The Honorable Shaun Donovan Director, The Office of Management and Budget 725 17th Street, NW Washington, DC 20503

Dear Mr. Donovan,

I am the co-founder of the Castleman Disease Collaborative Network (CDCN), a global initiative dedicated to accelerating research and treatment for Castleman disease (CD). CD is a deadly immune system disorder that is estimated to be diagnosed in approximately 6,500 to 7,700 patients of all ages each year in the U.S.

I am writing in response to the proposed regulation to reclassify blood stem cells as bone marrow. As a physician-scientist and also as a patient battling CD, I do not believe this is accurate. Peripheral blood stem cells have left the bone marrow and thus are no longer part of the bone marrow. The peripheral blood stem cells are blood cells more similar to red blood cells, white blood cells, and platelets, none of which are classified as bone marrow.

One emerging treatment for CD is a blood stem cell transplant. It is critical that the greatest number of potential blood stem cell donors be identified and registered, since finding unrelated matched donors for our patients is often a matter of life and death.

Each of our patients who are eligible for blood stem cell transplant first seek a matched related donor, but the only option for many patients is to find an unrelated donor. As I stated before, identifying the greatest number of potential donors is essential to finding matches for the greatest number of patients. If compensating donors is part of expanding that pool, then doing so should not be prohibited, as intended by this proposed regulation.

We respectfully request reconsideration of the proposed regulation to classify blood stem cells as bone marrow.

Sincerely,

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David Fajgenbaum, MD, MBA, MSc Co-Founder & Executive Director, <u>Castleman Disease Collaborative Network</u> Assistant Professor of Medicine, Translational Medicine & Human Genetics Associate Director, Patient Impact, Orphan Disease Center, University of Pennsylvania