Amgen Submits Testimony to House Ways & Means Committee

December 6, 2006

Given the State of Evidence and Current Regulatory Policy, Amgen Questions the Justification for Congress to Legislate Medical Practice, and Addresses Significant Risks to Patient Quality and Access

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Dec. 6, 2006--Amgen (NASDAQ:AMGN), today submitted testimony for the record of the Committee on Ways & Means hearing on "Patient Safety and Quality Issues in End Stage Renal Disease Treatment." In its testimony, Amgen reinforces the patient benefits of EPOGEN(R) (Epoetin alfa) and underscores the quality of care and safety of EPOGEN when used in accordance with the Food and Drug Administration (FDA) approved product labeling. Amgen also documents that the majority of physicians use EPOGEN appropriately and notes that current Center for Medicare & Medicaid Services (CMS) policies are consistent with the FDA label, and that CMS policy ensures appropriate EPOGEN utilization for Medicare beneficiaries. Amgen calls for completion of the already-mandated CMS bundling demonstration project before implementing a new payment policy that bundles dialysis services with separately billable dialysis drugs. Unless sophisticated and complex case-mix adjustment and quality safeguards are studied in the CMS demonstration project and appropriately analyzed, premature, incomplete changes in payment policy could put patients at serious risk and providers subject to financial impairment.

The introduction of EPOGEN in 1989 revolutionized the management of anemia in dialysis patients, reducing the need for potentially risky blood transfusions and improving quality of life by reducing fatigue, increasing energy levels, and improving physical function. EPOGEN has been shown to be safe and effective in multiple clinical trials with over a decade and a half of safety monitoring in more than 1.5 million dialysis patients.

"Those of us who experienced the transition from the pre-EPOGEN to post-EPOGEN era first hand, recognize this to be one of the most important advances in the delivery of care for dialysis patients," says Roger M. Perlmutter, M.D., Ph.D., executive vice president of Research and Development at Amgen. "Amgen is committed to the highest standards of patient safety. The well-being of patients is Amgen's top priority as is the appropriate use of all of our products," said Perlmutter. When used according to the FDA approved product labeling, which recommends that physicians target hemoglobin not to exceed 12 grams per deciliter (g/dL), the safety of EPOGEN is well-established and widely accepted.

Recent clinical studies published in the New England Journal of Medicine, the CREATE and CHOIR studies, evaluated non-dialysis patients whose maintenance hemoglobin levels were targeted to exceed substantially the recommended target levels on Epoetin's FDA approved label. "The recent CHOIR data raises some medical questions that should be thoughtfully considered," states Perlmutter. "However, there are some limitations to these studies that make it challenging to draw definitive conclusions." Amgen supports the recent FDA advisory on appropriate use of EPOGEN, and has proactively delivered copies to U.S. nephrologists.

Amgen submitted testimony also notes that hemoglobin levels in dialysis patients fluctuate greatly, and that single measures of hemoglobin as reported in the United States Renal Data System provide an incomplete picture of anemia management. "The key question to be answered is whether doctors are increasing or decreasing dose in response to these temporary fluctuations to bring patients into the target hemoglobin range. When hemoglobin levels are examined over time, we have observed that doctors are utilizing EPOGEN appropriately the majority of the time, without evidence of systemic overuse."

Since its inception, the CMS coverage policy for EPOGEN has been consistent with the FDA approved label. The claims monitoring policy (also known as the Erythropoietin Monitoring Policy or EMP) explicitly refers to the coverage policy for EPOGEN as well as the FDA label in the manual instructions, and ensure appropriate EPOGEN utilization for Medicare beneficiaries.

Commenting on the CMS EMP in last week's Inside CMS article, CMS's Chief Medical Officer, Barry Straube, M.D. said that CMS claims data, as well as data from large dialysis provider Fresenius Medical Care North America, demonstrate that patient hemoglobin levels have fallen since the implementation of the EMP. This suggests that the new CMS policy is having its intended effect of enforcing appropriate utilization. "Any changes to the policy should be rigorously considered based on input from physicians and other experts," said Joshua Ofman, M.D., M.S.H.S., vice president of Global Coverage and Reimbursement at Amgen.

The testimony also addresses the Committee concerns about rising CMS expenditures for EPOGEN. The increased expenditures are the result of steady growth in the dialysis patient population, meaningful improvement in meeting CMS' quality standards on dialysis patient health and an increasingly sicker dialysis population with higher EPOGEN requirements to achieve the desired hemoglobin levels. "A major factor has been the tremendous improvement in achieving the CMS performance measure, reducing the percentage of anemic patients with hemoglobin below 11 g/dL. This percentage has decreased from 85 percent in 1991 to only 17 percent in 2004, a tremendous achievement by the nephrology community for patients," says Ofman. Rising expenditures have not been the result of rising EPOGEN price. In fact, there has been a 14 percent reduction in the price per unit since its introduction in 1989, not accounting for inflation.

Amgen, in its testimony, also highlights the potential risks to patient care of prematurely implementing a new payment system that bundles dialysis services with separately billable dialysis drugs without proven and deliberate study and analysis, as is currently mandated. Amgen encourages Congress to wait for the results of the Medicare Modernization Act-mandated CMS bundling demonstration project. Carefully developed case-mix adjusters and quality safeguards must be established and tested within the demonstration project to assure patient quality of care and access to care are not compromised in this highly vulnerable ESRD population.

For the complete version of the testimony, click here.

For a summary of the testimony, click here.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have

changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

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