

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

CSL PLASMA INC.  
900 Broken Sound Parkway, Suite 400  
Boca Raton, FL 33487

CSL BEHRING L.L.C.  
1020 First Avenue  
King of Prussia, PA 19406

BIOMAT USA, INC.  
2410 Lillyvale Avenue  
Los Angeles, CA 90032

TALECRIS PLASMA RESOURCES, INC.  
2410 Lillyvale Avenue  
Los Angeles, CA 90032

GCAM, INC.  
1561 E. Orangethorpe Avenue, Suite 205  
Fullerton, CA 92831

*Plaintiffs,*

v.

U.S. CUSTOMS AND BORDER PROTECTION  
1300 Pennsylvania Avenue NW, MS: 1345  
Washington, DC 20229

TROY A. MILLER, *in his official capacity as Senior  
Official performing the duties of the Commissioner  
for U.S. Customs and Border Protection*  
1300 Pennsylvania Avenue NW, MS: 1345  
Washington, DC 20229

*Defendants.*

Civil Action No. 1:21-cv-2360

ADMINISTRATIVE PROCEDURE ACT  
REVIEW OF AGENCY ACTION

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs CSL Plasma Inc. and CSL Behring L.L.C. (together, “CSL Behring”), and Biomat USA, Inc., GCAM, Inc., and Talecris Plasma Resources, Inc. (together, “Grifols”), allege as follows:

## INTRODUCTION

1. This action challenges an unlawful new policy, recently “promulgated” by U.S. Customs and Border Protection (“CBP”) through a press release, banning B-1/B-2 visa holders from entering the United States to donate their blood plasma at plasma collection centers because those centers provide a payment to donors as part of the donation process. This “Plasma Ban” reverses CBP’s decades-long practice of allowing foreign-national plasma donors to enter this country on B-1/B-2 visas, and is based solely on CBP’s newfound determination that donating plasma is somehow “labor for hire,” and therefore inconsistent with the terms of the B-1/B-2 visa. The impact of the Plasma Ban will be felt not only by the Plaintiffs—CSL Behring and Grifols,<sup>1</sup> biopharmaceutical companies that, until the Plasma Ban, have for years collected and utilized plasma from foreign-national donors to manufacture life-saving therapies for those suffering from a variety of serious diseases. The Plasma Ban also will needlessly damage public health by making fewer plasma-derived therapies available to patients at the most inopportune time—when the critical need for such therapies continues to grow rapidly and U.S. plasma therapeutic suppliers work to rebound from the decrease in plasma donation throughout the U.S. over the last 18 months due to the pandemic. Because the Plasma Ban contravenes the Immigration and Nationality Act, ignores CBP’s longstanding prior practice of allowing B-1/B-2 visa holders to enter the U.S. to donate plasma, and was issued without the requisite notice-and-comment procedures, the Plasma

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<sup>1</sup> CSL Plasma Inc. operates plasma collection centers, and CSL Behring L.L.C. is the parent entity which uses the plasma to manufacture and distribute plasma-derived therapies. Biomat USA, Inc., GCAM, Inc., and Talecris Plasma Resources, Inc. are part of the Grifols family of companies that operate the plasma collection centers.

Ban is invalid and should be vacated under the Administrative Procedure Act. And because the Plasma Ban causes substantial irreparable harm to Plaintiffs and thousands of patients who rely on plasma-derived therapies, this Court should grant preliminary and permanent injunctive relief.

2. Human blood plasma is the critical ingredient necessary to produce essential life-saving treatments for serious diseases that affect more than 125,000 Americans, including primary and secondary immune deficiencies, respiratory diseases, neurological disorders, and hemophilia and other blood disorders. Plasma-derived therapies are also used in cardiac surgery, burn treatment, and to prevent hemolytic disease of the newborn. Grifols is also investigating the use of plasma to treat Alzheimer's, Parkinson's, and liver disease—pathologies that affect millions of Americans—while CSL Behring is investigating the use of plasma in transplant and cardiac areas. The human blood plasma used in the many existing treatments and in ongoing research is donated by individuals at collection centers, like those operated by the Plaintiffs, through a process called plasmapheresis, which has been safely used in plasma collection for more than 50 years.

3. For over 30 years, CBP largely allowed B-1/B-2 visa holders from Mexico to enter this country for the purpose of donating their plasma at collection centers that provide a payment to donors, as do all of the Plaintiffs' centers within the United States. Occasional public statements by CBP previously indicated that entering the U.S. to donate plasma would be subject to the "discretion" of Border Patrol agents on a "case-by-case basis," but as a practical matter B-1/B-2 visa holders have, until recently, been routinely allowed to enter the U.S. along most of the southern border to donate their plasma. Indeed, CBP has even *prioritized* plasma-donating B-1/B-2 visa holders over others: During the height of the COVID-19 pandemic, when B-1/B-2 visa holders were generally barred from entering the U.S. for virtually any purpose, Texas CBP officials coordinated with CSL Behring and Grifols to allow in those who were coming to donate their

plasma. This policy aligned with the U.S. national pandemic strategy, developed by the Department of Homeland Security, which designated plasma donors as “essential” and plasma collection a “critical infrastructure industry.” Those designations remain in effect today.

4. Based on CBP’s longstanding prior practice, U.S. plasma supply has come to rely on donations from Mexican nationals entering this country on B-1/B-2 visas. Such donations are responsible for an estimated 5-10% of plasma collections.<sup>2</sup> CSL Behring has established a network of 15 plasma collection centers near the southern border in Texas and Arizona, all of which were intentionally located within the zone where holders of Border Crossing Cards (a form of B-1/B-2 visas available to Mexican nationals) are permitted to travel in the U.S., and two more centers in the border areas are planned to open shortly, including CSL Behring’s first center on the California border with Mexico. Grifols operates 24 such centers, located in Arizona, Texas, and California. The companies each spend approximately \$2.5 million or more to locate, build-out, and equip a collection center with plasmapheresis machines, donor beds, and a host of other items; each company hires and trains roughly 60 employees or more to operate each center; and contributes millions of dollars more in employee payroll and donor payments per center. In total, the companies’ operations near the border have an annual economic impact of well over \$150 million.

5. On or around June 15, 2021, without notice or an opportunity for dialogue, CBP needlessly pulled the rug out from under the plasma industry and patients who rely on plasma-derived therapies. In a statement to the press, CBP announced that “[e]ffective immediately, ... donation of plasma for compensation in the U.S. by B1/B2 non-immigrant visa holders is a violation of the terms of their visa and crossing the border for that express purpose will no longer

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<sup>2</sup> Letter from Lynn H. Albizo, Vice President of Public Policy, Immune Deficiency Foundation, to Secretary Alejandro Mayorkas (June 29, 2021) (“IDF Letter”), <https://primaryimmune.org/sites/default/files/IDF%20letter%20to%20Secretary%20Mayorkas.pdf?fbclid=IwAR3Kxg8npDESAsJGdxNADTL7sSGF0gieFv8pWXh4kZpwOjH0wK3sSyD9aE>.

be permitted under any circumstances.” Notwithstanding the entrenched operations of Plaintiffs’ collection centers near the border and CBP’s decades-long practice of allowing Mexican plasma donors to enter the U.S. with Border Crossing Cards, CBP asserted for the first time that, because donors receive a payment, plasma donation constitutes “labor for hire,” an activity categorically prohibited by individuals here on B-1/B-2 visas. To be clear, CBP’s announcement was based *solely* on its determination that donating plasma now somehow constitutes “labor for hire” under the statute. CBP has not provided any other justification for its abrupt shift in legal construction, including any suggestion that visas are being abused or that the donors’ entry presents COVID-19-related or other health concerns. As a result, CBP is now turning away practically all Mexican nationals interested in donating plasma unless and until they procure a new visa, likely an H-type temporary work visa, that is, as a practical matter, impossible for any plasma donor to obtain.<sup>3</sup>

6. Notably, CBP’s new “labor for hire” position flatly contradicts the position of the U.S. Department of Justice, which, in a Statement of Interest recently submitted to another federal court, called it “mistaken” to describe plasma donation as “akin to employment or contract work,” even when the donor receives payment from the collection center, as occurs throughout the U.S. plasma collection system. The Justice Department has repeatedly expressed this view since at least 2015 in litigation brought under Title III of the Americans with Disabilities Act (“ADA”). According to the Justice Department, a plasma collection center is a “service establishment” (and thus a place of public accommodation subject to Title III of the ADA) because the center “offer[s] a service to the public, the extracting of plasma for money, with the plasma then used by the center in its business of supplying a vital product to healthcare providers.” U.S. Statement of Interest at

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<sup>3</sup> Temporary worker visas, for example, generally require a U.S. employer first to petition the U.S. government on behalf of the potential entrant. Since Plaintiffs are not employers of plasma donors, the companies would not be in a position even to file such a petition.

6, *Gomez v. CSL Plasma Inc.*, No. 20-cv-2488 (N.D. Ill. July 14, 2021) (ECF No. 50) (quoting *Matheis v. CSL Plasma Inc.*, 936 F.3d 171, 78 (3d Cir. 2019)). vThe fact that the donor receives a payment as part of the process is incidental to the service transaction and does not somehow transform the relationship into anything “akin to employment or contract work.” *Id.* This view espoused by the Department of Justice cannot be reconciled with CBP’s conflicting position in the Plasma Ban that donating plasma at centers that provide payment constitutes “labor for hire.”

7. The U.S. Food and Drug Administration (FDA) has likewise implicitly ratified the practice of collecting plasma donations from Mexican nationals. In its role as licensor of plasma collection centers, FDA has long been aware that Plaintiffs solicit and collect plasma from Mexican national donors and has never objected to the practice, never advised Plaintiffs to stop, never withheld or threatened to withhold a license due to the practice, and, to Plaintiffs’ knowledge, never reported or threatened to report the issue to CBP. What’s more, it is Plaintiffs’ understanding that FDA or the U.S. Department of Health and Human Services (HHS) were not consulted before CBP adopted and implemented the Plasma Ban, leaving those agencies charged with protecting the public health in the dark about this sudden change from longstanding practice. Industry advocates have been advised that officials from both health agencies are opposed to the Plasma Ban. CBP thus stands alone—at odds with DOJ, FDA, HHS, and 125,000 American patients who rely on plasma-derived therapies to treat a host of severe and life-threatening diseases.

8. With a large percentage of the donors visiting Plaintiffs’ border-region centers coming from Mexico (all of whom enter the U.S. with B-1/B-2 visas), CBP’s Plasma Ban has further constrained the blood plasma supply during a time of tremendous need. On top of the decline in plasma donations due to the COVID-19 pandemic, collections at these centers have dropped dramatically and immediately since CBP imposed the Plasma Ban. Plaintiffs have made

concerted efforts to overcome these reductions, but those efforts have been only partially successful thus far and collections at these centers continue to lag and clearly fail to keep pace with growing demand. The net result of yet another plasma supply shock—this one caused by CBP’s abrupt adoption and implementation of the Plasma Ban—is that less plasma will be available to produce plasma-derived therapies and there is very limited opportunity to obtain plasma from other collectors given the supply constraints and demand growth. This further reduction in plasma supply will inevitably harm patients in need of plasma-derived therapies, without which they are likely to experience lower-quality lives or even premature death.

9. CBP’s newfound interpretation in the Plasma Ban that B-1/B-2 visa requirements categorically bar B-1/B-2 visa holders from entering the U.S. to donate plasma at collection centers that provide a payment directly contravenes the relevant provisions of the Immigration and Nationality Act. CBP also failed to comply with mandatory procedural requirements, in both its failure to acknowledge and explain the Plasma Ban’s departure from CBP’s longstanding prior practice of allowing foreign-national plasma donors to enter the U.S. on B-1/B-2 visas, and in its failure to follow the requisite notice-and-comment rulemaking process, thereby denying key stakeholders—such as local leaders in the affected border towns, affect patient groups, plasma industry advocates, and other plasma collectors and therapeutics suppliers—to comment.

10. For each of these reasons, and as explained further below, Plaintiffs seek a declaration that the Plasma Ban is invalid and set aside under the Administrative Procedure Act (“APA”), a preliminary and permanent injunction preventing the Defendants from implementing or enforcing the Plasma Ban, and such other relief as the Court deems appropriate.

## **JURISDICTION AND VENUE**

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory and other relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 705–06.

12. Defendants’ statement of policy issued on or around June 15, 2021—announcing that “effective immediately,” B-1/B-2 visa holders will no longer be permitted to enter the United States to donate blood plasma if they receive a payment as part of the donation process—constitutes a final agency action subject to judicial review under the APA. 5 U.S.C. §§ 704, 706.

13. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this action seeks relief against federal agencies and officials acting in their official capacities, one or more Defendants are located in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

## **PARTIES**

14. CSL Behring L.L.C., a Delaware limited liability company, is a biotherapeutics leader driven by its promise to save lives. It develops and delivers innovative therapies that are used to treat primary and secondary immune deficiencies, hereditary angioedema, respiratory disease, neurological disorders, and coagulation disorders. The company’s products are also used in cardiac surgery, burn treatment, and to prevent hemolytic disease of the newborn.

15. CSL Plasma Inc., a Delaware corporation, employs about 11,000 people and operates one of the largest and most sophisticated networks for collecting human blood plasma, with about 290 plasma collection centers throughout the United States. The plasma collected at these centers is used by CSL Behring for the sole purpose of manufacturing and delivering life-saving therapies to people in the United States and around the world.

16. GCAM, Inc., a California corporation, operates 12 plasma collection centers and employs about 350 people.

17. Talecris Plasma Resources, Inc., a Delaware corporation, operates 75 plasma collection centers and employs about 2,500 people.

18. Biomat USA, Inc., a Delaware corporation, operates 151 plasma collection centers and employs about 5,600 people.

19. Collectively, the Grifols plasma organization as a whole is one of the largest and most sophisticated networks for collecting human plasma, with about 298 plasma collection centers throughout the United States. The plasma collected at these centers is used by Grifols' related entities under common ownership and control for the sole purpose of manufacturing and delivering life-saving therapies to people in the United States and around the world.

20. Defendant Troy A. Miller is the Senior Official Performing the Duties of the Commissioner for U.S. Customs and Border Protection.

21. Defendant U.S. Customs and Border Protection is an executive agency of the United States Government headquartered in Washington, D.C., and has responsibility for enforcement of immigration laws. On or around June 15, 2021, CBP issued a statement of policy announcing that "effective immediately," "donation of plasma for compensation in the U.S. by B1/B2 non-immigrant visa holders is a violation of the terms of their visa and crossing the border for that express purpose will no longer be permitted under any circumstances."

## **BACKGROUND**

### ***Human Blood Plasma Is Vital to Life-Saving Healthcare Treatments***

22. Human blood plasma is the essential ingredient in the preparation of therapies crucial to treating over 125,000 patients suffering from many life-threatening diseases and

conditions, including immune deficiencies, shock or trauma, hemophilia, and other disorders. In manufacturing treatments for certain conditions, such as immune deficiencies, no other substance currently is available to substitute for human blood plasma. Many therapies are so plasma-intensive that patients require vast quantities of plasma each year. For instance, immunoglobulin therapy for a single patient suffering from one of a host of primary and secondary immune deficiencies requires about 130 donations of plasma annually,<sup>4</sup> and a year of therapy for a single hemophilia patient requires about 1,200 donations.<sup>5</sup> Global demand for plasma and plasma-derived therapies has steadily risen as medical practitioners are more familiar with various diseases such as the variety of immune deficiencies and as many countries' populations age.

23. Plasma is extracted from the human body through a process known as plasmapheresis, in which the donor's blood is drawn, the plasma is separated out, and the remainder (red cells, white cells, and platelets) is returned to the donor. CSL Behring and Grifols each obtain plasma from qualified donors who visit their respective collection centers located throughout the United States. The first donation usually takes about two-and-a-half hours, including a health assessment, and subsequent donations take about one to one-and-a-half hours.

24. The collection of plasma is safe. Plasmapheresis has been used in plasma collection for more than 50 years. The practice is regulated closely by the FDA, and all prospective donors must meet FDA eligibility requirements. FDA regulations prescribe that a person may donate

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<sup>4</sup>Over 250,000 people in the United States are estimated to be affected with primary immune deficiency diseases. See Nat'l Institute of Allergy and Infectious Diseases, *Primary Immune Deficiency Diseases*, [https://www.cdc.gov/ncbddd/hemophilia/data.html](https://www.niaid.nih.gov/diseases-conditions/primary-immune-deficiency-diseases-pidds#:~:text=There%20are%20more%20than%20200,chronic%2C%20debilitating%2C%20and%20costly. Hemophilia A, for instance, affects about 33,000 people in the United States. See Centers for Disease Control and Prevention (CDC), <i>Data & Statistics on Hemophilia A</i>, <a href=).

<sup>5</sup> See Plasma Protein Therapeutics Ass'n, *10 Facts About Plasma Donation*, [https://www.pptaglobal.org/images/Fact\\_Sheets/Redone/PPTA\\_Fact\\_Sheet\\_10Facts\\_FINAL\\_rev2.pdf](https://www.pptaglobal.org/images/Fact_Sheets/Redone/PPTA_Fact_Sheet_10Facts_FINAL_rev2.pdf).

plasma no more two times within a seven-day period, with at least 48 hours between each donation. Due in part to this limitation, plasma donation “in the United States ... is a safe process.”<sup>6</sup>

25. Plasma donors throughout the United States routinely receive a payment in connection with their donation—generally about \$50.

***Plasma Donations from Mexican Nationals on B-1/B-2 Visas Are Critical to Plasma Supply***

26. For decades, Mexican nationals who enter the U.S. on B-1/B-2 visas to donate their plasma have been important contributors to the U.S. plasma supply.

27. B-1 visas allow foreign nationals residing overseas to enter the U.S. “temporarily for business,” and B-2 visas allow entry “temporarily for pleasure.” 8 U.S.C. § 1101(a)(15)(B). For citizens of Mexico, the U.S. Government issues either a visa (which typically is issued as a B-1/B-2) or a so-called “Border Crossing Card,” a form of B-1/B-2 visa that allows the cardholder to make temporary business trips ranging from 25 to 75 miles past the port of entry into the United States over the course of the Border Crossing Card’s ten-year validity, without having to reapply for a separate B-1/B-2 visa for each trip. *See* 8 C.F.R. § 235.1(h)(1) (permitted zone is generally 25 miles past the port of entry in Texas, 55 miles in New Mexico, and 75 miles in Arizona).

28. Plasma donations by Mexican nationals on B-1/B-2 visas or Border Crossing Cards are critical to the U.S. plasma supply. The impact of the loss of such donations is significant. For example, plasma donations from foreign nationals entering the United States on B-1/B-2 visas are responsible for 5-10% of the plasma used for life-saving therapies.<sup>7</sup> Such a disruption in plasma donations is especially critical now, when more plasma than ever is required to meet the growing

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<sup>6</sup> George B. Schreiber et al., *Plasmavigilance—Adverse Events Among US Source Plasma Donors*, 2021 *Transfusion* 1, 11 (July 19, 2021).

<sup>7</sup> *See* IDF Letter, *supra* note 4.

need for plasma-based therapies, and when the United States has already suffered a 20% industry-wide drop in donations due to the pandemic.

29. Plasma collected at centers near the Mexican border has been consistently shown to have higher levels of the antibodies that fight Hepatitis A than plasma collected elsewhere. *See* Jonathan M. Ciencewicki, *et al.*, Plasma Donors in the Southwestern United States Positively Contribute to the Diverse Therapeutic Antibody Profile of Immune Globulin Products, *Scientific Reports* 10:6850 (2020), <https://doi.org/10.1038/s41598-020-63794-y>.

***Plaintiffs Rely on Plasma Donations from B-1/B-2 Visa Holders***

30. Like the plasma industry generally, CSL Behring and Grifols each have long relied on donations from Mexican nationals entering the U.S. on B-1/B-2 visas to donate their plasma. Since 2013, in reliance on the continuing availability of Mexican donors, CSL Behring has opened or acquired 15 collection centers near the southern border in Texas and Arizona, each located specifically within the port-of-entry distance limitations allowed to Mexican nationals with Border Crossing Cards. Since 2002, Grifols has established 24 centers, located within the port-of-entry distance limitations in Texas, Arizona, and California. Collectively, these centers operated by CSL Behring and Grifols represent about 80% of all plasma collection centers located near the southern border. Many of these border-region centers receive more donations than an average center. Accordingly, while border-region centers account for only about 5% of all plasma collection centers nationwide (52 of 1,001),<sup>8</sup> they account for 5-10% of plasma collections.<sup>9</sup>

31. Until recently, CSL Behring advertised to donors located in the border regions of Mexico. The company's social media and personal mail advertisements informed Mexican

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<sup>8</sup> *See* Plasma Protein Therapeutics Ass'n, *Find a Donor Center*, <https://www.donatingplasma.org/donation/find-a-donor-center>.

<sup>9</sup> *See* IDF Letter, *supra* note 2.

nationals that its centers are conveniently located on the U.S. side of the border, that the donated plasma is used to develop life-saving therapies, and that donors will receive a payment as part of the donation process. These advertisements were made consistent with CBP's longstanding practice of allowing B-1/B-2 visa holders to enter the U.S. to donate plasma and receive a payment in connection with the donation. CBP's recent policy statement barring Mexican nationals from entering the U.S. on B-1/B-2 visas to donate plasma (discussed in detail below) has forced CSL Behring to cease all advertising intended for those located on the Mexican side of the border.

32. Similarly, Grifols has spent several million dollars in the last several years toward advertising to donors living in Mexico, intending to attract them to Grifols collection centers near the border in Texas, California and Arizona. Like CSL Behring, Grifols purchased this advertising consistent with its understanding—and CBP's longstanding prior practice—that B-1/B-2 visa holders have been allowed to enter the U.S. to donate plasma at centers, like Grifols', that provide a payment. Grifols, too, has ceased all new advertising efforts to attract prospective donors entering the U.S. on a B-1/B-2 visa. To the extent Plaintiffs' ability to collect plasma at any of their respective centers is reduced, so too is their ability to manufacture life-saving plasma therapies. Any reduction in the supply of plasma collected from donors at their collection centers reduces Plaintiffs' ability to meet the growing demand for life-saving plasma-derived therapies.

***CBP Historically Allowed B-1/B-2 Visa Holders to Enter the U.S. to Donate Their Plasma***

33. For decades, dating back to at least the 1990s, CBP largely allowed B-1/B-2 visa holders (primarily Mexican nationals with Border Crossing Cards) to enter the United States for the purpose of donating plasma at collection centers like Plaintiffs' that provide a payment to donors in connection with the donation process.

34. The practice of providing a payment to plasma donors as part of the donation process is far from new. It has been the norm since CBP first permitted Mexican nationals to enter the U.S. on B-1/B-2 visas to donate plasma decades ago, and plasma collectors with locations near the southern border provide such payments at both those locations and at all other collection centers throughout the United States. CBP border patrol agents in Texas have long been aware of such payments and have largely allowed B-1/B-2 visa holders to enter the U.S. to donate plasma without issue. (CBP officials have even visited Grifols' center in Eagle Pass, Texas, demonstrating the collaborative relationship that governed before the Plasma Ban.) In Arizona, the situation has occasionally been less certain. Before 2017, CBP officials in Arizona, like their counterparts in Texas, generally allowed Mexican national donors to cross the border on B-1/B-2 visas. In March 2017, for instance, Arizona CBP officials told representatives of CSL Behring that B-1/B-2 visa holders could donate plasma and receive payment. But in 2018, Arizona officials at the San Luis port of entry switched to a more ambiguous stance, unevenly and occasionally barring donors from entry.<sup>10</sup> Enforcement of this more ambiguous stance was so uneven that Grifols was not even aware of it, receiving no reports of donors on B-1/B-2 visas having difficulty crossing the border into Arizona, Texas, or California until the early onset of the COVID-19 pandemic in March 2020.

35. During the global shutdown occasioned by the pandemic in 2020, Texas CBP officials expressly allowed B-1/B-2 visa holders who intended to donate plasma to enter the United States, despite otherwise banning entry by other B-1/B-2 visa holders due to the pandemic. And Texas CBP officials generally permitted Mexican nationals to enter the U.S. to donate plasma with full awareness of the payment they received; in fact, they coordinated directly with managers at

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<sup>10</sup> See Catalina Navarro, *Pueden quitar visa en EU por vender plasma*, Tribuna de San Luis (Jan. 26, 2018).

CSL Behring and Grifols collection centers to enable Mexican nationals to enter the U.S. to donate and then return to Mexico. That practice by CBP continued—while the U.S.-Mexico border remained otherwise largely closed—until CBP issued the Plasma Ban on or around June 15, 2021. (To the best of Plaintiffs’ knowledge, Arizona and California CBP officials did not grant a similar exemption for Mexican national plasma donors to cross the border during this shutdown period.)

36. CBP’s practice in Texas of allowing Mexican nationals to enter the U.S. to donate plasma during the COVID-19 pandemic aligned with the Department of Homeland Security’s designation of plasma donors as “essential.”<sup>11</sup> Indeed, the nation’s supply of blood plasma is so critical to the U.S. national interest that the Committee on Foreign Investment in the United States—an executive-branch body charged with ensuring that vital U.S. interests are not compromised by foreign acquisition of domestic assets—prevented a Chinese company from acquiring the U.S. operations of Biotest, a German blood plasma products maker.<sup>12</sup> Biotest’s U.S.-based plasma operations were considered too “sensitive” to “fall[] into Chinese hands.” *Id.*

***CBP’s Recent Policy Statement Reversing Longstanding Practice***

37. On or around June 15, 2021, CBP reversed its longstanding practice with respect to B-1/B-2 visa holders, providing the following statement (the “Plasma Ban”) to the press:

Effective immediately, U.S. Customs and Border Protection advises that donation of plasma for compensation in the U.S. by B1/B2 non-immigrant visa holders is a violation of the terms of their visa and crossing the border for that express purpose will **no longer be permitted** under any circumstances.

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<sup>11</sup> DHS, Cyber Security and Infrastructure Security Agency, *Advisory Memorandum on Ensuring Critical Infrastructure Workers’ Ability to Work During the COVID-19 Response* (Dec. 16, 2020), [https://www.cisa.gov/sites/default/files/publications/ECIW\\_4.0\\_Guidance\\_on\\_Essential\\_Critical\\_Infrastructure\\_Workers\\_Final3\\_508\\_0.pdf](https://www.cisa.gov/sites/default/files/publications/ECIW_4.0_Guidance_on_Essential_Critical_Infrastructure_Workers_Final3_508_0.pdf); *see also* FDA, *Donate COVID-19 Plasma* (Oct. 10, 2020) (encouraging COVID-19 survivors to donate plasma), <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>.

<sup>12</sup> *Biotest sheds U.S. business to allay U.S. concerns of Chinese takeover*, Reuters (Jan. 29, 2018), <https://www.reuters.com/article/us-biotest-m-a-creat/biotest-sheds-u-s-business-to-allay-u-s-concerns-of-chinese-takeover-idUSKBN1F82FC>.

Selling plasma constitutes labor for hire in violation of B-1 non-immigrant status, as both the labor (the taking of the plasma) and accrual of profits would occur in the U.S., with no principal place of business in the foreign country.

This does not affect the ability of non-immigrant visa holders to receive medical treatment in the U.S. or to make a true donation of blood, tissue or an organ without receiving compensation.

(Emphasis added).

38. This Plasma Ban rests solely on CBP's newfound view that donating plasma at centers that provide a payment to donors as part of the donation process "constitutes labor for hire." Under the Plasma Ban, B-1/B-2 visa holders are no longer permitted to enter the United States to donate plasma if they receive a payment, as occurs at all plasma collection centers operated by Plaintiffs and, indeed, at all plasma collection centers throughout the United States.

39. Despite the reversal of its longstanding practice of generally allowing B-1/B-2 visa holders to enter the U.S. to donate plasma at centers that provide a payment, CBP did not even acknowledge this longstanding prior practice in announcing the Plasma Ban. Nor did CBP make any attempt to explain or justify its departure from this longstanding prior practice. CBP also did not conduct a notice-and-comment process or anything like it before issuing the Plasma Ban.

40. Plaintiffs and other key stakeholders—including other plasma collectors, industry advocates, affected patient groups, and impacted local communities in the U.S.—were given no formal notice of the policy change, despite their significant reliance interests in CBP's prior longstanding practice. Federal health agencies are apparently were not notified in advance of the policy change by CBP, despite its significant impact on U.S. public health.

41. Immediately after CBP's sudden announcement of the Plasma Ban, CSL Behring and Grifols each reached out to executive-branch and legislative-branch decisionmakers. That political outreach failed to resolve the situation, necessitating the filing of this action.

42. Patient groups like the Immune Deficiency Foundation and the Guillan-Barre Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy Foundation also engaged in political advocacy opposing the Plasma Ban, but to no avail. *See, e.g.*, IDF Letter, *supra* note 4. The American Plasma User Coalition was likewise unsuccessful in its political outreach.<sup>13</sup>

***CBP's Plasma Ban Is Inconsistent with the Immigration and Nationality Act***

43. The Plasma Ban conflicts with the text, structure, and purpose of the Immigration and Nationality Act (the “Act”). Section 101 of the Act provides that a foreign national “other than one coming for the purpose of study or of performing skilled or unskilled labor . . . having a residence in a foreign country which he has no intention of abandoning and who is visiting the United States temporarily for business” is not considered an “immigrant,” and therefore does not require an immigrant visa. 8 U.S.C. § 1101(a)(15)(B). In its June 15, 2021 press release announcing the Plasma Ban, CBP asserted that donating plasma constitutes prohibited “labor for hire” if the donor receives a payment as part of the process. That is incorrect as a matter of law.

44. The Act distinguishes between a foreign national entering the U.S. “temporarily for business,” who qualifies for a B-1 visa (a type of non-immigrant visa), as opposed to a person entering the U.S. to “perform[] skilled or unskilled labor,” who does not qualify for a B-1 visa. Entering the U.S. to donate plasma and receiving a payment constitutes international “business” activity, which qualifies for a B-1 visa, rather than the performance of domestic “labor,” which does not. That conclusion flows from the straightforward meaning of the statutory terms “business” and “labor.” The word “business” carries a broad meaning—*i.e.*, “[c]ommercial

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<sup>13</sup> *See, e.g.*, Letter from The American Plasma Users Coalition to The Honorable Alejandro Mayorkas (June 30, 2021), <https://www.alpha1.org/alpha-1-foundation-signs-on-to-aplus-plasma-collection-concerns-letter/>. The American Plasma User Coalition spoke for the Alpha-1 Foundation, the GBS|CIDP Foundation International, the Hemophilia Federation of America, the Immune Deficiency Foundation, the Jeffrey Modell Foundation, the US Hereditary Angioedema Association, and the Platelet Disorder Support Association. *Id.*

transactions.” Business, *Black’s Law Dictionary* (11th ed. 2019). The word “commercial,” in turn, means “[o]f, relating to, or involving the buying and selling of goods.” Commercial, *Black’s Law Dictionary* (11th ed. 2019). Under these capacious terms, the donation of plasma, accompanied by a payment to the donor, is a “commercial transaction,” *i.e.*, “business.” *See, e.g., Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1234 (10th Cir. 2016) (“[Plasma donation centers] are place[s] of business.”); *Matheis v. CSL Plasma Inc.*, 936 F.3d 171, 178 (3d Cir. 2019) (similar); *Scott v. CSL Plasma Inc.*, 151 F. Supp. 3d 961, 965 (D. Minn. 2015) (“CSL does business with its plasma donors.”); *see also Ancar v. Sara Plasma, Inc.*, 964 F.2d 465, 469 (5th Cir. 1992) (referring to the “purchase price of plasma”). Consistent with the plain language of the statute, Mexican plasma donors have for decades been “visiting the United States temporarily for business.”

45. The Act’s structure reinforces this interpretation, as the general term “business” is juxtaposed with a specific exception: those “coming for the purpose of . . . performing skilled or unskilled labor” are not considered to be “visiting the United States temporarily for business.” 8 U.S.C. § 1101(a)(15)(B). This “definitional framework”—a broad term accompanied by specific examples—“strongly suggests that Congress intended an all encompassing definition” of the general term “business.” *Patel v. Quality Inn S.*, 846 F.2d 700, 702 (11th Cir. 1988).

46. Crossing the border for a short period of time to donate plasma is a paradigmatic example of “visiting the United States temporarily for business.” The vast majority of Mexican national plasma donors cross the border into the U.S. to visit the plasma collection center, spend about 90 minutes there donating plasma after their initial visit, receive a payment, perhaps buy a few items in the U.S. (or not), and then return to Mexico on the same day.

47. Contrary to CBP’s assertion in the Plasma Ban, donating one’s human blood plasma cannot reasonably be considered “labor” or “labor for hire.” The word “labor” means to “work,

esp. with great exertion.” Labor, *Black’s Law Dictionary* (11th ed. 2019). And the word “work” means “[p]hysical and mental exertion to attain an end.” Work, *Black’s Law Dictionary* (11th ed. 2019). Neither definition plausibly encompasses plasma donation, which involves no “work” or “exertion” by the donor. The fact that Plaintiffs provide payment to donors in connection with the donation process does not alter this conclusion: “[T]he fact that [CSL Plasma] technically pays donors for their time spent in the donation process, rather than for their plasma, does not change the fact that it pays them and receives, in exchange, plasma. In this way, CSL is like a resale shop that purchases items from individuals to stock its inventory of merchandise, which the shop sells for profit.” *Scott v. CSL Plasma Inc.*, 151 F. Supp. 3d 961, 965 (D. Minn. 2015) (citation omitted). In short, plasma donors are not performing anything that remotely resembles “labor for hire.”

48. Importantly, the U.S. Department of Justice agrees on this dispositive point. In a Statement of Interest recently filed in another federal court, the Justice Department unequivocally called it “mistaken” to assert that the relationship between a plasma donor and a collection center is “akin to employment or contract work,” explaining that plasma collection is a *service* that the collection center provides *to the donor*. U.S. Statement of Interest at 8, *Gomez v. CSL Plasma*, No. 1:20-cv-2488. The Statement of Interest was filed on July 14, 2021, just one month after CBP’s contrary assertion in the Plasma Ban that plasma donation constitutes “labor for hire.”

49. The *Gomez* case in which the Justice Department recently filed the Statement of Interest involves the proper characterization of plasma collection centers, which in turn impacts whether such centers are subject to various provisions of the ADA. The Third and Tenth Circuits have held that plasma collection centers are “service establishments” and thus “public accommodations” subject to the anti-discrimination provisions under Title 3 of the ADA, while the Fifth Circuit held that they are not. *See Matheis v. CSL Plasma Inc.*, 936 F.3d 171, 178 (3d

Cir. 2019) (collection center is service establishment); *Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1234 (10th Cir. 2016) (same); *Silguero v. CSL Plasma Inc.*, 907 F.3d 323, 328 (5th Cir. 2018) (collection center is not service establishment). In holding that plasma collection centers are not service establishments, the Fifth Circuit reasoned that donating plasma is “more akin to employment or contract work” because donors receive a payment. *Silguero*, 907 F.3d at 330.

50. In its recent Statement of Interest, the Department of Justice explained that the Fifth Circuit is “mistaken” in its view that plasma donors receiving payment are engaged in “employment or contract work” (*i.e.*, labor). U.S. Statement of Interest at 8, *Gomez* No. 1:20-cv-2488. According to the Justice Department, plasma collection centers are service establishments that provide donors with the service of collecting their plasma, notwithstanding that the centers provide a payment to donors as part of the donation process. The Justice Department’s Statement of Interest explains at length that it is not at all unusual for service establishments to make payments to their customers, citing as examples “banks, recycling centers, pawnshops, and consignment shops.” *Id.* Because plasma donation is not an employment or work relationship but rather a service relationship, the inescapable conclusion, according to the Justice Department, is that plasma collection centers are service establishments and thus public accommodations subject to the anti-discrimination provisions of Title III of the ADA. The Justice Department has held this position since at least 2015, based on amicus curiae briefs filed in prior ADA cases raising the same issue concerning plasma collection centers. *See* Br. for U.S. as Amicus Curiae Supporting Neither Party, *Silguero v. CSL Plasma Inc.*, 907 F.3d 323 (5th Cir. 2018) (No. 17-41206), 2018 WL 889624; Br. for U.S. as Amicus Curiae Supporting Appellant and Urging Reversal, *Levorsen v. Octapharma Plasma, Inc.*, 828 F.2d 1227 (10th Cir. 2016) (No. 14-4162), 2015 WL 2148078.

51. The Department of Justice is right and CBP is wrong: plasma donation is not akin to employment or contract work, including when the collection center provides a payment to a donor as part of the donation process. Donation thus cannot be considered “labor for hire.”

52. In addition to the statutory text, CBP’s Plasma Ban is also at odds with the history and purpose of the Immigration and Nationality Act. The key provision of the Act regarding B-1/B-2 visas is designed to protect “American workers from unnecessary foreign competition.” *Int’l Union of Bricklayers & Allied Craftsmen v. Meese*, 616 F. Supp. 1387, 1401 (N.D. Cal. 1985). But plasma donors are not performing “labor” and thus are not “workers,” and Mexican nationals who choose to donate plasma are in no manner “competing” with “American workers” in doing so. There is no zero-sum game here, as allowing Mexican nationals to donate their plasma on B-1/B-2 visas does not in any way impact the ability of U.S. citizens to likewise donate their plasma as well. Instead, the Plasma Ban actually inflicts substantial harm on American workers (such as those employed at border-region plasma collection centers) and creates substantial harm to public health by reducing the supply of plasma needed for life-saving healthcare therapies and ongoing medical research. In any event, the Plasma Ban does not advance the Act’s purpose in any respect.

53. Judicial precedent further refutes CBP’s position that donating plasma constitutes impermissible domestic “labor” rather than international “business.” Courts have adopted the Board of Immigration Appeals’ (“BIA”) construction of the Act in *Matter of Hira*. See, e.g., *United States ex rel. Krawitt v. Infosys Techs. Ltd., Inc.*, 342 F. Supp. 3d 958, 965 (N.D. Cal. 2018) (citing *Matter of Hira*, 11 I&N Dec. 824 (BIA 1965 aff’d by A.G. in 1966)). *Hira* identifies the following “significant considerations” in determining whether a person’s conduct is an appropriate B-1 international business activity as opposed to the performance of domestic labor in the U.S.:

- a. There is a clear intent on the part of the alien to continue the foreign residence and not to abandon the existing domicile;

- b. The principal place of business and the actual place of eventual accrual of profits, at least predominantly, remains in the foreign country;
- c. The business activity itself need not be temporary, and indeed may long continue; and
- d. The various entries into the United States made in the course thereof must be individually or separately of a plainly temporary nature in keeping with the existence of the two preceding considerations.

54. Those factors, which CBP's Plasma Ban fails even to acknowledge, establish that B-1/B-2 visa holders are eligible to enter the U.S. to donate plasma under the statute. Many Mexican plasma donors enter at a port of entry, donate plasma at a collection center conveniently located near the border, and return to Mexico all on the same day, thus showing a "clear intent on the part of the alien to continue the foreign residence" and the "plainly temporary nature" of the entry. The "business activity itself" is the donation of plasma, which is plainly "temporary" as it takes just a few hours. And because the donors are "based . . . overseas," their "principal place of business" under the second factor is considered to be overseas as well. *See United States ex rel. Krawitt v. Infosys Techs. Ltd., Inc.*, 342 F. Supp. 3d 958, 965 (N.D. Cal. 2018) (applying *Hira*).

55. While Mexican plasma donors, like all others who donate plasma, receive payment in the United States (and have done so for decades), this has never been considered a dispositive factor in favor of denying eligibility for a B-1 visa under the *Hira* factors. Indeed, in *Matter of Camilleri*, a Canadian truck driver who was paid *in the United States* was nevertheless found to be eligible for a B-1 visa. 17 I&N Dec. 441 (BIA 1980); *see also Matter of Duckett*, 19 I&N Dec. 493 (BIA 1987) (allowing B-1 visa for foreign national whose "duties are performed on a regular and permanent basis at a fixed place of employment in the United States").

56. Similarly, a General Counsel opinion issued by CBP's predecessor agency addressed a highly analogous situation and again found that B-1 visas were appropriate. *See Genco Op. No. 93-95, HQ 235-C, 1993 WL 1504042* (Dec. 28, 1993). That Immigration and

Naturalization Service opinion discussed Mexican couriers who would carry lab samples from Mexico to the U.S. and lab reports from the U.S. to Mexico. *Id.* The couriers were paid *in the United States*, just like plasma donors at Plaintiffs' collection centers. *Id.* The General Counsel nevertheless opined that the couriers should be allowed to enter the U.S. on B-1 visas. *Id.* If anything, donating one's own blood plasma is even farther removed from "labor for hire" than the activities of the couriers addressed in the General Counsel opinion (delivering materials from one location to another). *See also* 9 FAM 402.2-5(C)(4)(a)(U) (professional athletes are eligible for B-1 visas, even if competing for prize money which will be paid to them in the United States).

57. The BIA "is entitled to deference in interpreting ambiguous provisions of the INA," *Negusie v. Holder*, 555 U.S. 511, 516 (2009), as it did in *Hari* and in opinions supporting *Hari*'s reasoning thereafter. CBP's Plasma Ban, promulgated abruptly through a press statement—constituting "little more than uncited, conclusory assertions of law in a short, informal document"—is not. *Fox v. Clinton*, 684 F.3d 67, 78 (D.C. Cir. 2012); *see also Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."); *Tangney v. Burwell*, 186 F. Supp. 3d 45, 54 (D. Mass. 2016) ("This press release . . . does not receive *Chevron* deference.").

### ***The Plasma Ban Is Arbitrary and Capricious***

58. Aside from being inconsistent with the governing statute, the Plasma Ban is arbitrary and capricious. Even when an agency "has acted within the scope of his statutory authority," section 706(2)(A) of the APA "requires a finding that the actual choice made was not arbitrary and capricious." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

“To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Id.*

59. Relevant here, when an agency changes course from a “prior policy [that] has engendered serious reliance interests,” the agency must provide a “more detailed justification than would suffice for a new policy created on a blank slate.” *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (holding that agency’s decision was arbitrary and capricious because agency “provide[d] no significant justification for a *change* of policy” (emphasis in original)). At the very least, this well-established standard “require[s] the agency to ‘display awareness that it is changing position’ and not to ‘depart from a prior policy sub silentio or simply disregard rules that are still on the books.’” *Dillmon v. Nat’l Transp. Safety Bd.*, 588 F.3d 1085, 1089 (D.C. Cir. 2009) (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515) (emphasis by Supreme Court). And “where an agency departs from its precedent, it must do so by reasoned analysis.” *Id.* (internal quotation marks omitted); *see also Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) (“[I]f an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute.”). “This permits [a reviewing court] to ensure the agency’s prior policies and standards are being deliberately changed, not casually ignored.” *Dillmon*, 588 F.3d at 1089 (internal quotation marks omitted). “[A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *Fox Television Stations, Inc.*, 556 U.S. at 515.

60. Plasma collection centers have operated near the southern border for over three decades, with a predecessor to CSL Behring having operations in El Paso, Texas, as far back as the 1990s. And, as stated above, even during the height of the COVID-19 pandemic in 2020, CBP border patrol agents in Texas actively *prioritized* the entry of Mexican nationals with Border

Crossing Cards coming to donate plasma at Plaintiffs' collection centers, even as B-1/B-2 visa holders were denied entry for other purposes. To the extent CBP ever previously addressed the issue—either publicly or in communications with CSL Behring, for instance—officials claimed that their approach was to evaluate each attempted entry with “discretion” on a “case-by-case basis”—the opposite of the categorical prohibition now set forth in the Plasma Ban.<sup>14</sup>

61. FDA's practice of inspecting plasma collection centers further demonstrates the U.S. Government's policy of allowing Mexican nationals to donate plasma on B-1/B-2 visas without concern as to payment. FDA officials conduct routine audits of plasma collection centers, including those located near the southern border. During the course of these audits, FDA officials are provided access to the addresses of individuals who have donated plasma at the center being audited. FDA officials would have seen a large number of Mexican addresses when auditing a border center given that Mexican nationals comprise the majority of donors at most of the border centers. FDA officials would have also been aware that donors receive a payment in connection with their donation, as that information is displayed prominently on the walls of the centers. FDA was therefore aware that large numbers of Mexican nationals were donating plasma and receiving payment, and acquiesced in that practice. Indeed, paying a donor in connection with plasma donation is expressly contemplated by an FDA regulation that defines a “paid donor” as a person who receives monetary payment for a blood donation. *See* 21 C.F.R 606.121(c)(8)(v)(A).

62. The U.S. Government as a whole, as evidenced by the Department of Justice's past amicus briefs and recent Statement of Interest in the *Gomez* case, has rejected the notion that plasma donation is “akin to employment or contract work.” *See supra* ¶¶ 48-51. CBP's

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<sup>14</sup> *See, e.g.*, “CBP Confirms Plasma Contributions Could Jeopardize Travel Visas,” KRGV (Dec. 23, 2019), <https://www.krgv.com/news/cbp-confirms-plasma-contributions-could-jeopardize-travel-visas/>; *see also id.* (quoting the State Department as expressly declining to opine on the legality of plasma donations by B-1/B-2 visa holders).

longstanding prior practice of allowing B-1/B-2 visa holders to enter the U.S. to donate plasma at collection centers that provide payment to donors “has engendered serious reliance interests that must be taken into account.” *Fox Television Stations, Inc.*, 556 U.S. at 515. As described above, CSL Behring and Grifols, in reliance on CBP’s longstanding prior practice, each have invested millions of dollars in establishing collection centers located conveniently to the U.S.-Mexico border and in advertising to Mexican nationals, and they each continue to invest significant sums to maintain and grow those operations. Operations at these border centers will be reduced dramatically should the Plasma Ban be allowed to remain in effect, negatively impacting the corresponding local economies.

63. CBP’s Plasma Ban comes as the need for life-saving plasma-derived therapies is significantly increasing; for instance, the demand for immunoglobulin is growing at a compound annual growth rate of 10 percent over the last decade. Plaintiffs’ efforts to compensate for these reductions has been only partially successful, despite determined efforts to increase collections across their respective networks. What’s more, Plaintiffs’ entire supply chains were designed in reliance on the ability to collect plasma from border centers. Thus, the harm from the Plasma Ban is not limited to those local centers: Plaintiffs’ manufacturing operations rely on as much plasma as they can collect to fulfill demand for their life-saving therapies. In short, as a result of the CBP’s failure to take into account Plaintiffs’ significant reliance interests, plasma collections will drop, employees and their local communities will suffer, and, most importantly, patients who rely on life-saving plasma-derived therapies may no longer be able to receive them as prescribed.

64. CBP’s Plasma Ban does not acknowledge, much less attempt to explain, the change from CBP’s longstanding prior practice of largely allowing B-1/B-2 visa holders to enter the U.S. to donate plasma at collection centers that provide payment as part of the donation process.

65. CBP's Plasma Ban also does not attempt to explain how the Plasma Ban comports with DHS's designation of plasma donors as "essential." *See supra* ¶ 36.

66. Nor did CBP give any indication that it considered the impact of the Plasma Ban on patients who rely on plasma-derived therapies or U.S. patient health generally, such as by consulting with HHS before suddenly reversing the agency's longstanding prior practice. For example, the Plasma Ban could cause disruption to the manufacture of life-saving therapies or cause patients to have to pay higher prices for their needed treatments.<sup>15</sup> Some patients may be able to obtain less-efficacious non-plasma alternative treatments, but other patients may be forced to go without any treatment at all. CBP appears not even to know of this consequence of its Plasma Ban. CBP "should have, but did not, respond properly to [patients'] well-founded concerns." *See Delaware Dep't of Nat. Res. & Env't Control v. E.P.A.*, 785 F.3d 1, 14 (D.C. Cir. 2015).

67. Indeed, industry advocates were advised that officials at FDA and HHS did not receive notice before CBP's adoption and implementation of the Plasma Ban. Industry advocates were further advised about federal health officials' concerns over the Plasma Ban's negative impact on the critically important system of plasma collections in the U.S., and their concerns for the 125,000 patients who rely on plasma-derived therapies and whose well-being could be affected.

68. Worse, it appears that, to the extent CBP considered the health effects of the Plasma Ban at all, it did so only *after* the Plasma Ban had been put in place. On July 20, 2021, well after CBP implemented the Plasma Ban, the Plasma Protein Therapeutics Association received a letter from Michael Millich, Supervisory Border Security Officer at CBP, requesting information on such issues as the "percentage of plasma donations believed to be provided by noncitizens coming

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<sup>15</sup> Letter from The American Plasma Users Coalition to The Honorable Alejandro Mayorkas (June 30, 2021), available at <https://www.alpha1.org/alpha-1-foundation-signs-on-to-aplus-plasma-collection-concerns-letter/>

to the U.S. in visitor status,” “blood plasma levels in the U.S. overall and with confirmation of whether there is a shortage of supplies in the U.S.,” and “percentage of blood plasma used for non-life-threatening treatments such as cosmetics.” These are important questions that CBP should have addressed—and was legally required to address—*before* dramatically damaging the nation’s ability to collect blood plasma. (PPTA was unequipped to answer CBP’s question about cosmetic use; the association’s members use plasma for life-saving therapies.)

69. Because CBP did not acknowledge or explain the change from its longstanding prior practice, because CBP did not acknowledge and explain the important reliance interests at stake, and because CBP did not acknowledge and explain the negative impact on public health, the Plasma Ban is arbitrary and capricious. *Fox Television Stations, Inc.*, 556 U.S. at 515.

***The Plasma Ban Is a Legislative Rule Adopted Without Notice and Comment***

70. Because the Plasma Ban is inconsistent with existing regulations, it must be considered a legislative rule and is therefore invalid due to CBP’s failure to follow the notice-and-comment procedures prescribed by 5 U.S.C. § 553. “If a rule is inconsistent with or amends an existing legislative rule, then it cannot be interpretive. Such a rule would impose new rights or obligations by changing an existing law and must follow the applicable procedures of the APA.” *Gunderson v. Hood*, 268 F.3d 1149, 1154 (9th Cir. 2001) (footnote omitted).

71. The relevant existing regulation defines the term “business,” as used in 8 U.S.C. 1101(a)(15)(B), to mean “conventions, conferences, consultations and other legitimate activities of a commercial or professional nature.” 22 C.F.R. § 41.31. Under the regulation, “business” does “not include local employment or labor for hire” and payment associated with the applicable activity is not expressly addressed. *Id.* This regulation’s definition of “business,” in particular its catch-all phrase “legitimate activities of a commercial nature,” underscores the invalidity of the

Plasma Ban. Such broad language plainly encompasses donating plasma at a collection center that provides payment as part of the donation process. *See, e.g., Fischbein v. Olson Rsch. Grp., Inc.*, 959 F.3d 559, 563 (3d Cir. 2020) (blood donation with payment is a “commercial transaction”).

72. By categorically excluding plasma donation from the scope of “legitimate activities of a commercial nature” that are considered permissible “business” on a B-1 visa, the Plasma Ban is “irreconcilable” with 22 C.F.R. § 41.31. It effectively casts plasma donation—an essential business as determined by the Department of Homeland Security’s Cyber Security and Infrastructure Security Agency, and an industry closely regulated by the FDA and other federal agencies—somehow not to be a legitimate activity of a commercial nature. And “if a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative.” *Ass’n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 718 (D.C. Cir. 2015).

73. The Plasma Ban also must be considered a legislative rule—and not mere interpretative guidance—because it “does more than simply clarify or explain a regulatory term, or confirm a regulatory requirement, or maintain a consistent agency policy.” *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014). The Plasma Ban “expand[s] the footprint of a regulation by imposing new requirements”—*i.e.*, mandating that B-1 visa holders may no longer donate plasma if they receive payment. *Children’s Hosp. of the King’s Daughters, Inc. v. Azar*, 896 F.3d 615, 620 (4th Cir. 2018) (citing *Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 873 (8th Cir. 2013)).

74. Legislative rules must be promulgated in accordance with the notice-and-comment procedures set forth at 5 U.S.C. § 553. *See, e.g., Steinhorst Assocs. v. Preston*, 572 F. Supp. 2d 112, 120 (D.D.C. 2008).

75. CBP did not come close to following notice-and-comment procedures, choosing instead to promulgate the Plasma Ban through an abrupt statement to the press. The APA does not allow agencies to adopt legislative rules in such a slap-dash manner.

***Plaintiffs Have Standing to Challenge the Plasma Ban***

76. As stated, Plaintiffs rely on plasma donations from B-1/B-2 visa holders. By banning B-1/B-2 visa holders from entering the U.S. to donate their plasma at Plaintiffs' collection centers, the Plasma Ban "will result in known, predictable consequences" for Plaintiffs, including substantial economic harm. *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1199 (9th Cir. 2004); *see also, e.g., Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 164 (3d Cir. 2017) ("economic harms sufficient injuries for standing"). While CBP has indicated that these individuals could be allowed entry if they obtain another type of visa, like an H-type temporary work visa, as a practical matter it is impossible for Mexican plasma donors to get any other visa, as evidenced by the steep decline in donations following CBP's adoption and immediate implementation of the Plasma Ban.

77. Plaintiffs and other plasma collectors with collection centers located near the southern border will collect less plasma, despite their other efforts to respond and seek to bridge the growing gap between plasma supply and demand to meet the needs of patients who rely on plasma-derived therapies. As a result, Plaintiffs and other plasma collectors will be forced to provide less plasma-derived therapies to patients, put contractual relationships at risk, potentially derail research projects, and generally damage standing with the patient community.

78. Furthermore, in response to the Plasma Ban, Plaintiffs stopped advertising to potential donors in Mexico, as doing so could be deemed inducing them to break the law. Such a change in Plaintiffs' conduct, caused by the unlawful Plasma Ban, is also an injury that confers standing. *See, e.g., Suhre v. Haywood Cty.*, 131 F.3d 1083, 1087 (4th Cir. 1997).

79. But for CBP's Plasma Ban, Plaintiffs would continue to advertise to potential donors in Mexico, as part of their continuing efforts to increase collections in the face of ongoing supply concerns. Both the economic harm to Plaintiffs and the illegal constraint on their ability to advertise could be redressed by a declaration that the Plasma Ban is unlawful. *See, e.g., Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992) (addressing "causation and redressability").

80. The Plasma Ban also harms patients, as less plasma collected inevitably means that less plasma-derived therapies will be available. Affected patient communities have already expressed concern over the Plasma Ban's serious impact on public health. *See, e.g., Immune Deficiency Foundation, Plasma Donors at the Border: An International Concern* (July 1, 2021), <https://www.plasmahero.org/news/plasma-donors-border-international-concern>. Plaintiffs, as providers of life-saving medicines, have standing to assert these injuries suffered by patients who rely on those medicines. *See, e.g., Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc. v. Parson*, No. 19-2882, 2021 WL 2345256, at \*5 (8th Cir. June 9, 2021).

81. CBP's Plasma Ban represents a profound break—a break with the 125,000 patients who rely on plasma collected from Plaintiffs' border centers; a break with the FDA, which, as the licensor of plasma collection centers, has acquiesced to collecting plasma from Mexican nationals for years; a break with the Department of Health and Human Services, the agency charged with protecting the public health; a break with the Justice Department, which has long considered plasma donation a service, not work or labor; and a break with CBP's own decades long past practice of allowing donors to cross the border on B-1/B-2 visas. The reason CBP stands alone in advancing the Plasma Ban is clear: the text, structure, and purpose of the Immigration and Nationality Act make clear that B-1/B-2 visa holders may enter the United States to donate their blood plasma at collection centers that provide payment as part of the donation process.

## CLAIMS FOR RELIEF

### Count 1

#### **Declaratory/Injunctive Relief Under Section 706(2)(A), (C) of the APA — the Plasma Ban Is Contrary to Law and Exceeds CBP’s Authority Under 5 U.S.C. § 1101(a)(15)(B)**

82. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

83. The APA requires courts to “hold unlawful and set aside” agency action that is “not in accordance with law” or is “in excess of statutory jurisdiction, authority, or limitations.” 5 U.S.C. § 706(2)(A), (C).

84. The Plasma Ban is contrary to 8 U.S.C. § 1101(a)(15)(B), which allows B-1/B-2 visa holders to enter the U.S. “temporarily for business.” The broad term “business” encompasses the donation of blood plasma at collection centers that provide payment to donors as part of the process. While the statute bars B-1/B-2 visa holders from entering the U.S. “for the purpose of performing . . . labor,” 8 U.S.C. § 1101(a)(15)(B), the donation of plasma cannot plausibly be considered “labor.” Even the U.S. Department of Justice has rejected the view that plasma donation at centers that provide payment constitutes “employment or contract work” of any kind.

85. The Plasma Ban is thus “not in accordance with law,” is “in excess of statutory jurisdiction, authority, or limitations,” and must be set aside under 5 U.S.C. § 706(2)(A), (C).

### Count 2

#### **Declaratory/Injunctive Relief Under Section 706(2)(A) of the APA — the Plasma Ban Is Arbitrary and Capricious**

86. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs

87. The APA requires courts to “hold unlawful and set aside” agency action that is “arbitrary” or “capricious.” 5 U.S.C. § 706(2)(A).

88. The Plasma Ban suddenly upended CBP’s longstanding prior practice of allowing B-1/B-2 visa holders to enter the U.S. to donate plasma at collections centers and receive payment

associated with the donation process. Yet in issuing the Plasma Ban, CBP did not even acknowledge the prior longstanding practice, much less offer an explanation for the sudden change. Nor did CBP give consideration to the well-established reliance interests inherent in the prior longstanding practice, including the significant reliance interests of Plaintiffs, other companies in the plasma industry, and patients who rely on plasma-derived therapies.

89. The Plasma Ban is therefore “arbitrary” and “capricious” and should be set aside under 5 U.S.C. § 706(2)(A).

### **Count 3**

#### **Declaratory/Injunctive Relief Under Section 706(2)(D) of the APA — the Plasma Ban Is a Legislative Rule Impermissibly Promulgated Without Notice-And-Comment Procedures**

1. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.
2. The APA requires courts to “hold unlawful and set aside” agency action taken “without observance of procedure required by law.” 5 U.S.C. § 706(2)(D).
3. The Plasma Ban is a legislative rule because it purports to alter the terms of a prior legislative rule, 22 C.F.R. § 41.31, and imposes a new legal requirement.
4. Because the Plasma Ban is a legislative rule, CBP was required to conduct notice-and-comment rulemaking according to the procedures set forth in 5 U.S.C. § 553.
5. CBP did not conduct the requisite notice-and-comment rulemaking procedures, but rather issued the Plasma Ban through a sudden statement to the press.
6. The Plasma Ban was therefore enacted “without observance of procedure required by law” and should be set aside under 5 U.S.C. § 706(2)(D).

**PRAYER FOR RELIEF**

**NOW, THEREFORE**, Plaintiffs CSL Plasma Inc., CSL Behring L.L.C., Biomat USA, Inc., GCAM, Inc., and Talecris Plasma Resources, Inc. request a judgment in their favor against Defendants as follows:

1. Declare that the Plasma Ban is not in accordance with 8 U.S.C. § 1101(a)(15)(B), is in excess of CBP's statutory authority, and is therefore invalid under the Administrative Procedure Act;
2. Declare that the Plasma Ban is arbitrary and capricious and is therefore invalid under the Administrative Procedure Act;
3. Declare that the Plasma Ban is a legislative rule promulgated without observance of notice-and-comment rulemaking procedures required by 5 U.S.C. § 553 and is therefore invalid under the Administrative Procedure Act;
4. Set aside and vacate the Plasma Ban;
5. Preliminarily and permanently enjoin Defendants from implementing or enforcing the Plasma Ban;
6. Award Plaintiffs reasonable attorneys' fees and costs; and
7. Grant such other and further relief as the Court may deem appropriate.

DATED: September 7, 2021.

Respectfully submitted,

/s/ Baruch Weiss

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\* Application for admission to practice  
before this Court pending