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August 3, 2021

Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**RE: Changes in federal policy could affect the supply of plasma in the United States that is critical in treating patients with liver disease awaiting liver transplant**

Dear Secretary Becerra,

Collectively, liver diseases impact more than 120 million Americans. Over the last year, the burden of liver disease has only intensified due to the impact of COVID-19 on overall liver health as well as our healthcare system.<sup>1 2</sup> Many people impacted by liver disease are at an increased risk of their disease progressing to more serious stages with life-threatening complications like cirrhosis, liver cancer, and other end-stage liver diseases. In these dangerous situations, a liver transplant is their only hope.

As a global 501(c)3 nonpartisan nonprofit liver health organization, we are committed to improving the lives of individuals and families impacted by liver disease by promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver diseases. We applaud the steps that you have already taken to seek and then follow recommendations from the scientific community during the deadly COVID-19 pandemic. Your early actions recognize the value of collaboration and that investments in public health, along with scientific discovery, are crucial to improving the nation's overall health in both the near- and long-term.

However, today, we are writing to share our concerns over changes in federal policy that could adversely affect the supply of plasma in the United States that is critical to treating these individuals. We respectfully request that the Department refrain from implementing changes that would block Mexican nationals with B1/B2 tourist visas from donating plasma, a move that would imperil the lives of Americans struggling with serious illness.

For patients with critical liver failure, liver transplantation is their only option. Before the COVID-19 pandemic, on average there would be more than 13,000 liver patients in the U.S.

<sup>1</sup> [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(20\)30432-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30432-6/fulltext)

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/liver-disease.html>

waiting for a lifesaving transplant every year, and, sadly, three people would die everyday while waiting.<sup>3</sup> Now with the increased risk of organ failure in addition to the serious health outcomes due to COVID-19, those same patients are at an even greater risk of death.<sup>4 5</sup> On top of these startling numbers is the reality that from getting on the waitlist, to finding a match, to becoming a donor, patients of color who need an organ have more adverse experiences within an organ donation system deeply rooted in inequity.<sup>6</sup>

Until an organ donor becomes available, these patients are treated with therapeutic plasma exchange. These treatments are critical in removing toxins and in enabling blood clotting. Patients in liver failure can require two to six units of donated plasma per day. These patients would be severely harmed by a policy decision announced by the U.S. Customs and Border Protection (CBP) to treat plasma donations as “labor for hire.” Under this new definition, Mexican nationals with B1 and B2 visas who have, for years, crossed the border into the United States legally to donate plasma would be in violation of the terms of their visas.

It is impossible to overstate the damaging impact of a policy change that blocks these plasma donations from Mexican nationals. These donors have collectively played a critical role in the U.S. donor pool for over a decade. Prohibiting their donations now would exacerbate plasma shortages already occurring as a result of the COVID-19 pandemic. Plasma demand is exceeding supply and this affects not only patients with serious liver disease but tens of thousands of Americans with chronic diseases requiring plasma protein therapies.

We urge you to consider how this policy change would drastically impact the lives of so many Americans impacted by liver disease. We believe strongly that any implementation actions should be paused at least until the consequences of such a significant policy change can be fully reviewed and discussed. We also plead for your senior decision makers to meet with representatives of the Global Liver Institute and other key opinion leaders within the patient advocacy community so that we can elaborate on our concerns.

As we continue to cope with a global pandemic that has severely disrupted the health care supply chain, the last thing we need is further reduction in available source plasma that is utilized to create lifesaving treatments. We thank you for considering our recommendations and we welcome the opportunity to discuss this important issue in greater detail. If you have any questions, please don't hesitate to reach out to Global Liver Institute's Policy Director, Andrew Scott, at [ascott@globalliver.org](mailto:ascott@globalliver.org) or 831-246-1586.

With appreciation and respect,



Donna R. Cryer, JD  
President & CEO

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<sup>3</sup> Organ Procurement Transplantation Network, U.S. Department of Health and Human Services

<sup>4</sup> [https://www.journal-of-hepatology.eu/article/S0168-8278\(20\)30305-6/fulltext#%20](https://www.journal-of-hepatology.eu/article/S0168-8278(20)30305-6/fulltext#%20)

<sup>5</sup> [https://natap.org/2020/AASLD/AASLD\\_116.htm](https://natap.org/2020/AASLD/AASLD_116.htm)

<sup>6</sup> “[Comparison of black and white families’ experiences and perceptions regarding organ donation requests.](#)” Crit Care Med, 2003

