said WLF Chief Counsel Richard Samp after filing WLF's petition. "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," Samp said.

Extensive clinical trials conducted over the past 15 years demonstrated that while BiDil does not provide significant benefit for the overall heart failure patient population, it provides a significant benefit among self-identified African-Americans. Accordingly, FDA in 2005 granted marketing approval for BiDil (the brand name given to a fixed-dose combination of isosorbide dinitrate (ISDN) and hydralazine hydrochloride (HYD)) as a new drug for the treatment of heart failure among blacks. Medical experts outside FDA concur regarding the importance of BiDil in the treatment of heart failure among blacks.

Nonetheless, black heart failure patients are not being prescribed the drug in any significant numbers. A principal reason for the tepid sales is that CMS opposes reimbursement for BiDil under Medicare, Medicaid, and other federal healthcare

programs. CMS contends that patients instead should be provided separate prescriptions for ISDN and HYD, two generic drugs that are considerably less expensive than BiDil. But for a variety of reasons, doctors are reluctant to adopt CMS's proposed generic substitute. Those reasons include: (1) ISDN and HYD are not available in prescription sizes that match the fixed-dose combination offered in BiDil -- the only combination determined to be effective in clinical trials; (2) because neither ISDN nor HYD is approved for treatment of heart failure, there is no labeling available to guide doctors in making such prescriptions; and (3) asking patients to take many more pills each day substantially increases the likelihood that patients will not comply with treatment regimens.

The result is that fewer than 2% of all black heart failure patients are being prescribed a medication that has been shown to decrease mortality by more than 43%. Slow sales recently forced BiDil's manufacturer to lay off its entire sales force, meaning that improved treatment is unlikely to come about any time soon unless CMS reverses it policy.

WLF also argued that CMS's non-reimbursement policy is penny-wise but pound-foolish. It cited studies demonstrating that increased usage of BiDil actually leads to reduced overall healthcare expenditures, due primarily to substantial reductions in both the number and length of heart failure-related hospitalizations.

WLF also argued that by second-guessing the determinations of the Patent Office and FDA that BiDil is a real advance in medical treatment, CMS is undermining the patent system. WLF argued that 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.

WLF is a public interest law and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts to promote economic liberty and a limited and accountable government. In particular, WLF devotes a substantial portion of its resources to promoting patients' rights and improved health care.

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For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's comments is posted on WLF's web site, www.wlf.org.