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Indiana University Health

July 23, 2020

The Honorable Frank Pallone Chair, House Committee on Energy and **Energy Commerce** U.S. House of Representatives 2107 Rayburn House Office Building Washington, DC 20515

The Honorable Greg Walden Ranking Member, House Committee on **Energy and Commerce** U.S. House of Representatives 2185 Rayburn House Office Building Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden:

We are writing to ask for your leadership in expediting consideration of H.R. 4764, the TRANSPLANT Act, to reauthorize the C.W. Bill Young Cell Transplantation Program (the "Program") before the Program's authorization lapses on September 30, 2020.

Our organizations represent the bone marrow, peripheral blood stem cell (PBSC), cell therapy, and cord blood transplant community throughout the United States. We work daily to assist patients and their families so they can access what may be the only curative option available for life-threatening blood cancers or blood disorders: a bone marrow, cord blood, or PBSC transplant.

National Marrow Donor Program (NMDP) operates the federally authorized Program that matches unrelated volunteer bone marrow donors and cord blood units with patients who have been diagnosed with leukemia or over 70 otherwise fatal blood disorders and diseases. Under contract with the Department of Health and Human Services/Health Resources & Services Administration, the Program, which includes the National Cord Blood Inventory (NCBI), is charged with providing equal access for all patients in need of a life-saving cellular therapy. The Medical College of Wisconsin (MCW) operates the Stem Cell Therapeutic Outcomes Database (SCTOD) in collaboration with NMDP that reports outcomes of cellular therapy. Data collected through the Program since March 2020 will provide the essential information necessary to evaluate the impact of the COVID-19 pandemic on patients. Another of the Program's primary missions is coordinating the delivery of bone marrow domestically and internationally to patients in the United States and abroad. NMDP marked a major milestone in its exceptional history last December with the celebration of facilitating 100,000 transplants.

H.R 4764 is a simple five-year reauthorization of this life-saving Program. The Program has been reauthorized twice, with strong bipartisan support. Never has the need to reauthorize the Program on time been more important than now, during the COVID-19 pandemic and in a time of rapidly evolving science and innovation in cell therapy. Restrictive domestic and international travel bans, border closings, and the declining availability of scheduled commercial passenger aviation service on international and domestic routes have created near catastrophic barriers to NMDP's ability to facilitate timely transplants for patients in dire need. Those patients, who are in the midst of treatment protocols, suffer from conditions that have deteriorated to the point that a bone marrow transplant is the only course of treatment that will save their life.

Throughout the pandemic, NMDP has thus far been able to mitigate disruption and has delivered 2,100 life-saving therapies to patients who are relying on them, without missing a single delivery. It has been able to do that because of its designation in Federal law as the nation's bone marrow registry, a designation that will lapse on September 30 without quick action by the Committee and Congress. Thanks in large part to the authorizing statute, NMDP was:

- Granted a waiver in March from the Director of the Centers for Disease Control to the European Travel Ban that was issued by the President. The waiver was issued in "the national interest" to allow international bone marrow couriers to travel to and from the United States to deliver cellular products from abroad to U.S. patients.
- Received CISA classification by the Department of Homeland Security as Critical Infrastructure for the Program to include "Donors of blood, bone marrow, blood stem cell, or plasma, and the workers of the organizations that operate and manage related activities."
- Authorized by a subcontract with the Department of Health and Human Services to use private aircraft donated to the government, renewed on a monthly basis, to deliver life-saving cells to patients when commercial flights were not available.
- Able to access support from U.S. Embassies and Consulates to liaison with host governments to facilitate timely travel authorizations for individual donor and courier

- travel and to coordinate private and/or humanitarian flights in and out of countries that have closed their borders to international travel.
- Granted temporary clearance from U.S. Customs and Border Protection that ensures bone marrow and blood stem cells coming from Canada to American patients will have uninterrupted transport into the United States.
- Quickly applied for and received OMB approval to revise data collection instruments on behalf of the program to evaluate impacts of COVID-19 on patients.

NMDP's ability to call upon our Federal partners in these extreme circumstances, and NMDP's standing in the eyes of foreign governments, could be compromised after September 30th if the Program's authorization expires. This could put our patients' lives at risk.

We realize that the current pandemic has severely impacted your legislative schedule. As the Committee prioritizes legislation for the remainder of this summer, we would ask that you include the TRANSPLANT Act (H.R. 4764) to reauthorize the C.W. Bill Young Cell Transplantation Program on that list of important must pass bills.

## Sincerely,

## **AABB**

Allegheny Health Network Cancer Institute, West Penn Hospital

American Society for Transplantation and Cellular Therapy (ASTCT)

American Society of Gene and Cell Therapy (ASGCT)

American Society of Hematology

Be The Match Hawaii/Hawaii Bone Marrow Donor Registry

**Bloodworks Northwest** 

Cardinal Glennon Children's Hospital

Carolinas Cord Blood Bank

Center for International Blood and Marrow Transplant Research (CIBMTR)

Children's Hospital Colorado

Children's Hospital of Michigan

City of Hope

Cleveland Clinic

Cleveland Cord Blood Center

Dana-Farber Cancer Institute

Dartmouth-Hitchcock Norris Cotton Cancer Center

**Duke University Medical Center** 

Foundation for the Accreditation of Cellular Therapy (FACT)

GenCure

Helen Devos Children's Hospital

IU Health Blood and Bone Marrow Stem Cell Transplant and Immune Cell Therapy Program

Kapi'olani Medical Center for Women & Children

Leukemia & Lymphoma Society (LLS)

Levine Cancer Institute

Loyola University Medical Center

Mayo Clinic

Medical College of Wisconsin

Medical University of South Carolina

Memorial Sloan Kettering Cancer Center

Mount Sinai Hospital

National Marrow Donor Program/Be The Match

New York-Presbyterian Hospital/ Weill Cornell Medical Center

North Shore University Hospital

Ohio State University Comprehensive Cancer Center - James Cancer Hospital

Oregon Health & Science University

Presbyterian St. Luke's Medical Center

Roger Williams Medical Center

St. Louis Cord Blood Bank

Stanford Blood Center

Stanford Health Care

StemCyte Inc

UCSF Benioff Children's Hospital Oakland

University of California San Francisco

University of Colorado Hospital

University of Kansas Blood and Marrow Transplant and Cellular Therapy Program

University of Mississippi Medical Center

University of Nebraska Medical Center

University of Rochester Medical Center

University of Texas-MD Anderson Cancer Center

Vitalant Cord Blood Bank