

APPEALS COURT OPENS DOOR TO SUITS ON MEDICARE AGENCY DECISIONS

by
David Price

In a decision of importance to pharmaceutical companies and other sectors of the health care industry, the U.S. Court of Appeals for the District of Columbia Circuit recently ruled that drug makers have standing to challenge reimbursement policies of the Centers for Medicare and Medicaid Services (CMS), the unit of the U.S. Department of Health and Human Services that administers the Medicare program.

The ruling in *Amgen Inc. v. Smith*, 2004 U.S. App. LEXIS 2406 (Feb. 13, 2004), overturns a contrary district court decision, which found that drug makers are not within the zone of interests protected by the Medicare statute, and thus lack standing to sue. Under the district court's view of the Medicare statute, only patients (and possibly providers) had standing to challenge reimbursement decisions. In reversing that holding, the appeals court decision noted, "Parties motivated by purely commercial interests routinely satisfy the zone of interests test under this court's precedents," and determined that "Amgen's interests are sufficiently aligned with the purpose of [the statute] in ensuring the access of Medicaid beneficiaries to new technology. . . ." The D.C. Circuit also rejected the Fourth Circuit's contrary holding in *TAP Pharmaceuticals v. HHS*, 163 F.3d 199 (4th Cir. 1998).

The D.C. Circuit's ruling did not have the effect of reviving the underlying lawsuit, however. That suit is a challenge to CMS's decision to treat Amgen's anemia drug Aranesp as functionally equivalent to Ortho Biotech's drug Procrit, a move that meant hospitals would not receive supplemental "pass-through" reimbursements for Aranesp as a new drug. While siding with Amgen on the issue of standing, the appeals court went on to hold that Congress had precluded judicial review of CMS decisions concerning adjustments to pass-through payments under CMS's Outpatient Prospective Payment System.

The *Amgen* decision on standing is likely to take on added significance as CMS implements the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Act provides Medicare beneficiaries with discounts on prescription drugs starting in Spring, 2004, and also establishes Medicare prescription drug coverage effective January 1, 2006. By opening the door to lawsuits by drug makers (and presumably by medical device OEMs), the D.C. Circuit has increased the likelihood of judicial scrutiny of CMS's policy decisions turning the reform law into practice.

David Price is Senior Vice President, Legal Affairs of the Washington Legal Foundation.

About WLF and the COUNSEL'S ADVISORY

The Washington Legal Foundation (WLF) is the nation's largest non-profit, free enterprise public interest law and policy center. WLF litigates *and* publishes in order to advocate legal policies that promote economic growth, job creation, and the civil liberties of business. As a 501(c)(3) tax exempt organization, WLF relies upon the charitable support of individuals, businesses, associations, and foundations to fund its programs.

This COUNSEL'S ADVISORY is one of WLF's seven publication formats. Its purpose is to inform the free enterprise community about a development in the legal policy world that can be favorably influenced by the immediate involvement of legal experts and business and community leaders.

For more information on the Washington Legal Foundation, please contact Daniel J. Popeo, Chairman, at (202) 588-0302.