



# PARTNERSHIP TO FIGHT CHRONIC DISEASE

The Honorable Alejandro Mayorkas  
Secretary  
U.S. Department of Homeland Security

The Honorable Troy Miller  
Senior Official Performing the Duties of the Commissioner  
U.S. Customs and Border Protection

July 7, 2021

Dear Secretary Mayorkas and Mr. Miller:

We write to express our serious concerns over a recent change in federal policy by U.S. Customs and Border Protection (CBP) that threatens the U.S. supply of blood plasma and plasma-derived therapies. Americans living with chronic conditions rely upon these treatments for their health. We urge you to reconsider this decision given the significant consequences to the public's health, particularly in the midst of a dangerous pandemic.

The Partnership to Fight Chronic Disease (PFCD) is an internationally recognized organization of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease. Plasma, rich in antibodies and anti-clotting agents, are valuable tools in treating a wide variety of both chronic and acute conditions ranging from burn victims to trauma with significant blood loss and from cancers to kidney failure. The pandemic has already hindered plasma donations and, with a seven- to twelve-month lead time on product manufacturing, the full effects of this shortfall are now beginning to impact supplies.

Last month, CBP announced a policy decision to treat plasma donations as "labor for hire" and as such consider donations as a violation of the terms of B1 and B2 non-immigrant visas. For years, B1 and B2 visa holders, particularly from Mexico, have crossed the US-Mexico border legally to donate plasma. Plasma donors often receive a payment associated with their donations. Blood plasma donations are subject to FDA regulation, including how often and under what circumstances a person can donate. Current regulations limits plasma donations to no more than once in a 24-hour period or no more than two times a week.<sup>1</sup>

---

<sup>1</sup> [SECTION 2 | FDA](#)



# PARTNERSHIP TO FIGHT CHRONIC DISEASE

There is a significant need for plasma that the pandemic has exacerbated both in increasing demand and limiting donations. Currently, 75 active clinical trials are ongoing in the U.S. investigating the use of blood plasma therapies to treat a host of serious illnesses, including COVID-19-related illnesses. For example, intravenous immunoglobulin (IVIg), a plasma-derived product is also being used and studied as a treatment for severe COVID-19 cases, including children suffering from Multisystem Inflammatory Syndrome in Children (MIS-C).<sup>2</sup>

Moreover, many people with chronic conditions rely heavily on plasma donations. Treating one person with the blood clotting disease hemophilia for a year requires 1,200 plasma donations.<sup>3</sup> There are more than 200 different forms of primary immune deficiency affecting about 500,000 people in the United States.<sup>4</sup> To treat one person with primary immune deficiency disorder for a year requires 130 plasma donations.<sup>5</sup>

Among the other patient uses for plasma are:

- Albumin made from plasma proteins can be used to replace blood volume lost from trauma, including severe burns or an injury causing blood loss.
- Albumin also is used to treat people with acute liver failure and certain kidney diseases.
- Plasma is given to people with cancer who are bleeding because their blood is not clotting normally.<sup>6</sup> Children and adults with leukemia,<sup>7</sup> multiple myeloma,<sup>8</sup> and other cancers<sup>9</sup> may also receive treatments using plasma or plasma-derived therapies such as intravenous immunoglobulin (IVIg) because the cancer led to not having enough antibodies to fight infections.
- Immunoglobulin (Ig) also helps people with many different autoimmune conditions, weakened immune systems or other diseases. As of April 2021, there are 16 FDA-approved Ig products.<sup>10</sup> These treatments are used to treat many autoimmune-related conditions, including:<sup>11</sup>
  - Immune deficiencies, including immune thrombocytopenia
  - Lupus
  - Myositis
  - Guillain-Barre syndrome

---

<sup>2</sup> [Multisystem Inflammatory Syndrome in Children \(MIS-C\) Interim Guidance \(aap.org\)](https://www.aap.org)

<sup>3</sup> [Plasma - Plasma Protein Therapeutics Association \(PPTA\) \(pptaglobal.org\)](https://www.pptaglobal.org)

<sup>4</sup> [Primary Immune Deficiency Diseases \(PIDDs\) | NIH: National Institute of Allergy and Infectious Diseases](https://www.niaid.nih.gov)

<sup>5</sup> [Plasma - Plasma Protein Therapeutics Association \(PPTA\) \(pptaglobal.org\)](https://www.pptaglobal.org)

<sup>6</sup> [Blood Transfusions for People with Cancer](https://www.cancer.org)

<sup>7</sup> [Supportive Care for Chronic Lymphocytic Leukemia \(cancer.org\)](https://www.cancer.org)

<sup>8</sup> [Supportive Treatments for Patients with Multiple Myeloma \(cancer.org\)](https://www.cancer.org)

<sup>9</sup> [Palliative and Supportive Care for Non-Hodgkin Lymphoma \(cancer.org\)](https://www.cancer.org)

<sup>10</sup> [Addressing the Challenges to Immune Globulin Access \(igliving.com\)](https://www.igliving.com)

<sup>11</sup> [1-in-5-Brochure.pdf \(aarda.org\)](https://www.aarda.org)



## PARTNERSHIP TO FIGHT CHRONIC DISEASE

- Kawasaki disease
- Acute myasthenia gravis and other rare diseases

Given the depressive impact this decision could have on blood plasma supplies and the therapies derived from blood plasma donations, we urge you to reconsider and either withdraw the policy or withhold its implementation to allow for analysis of the health impacts of the decision and consideration of related factors.

Additional time would allow for a greater understanding of the impacts and consultation with experts and stakeholders across the federal government and from the public. Such a significant change with harmful health impacts, particularly in the midst of a global pandemic, should involve careful assessment and evaluation of the serious health consequences involved.

We value the commitment and service CBP provides to protecting our safety and securing the borders and respect the many challenges faced. We respectfully suggest that time spent revisiting and thoroughly vetting this potential policy change is worthwhile and much needed to protect the health and well-being of Americans depending upon these blood plasma donations.

We appreciate your consideration of this matter and welcome the opportunity to discuss our concerns further at your convenience.

Sincerely,

Kenneth E. Thorpe, PhD  
Chair

Cc: David Shahoulin, Assistant Secretary for Border and Immigration Policy  
Robert Perez, Deputy Commissioner  
Tim Quinn, Intergovernmental Public Liaison