COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

November 15, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., SW
Washington, D.C. 20201

Dear Ms. Norwalk:

On April 25, 2006, the Committee on Ways and Means wrote to you to express serious concern about CMS monitoring policy compared to the drug labeling criteria for the use of epoetin alpha set forth by the Food and Drug Administration (FDA). The FDA label says that a patient's hemoglobin level should be within a range of 10 to 12 g/dl. However, CMS has adopted a monitoring policy for dialysis patients that establishes a reimbursement incentive for providers to continue to increase doses up to a hemoglobin level of 13. The Committee expressed concern over the CMS monitoring policy, yet CMS has done nothing to address the issue.

The Committee asked the following questions:

- Does your current agency have regulations or guidance that specifically notifies the public concerning the burden of proof or evidence required for policies that differ from the FDA label?

- In the above-referenced matters, has your agency consulted, verbally or in writing, with FDA representatives, formally or informally, prior to instituting policies based on clinical determinations that differed from FDA determinations?

- Are there other instances where CMS has created special policies based on different information than in the FDA label? Please specifically identify such instances and provide an explanation for CMS policy or policies that differed from FDA guidance.

- Do you believe FDA determinations are helpful and should serve to guide your agency, especially in circumstances where the most current clinical evidence is inconclusive or even contradictory? Do you believe it would be helpful to use the FDA determinations under these circumstances, especially when this would result in significant savings while protecting patient safety?

No response was ever received by the Committee on these questions.

Today, the New England Journal of Medicine published a clinical trial whose results, when applied to the dialysis population, suggest that 20 percent have a hemoglobin level associated with higher risk, and another 20 percent are above the FDA recommended level. Moreover, the study finds no evidence to support the CMS monitoring policy, which allows hemoglobin levels above 13. Finally, two other papers have been recently published by academics that have documented the current cost of the overuse of Epogen at $257 per patient per month and reported on the lack of scientific evidence to support the current CMS monitoring policy.

We are deeply concerned that the current CMS policy is not aggressive enough to stem the systemic abuse of Epogen, resulting in costs to taxpayers and potential health dangers to patients. We believe that the CMS monitoring policy should enforce the levels described in the FDA label. Please respond no later than November 28, 2006.

Best regards,

Bill Thomas
Chairman
Ways and Means

Pete Stark
Ranking Member
Ways and Means Subcommittee on Health

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