

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

CSL PLASMA INC., et al.,

Plaintiffs,

v.

**UNITED STATES CUSTOMS AND
BORDER PROTECTION, et al.,**

Defendants.

Civil Action No. 21-cv-2360 (TSC)

HECTOR AMAYA., et al.,

Plaintiffs,

v.

**UNITED STATES CUSTOMS AND
BORDER PROTECTION, et al.,**

Defendants.

Civil Action No. 22-cv-0242 (TSC)

MEMORANDUM OPINION

Plaintiffs—five companies that collect and sell blood plasma (“Company Plaintiffs”), their employees (“Employee Plaintiffs”), their donors (“Donor Plaintiffs”), and patients who benefit from plasma-derived therapies (“Patient Plaintiffs”)—sued Defendants United States Customs and Border Protection (“CBP”), and Chris Magnus,¹ in his official capacity as CBP Commissioner, in two cases, initially filed separately. Compl., ECF No. 1 (“*CSL Plasma* Compl.”), *CSL Plasma, Inc., et al. v. United States Customs and Border Protection, et al.*, No.

¹ The Complaints name Troy A. Miller as an official capacity Defendant, but because Chris Magnus was sworn in as CBP Commissioner on December 13, 2021, he is substituted as the proper Defendant. Fed. R. Civ. P. 25(d).

21-cv-2360 (D.D.C. Sept. 7, 2021) (“*CSL Plasma*”); Compl., ECF No. 1 (“*Amaya* Compl.”), *Amaya, et al. v. United States Customs and Border Protection, et al.*, No. 22-cv-0242 (D.D.C. Jan. 31, 2022) (“*Amaya*”). The two cases were consolidated on June 30, 2022. Order of Consolidation, ECF No. 42, *CSL Plasma*; Order of Consolidation, ECF No. 21, *Amaya*. In both cases, Plaintiffs seek a preliminary injunction enjoining CBP from preventing B-1 and B-2 visa holders from crossing the U.S.-Mexico border to donate their blood plasma at the companies’ collection centers. Mot. for Prelim. Inj., ECF No. 7, *CSL Plasma* (“*CSL Plasma* Mot. for PI”); Mot. for Prelim. Inj., ECF No. 3, *Amaya* (“*Amaya* Mot. for PI”).

Of the four groups of plaintiffs, two—Donor Plaintiffs and Patient Plaintiffs—lack the necessary standing to bring suit, while Employee Plaintiffs have not made a clear showing of irreparable harm. Only Company Plaintiffs have made the clear showing necessary to merit injunctive relief. Therefore, the *Amaya* motion for a preliminary injunction, will be **DENIED**, and the *CSL Plasma* motion for a preliminary injunction will be **GRANTED**.

I. BACKGROUND

A. Statutory and Regulatory Framework

The Immigration and Nationality Act of 1952 (“INA”)² created the modern statutory framework governing the immigration, naturalization, and nationality of individuals seeking to enter the United States. While the INA primarily encompasses the immigration process, it also includes entry and removal considerations for “certain nonimmigrants,” 8 U.S.C. § 1102, who are exceptions to the broader default status of “immigrants,” and include “an alien . . . visiting the United States temporarily for business or temporarily for pleasure.” *Id.* § 1101(a)(15)(B).

² The Act was later amended to its current form in 1965. *See* Immigration and Nationality Act of 1965, Pub L. No. 89-236, 79 Stat. 911 (1965) (codified at 8 U.S.C. ch. 12). The current substantive provisions about the B-1/B-2 visa provisions were enacted in the 1952 law.

The State Department administers visa categories and regulates the entry of nonimmigrant aliens under a temporary “B-1” business visa or a “B-2” pleasure visa. 22 C.F.R. § 41.31(a) (2020). “Business” is defined as “conventions, conferences, consultations and other legitimate activities of a commercial or professional nature,” and explicitly excludes “local employment or labor for hire.” *Id.* § 41.31(b)(1). State Department consular officers are instructed to issue B-1/B-2 visas if an applicant shows they intend to engage in business activities “other than the performance of skilled or unskilled labor.” 9 FAM 101.1-3(b), 402.2-5(A)(a).

State Department regulations allow Mexican nationals to receive either a B-1/B-2 visa for each trip, or a “Border Crossing Card” (“BCC”) that allows multiple B-1/B-2 entries over a 10-year period. 22 C.F.R. § 41.32. Mexican BCC holders are limited to trips no longer than 72 hours and are restricted to a zone 25-75 miles from the border. 8 C.F.R. § 235.1(h)(iii), (v). CBP determines at the port of entry whether individuals seeking admission into the United States are admissible under the B-1/B-2 visa program. 8 U.S.C. § 1201(h).

B. Factual Background

Human blood plasma is a necessary element of many medical therapies for patients with serious medical conditions and immune deficiencies. *CSL Plasma* Compl. ¶ 22.³ Many of those therapies are resource intensive: a year of treatment may require vast quantities of plasma. *Id.* This has created an industry for the global supply of human blood plasma. *Id.* ¶¶ 1-2. Companies that sell blood plasma offer payment—around \$50—for donations of blood plasma through plasmapheresis, a process in which a donor’s blood is drawn, the plasma separated out,

³ The *CSL Plasma* and *Amaya* complaints and motions for a preliminary injunction are nearly identical. Thus, the court will primarily cite to the *CSL Plasma* docket for convenience, though will also cite in parallel to the *Amaya* docket when necessary.

and the remainder (red cells, white cells, and platelets) returned to the donor. *Id.* ¶¶ 23-25.

Donors may undergo plasmapheresis no more than twice in a seven-day period, with at least 48 hours between donations. *Id.* ¶ 24.

For at least 30 years, many blood plasma donors have been B-1 or B-2 visa holders (usually Mexican nationals) who enter the United States solely to donate their plasma. *Id.* ¶¶ 33-34. To accommodate these donations, some blood plasma collection companies—like CSL Behring and Grifols—have built or acquired collection centers along the U.S.-Mexico border. *Id.* ¶ 4. Employee and Donor Plaintiffs work and donate plasma at these locations, and Patient Plaintiffs benefit from plasma-derived therapies.

Plaintiffs represent that annually, over 30,000 Mexican nationals donated plasma at border-adjacent collection centers operated by Grifols alone. *Id.* ¶¶ 3-4. They allege that Mexican national blood plasma donation has been common knowledge and accepted custom for decades. *Id.* ¶ 36; *see also* *CSL Plasma* Mot. for PI, Sanchez Decl. ¶ 5-6, ECF No. 7-13. Defendants counter that CBP has “long taken the position” that B-1/B-2 visa holders may not enter the United States solely to donate plasma, and that any exceptions to that position were one-offs attributable to the challenges of enforcing that restriction. Defs.’ Opp. to *CSL Plasma* Mot. for PI (“*CSL Plasma* Defs.’ Opp.”) at 4, ECF No. 9.

In March 2020 blood plasma donation—tacitly sanctioned or not—shifted due to the onset of the COVID-19 pandemic. As the pandemic began, the Department of Homeland Security temporarily limited land border travel to “essential travel” only. *CSL Plasma* Defs.’ Opp., Davis Decl. ¶ 12. Ports of entry along the border, including in Arizona and California, deemed plasma donation to be an impermissible activity under the terms of the B-1/B-2 visa classification, and denied BCC holders entry into the United States for that purpose. *Id.*

In Texas, however, CSL Behring and Grifols issued so-called “safe passage” letters to employees and donors indicating that plasma donors were “essential,” and thus should be allowed to cross the border. *CSL Plasma* Mot. for PI, Mercado Decl. ¶¶ 5-6; *Id.* Sanchez Decl. ¶ 7. In response, some CBP port of entry supervisors in Texas coordinated with collection centers to determine whether BCC holders seeking entry to donate plasma were actually coming to collection centers to donate. *Id.* A system of sorts emerged: collection centers sent appointment lists showing the visa numbers of donors expected the next day to Texas CBP officials, who would then allow those BCC holders to cross the border to donate plasma. *Id.*

This system eventually came to the attention of CBP’s Office of Field Operations, which creates and oversees enforcement policy at ports of entry. *CSL Plasma* Defs.’ Opp., Davies Decl. ¶¶ 6, 13. After a review, the Office issued a guidance memorandum on June 14, 2021 clarifying that plasma donation is considered labor for hire that is impermissible for B-1/B-2 visa holders, regardless of their “essential” classification. *Id.* ¶ 14; *id.*, Ex. 1, Impermissible Nonimmigrant B-1/B-2 Activities – Paid Plasma Donations (“Plasma Guidance” or “Guidance”). The next day, CBP issued the following statement 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.

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.

CSL Plasma Compl. ¶ 39. After this statement was issued, CSL Behring and Grifols began contacting members of the executive and legislative branch to “resolve the situation.” *Id.* ¶ 43.

C. Procedural Background

CSL Behring and Grifols' outreach to the executive and legislative branches to reverse or mitigate the Guidance was unsuccessful. *Id.* Company Plaintiffs then filed suit in this court on September 7, 2021, alleging that the Guidance violated the Administrative Procedure Act ("APA") because it was: (1) contrary to law, per 5 U.S.C. § 1101(a)(15)(B); (2) arbitrary and capricious, per 5 U.S.C. § 706(2)(A); and (3) impermissibly promulgated without notice-and-comment, per 5 U.S.C. § 706(2)(D). Compl. ¶¶ 31-32. Company Plaintiffs also moved for a preliminary injunction. After briefing and oral argument, this court denied injunctive relief and dismissed the case. Mem. Op. at *11, ECF No. 28, *CSL Plasma*. Company Plaintiffs appealed that decision to the D.C. Circuit shortly thereafter. Amend. Not. of Appeal, ECF No. 32, *id.*

While that appeal was pending, a group of collection center employees, donors, and patients benefitting from plasma-derived therapies filed suit in *Amaya*, alleging the same causes of action as in *CSL Plasma*. See *Amaya* Compl. The *Amaya* Plaintiffs also sought a preliminary injunction.

Before the court could rule on the *Amaya* preliminary injunction motion, the D.C. Circuit reversed and remanded this court's dismissal of *CSL Plasma*, with the mandate returning to this court on June 21, 2022. Mandate, ECF No. 38, *CSL Plasma*. Because all parties indicated that they were in favor of consolidation of *CSL Plasma* and *Amaya*, on June 30, 2022, the court ordered both cases consolidated. Both motions for a preliminary injunction are now pending before the court.

D. Parties

Company Plaintiffs: Plaintiff CSL Behring collects and uses blood plasma to develop medical therapies and treatments. Plaintiff Grifols, through its subsidiaries Talecris Plasma

Resources, Inc., Biomat USA, Inc., and GCAM, Inc. operates hundreds of plasma collection centers. *CSL Plasma Compl.* ¶¶ 14-18.

Employee Plaintiffs: Plaintiffs Hector Amaya, Alejandro Angulo, Edgar Felix, Trisha McCrimmon, and Robert Miranda all work at plasma collection centers run by CSL Behring and Grifols near the United States-Mexico border. *Amaya Compl.* ¶¶ 14, 15 18, 20, 21. Each has spent significant portions of their careers in the plasma collection industry and have had their hours reduced since CBP’s guidance was issued. *Id.*

Donor Plaintiffs: Plaintiffs Daniel Estrada and Kevin Rasmussen are all regular donors at CSL Behring plasma collection centers. *Id.* ¶¶ 17, 22. Employee Plaintiffs Amaya and Miranda are also regular donors at CSL Behring plasma collection centers. *Id.* ¶¶ 14, 21.

Patient Plaintiffs: Plaintiffs John Boyle, William Hutsell, and Megan Ryan receive immunoglobulin—a plasma-derived therapy treatment. *Id.* ¶¶ 16, 19, 23.

Defendants: Defendant CBP is the federal agency responsible for the enforcement of immigration laws, and Chris Magnus is CBP’s Senior Official.

II. LEGAL STANDARD

A preliminary injunction is an “extraordinary and drastic” remedy that is “never awarded as of right.” *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). A movant must demonstrate a (1) likelihood of success on the merits; (2) a likelihood of irreparable harm absent injunctive relief; (3) that the balance of equities tips in their favor; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The last two factors “merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). Because “a preliminary injunction is an extraordinary and drastic remedy,” the court should not grant one “unless the movant, *by a clear showing*, carries the burden of persuasion.” *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (internal citation omitted) (emphasis in original).

Courts in this Circuit have typically applied a “sliding-scale” approach in analyzing these four factors; a particularly strong showing in one factor could outweigh weakness in another. *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011). It is unclear if this approach has survived the Supreme Court’s decision in *Winter*, however. *See, e.g., Banks v. Booth*, 459 F. Supp. 3d 143, 149-50 (D.D.C. 2020) (citing *Sherley*, 644 F.3d at 393)). Nonetheless, the movant still bears a burden to show that “all four factors, taken together, weigh in favor of the injunction.” *Abdullah v. Obama*, 753 F.3d 193, 197 (D.C. Cir. 2014) (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009)). Whatever the status of the sliding scale, the court “cannot dispense with the required showing of” either success on the merits or irreparable harm “simply because there is a strong likelihood of the other.” *Nken*, 556 U.S. at 438 (Kennedy, J. concurring).

III. ANALYSIS

A. Standing

A federal court has an independent obligation to assure itself that a plaintiff has constitutional standing to sue. *See, e.g., Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009). A plaintiff must show: (1) an injury-in-fact that is concrete and particularized and actual or imminent; (2) a causal connection between injury and the complained-of conduct; and (3) the likelihood that the injury may be redressable by a favorable judicial determination. *See, e.g., Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

Defendants do not challenge Company Plaintiffs’ Article III standing to bring suit, but argue that the Employee, Donor, and Patient Plaintiffs do not have injuries that are traceable to the Plasma Guidance or redressable by a favorable judicial determination. Defs.’ Opp. to *Amaya* Mot. for PI (“*Amaya* Defs.’ Opp.”) at 10-16, ECF No. 9, *Amaya*.

i. Injury-in-Fact

At the pleading stage, a plaintiff need only provide “general factual allegations of injury resulting from the defendant’s conduct” to demonstrate standing. *See, e.g., Sierra Club v. E.P.A.*, 292 F.3d 895, 898 (D.C. Cir. 2002) (quoting *Defenders of Wildlife*, 504 U.S. at 561). The court “presum[es] that general allegations embrace the specific facts that are necessary to support the claim.” *Id.* (quoting *Defenders of Wildlife*, 504 U.S. at 561). “Much more is needed,” however, when a claim arises from the “government’s allegedly unlawful regulation . . . of *someone else*.” *Defenders of Wildlife*, 504 U.S. at 562 (emphasis in original). In such cases, a plaintiff must “demonstrate a substantial likelihood that the third party directly injuring the plaintiff would cease doing so” were the plaintiff’s requested relief granted. *Renal Physicians Ass’n v. U.S. Dep’t of Health and Hum. Servs.*, 489 F.3d 1267, 1275 (D.C. Cir. 2007).

Patient Plaintiffs allege that, should the Guidance stand, their plasma derived therapies may be interrupted due to supply issues.⁴ Donor Plaintiffs allege that the plasma donation centers might close, imperiling their donation payments.⁵ But the mere possibility of harm, without any specificity or certainty, does not establish standing. *See, e.g., Kan. Corp. Comm’n v. FERC*, 881 F.3d 924, 930 (D.C. Cir. 2018) (quoting *Def. of Wildlife*, 504 U.S. at 564)) (“A petitioner that asserts a harm that may occur ‘some day,’ with no ‘specification of *when* the some day will be,’ does not establish its standing.”) (emphasis in original). Donor and Patient

⁴ *Amaya* Mot. for PI, Boyle Decl. ¶ 6 (“If another shortage occurs . . . I will be forced to dramatically alter my lifestyle.”); *id.* Hutsell Decl. ¶ 5 (“If a weekly treatment is delayed by even a few days I would have to seriously alter my lifestyle . . .”); *id.* Ryan Decl. ¶ 4 (same).

⁵ *See, e.g., id.*, Estrada Decl. ¶ 5 (The Guidance “may cause CSL Plasma to shut down the Nogales collection center. Should that happen . . . [I] would suffer financial harm”); *id.* Rasmussen Decl. ¶ 5-6 (Because of the Guidance, “CSL Plasma may be forced to close the Douglas center where I donate. Should this happen . . . I anticipate we would not be able to pay our bills and our credit score would be negatively affected.”).

Plaintiffs have not pleaded that these harms are certain to occur, let alone when they will happen, only that they *may* happen. And the harms would be the result of business decisions by the plasma companies, not the Guidance itself.

The court is sympathetic to the potential harms that Donor and Patient Plaintiffs face, especially given the impact of the COVID-19 pandemic on the immunocompromised and the economically disadvantaged. But that sympathy does not propel Patient and Donor Plaintiffs past the “irreducible constitutional minimum” needed for standing when there is no certain injury-in-fact.

Employee Plaintiffs, on the other hand, plead that their hours and wages have been reduced up to 40% since the Plasma Guidance was implemented. *See Amaya* Compl. ¶¶ 14, 15, 18, 20, 21, 79. This injury is concrete and non-speculative, and therefore is sufficient for constitutional standing. *See, e.g., Molock v. Whole Foods Market, Inc.*, 297 F. Supp. 3d 114, 129 (D.D.C. 2018) (reduced wages conferred standing); *cf. Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 5 (D.C. Cir. 2017) (“A dollar of economic harm is still an injury-in-fact for standing purposes.”) (citations omitted).

ii. Traceability and Redressability

Traceability and redressability “overlap as two sides of a causation coin” and rise and fall together, especially when a plaintiff challenges a government agency’s regulation of a third party. *See Exhaustless, Inc. v. Fed. Aviation Admin.*, 931 F.3d 1209, 1212 (D.C. Cir. 2019) (quoting *Dynalantic Corp. v. Dep’t of Def.*, 115 F.3d 1012, 1017 (D.C. Cir. 1997)). At the pleading stage, the court need not decide whether a plaintiff has definitively proven a causal link between agency action and a plaintiff’s injury, but instead determine if the facts alleged are “sufficient to demonstrate a substantial likelihood” that such a causal linkage exists, and that the court’s action might redress the injury. *See, e.g., Renal Physicians Ass’n*, 489 F.3d at 1275; *see*

also *Defenders of Wildlife*, 504 U.S. at 561. This is a low bar; a plaintiff need only allege general facts that “embrace those specific facts necessary to support the claim.” *Id.* (citing *Lujan v. Nat’l. Wildlife Fed.*, 497 U.S. 871, 883-89 (1990)).

Employee Plaintiffs’ allegations establish the requisite traceability and redressability. They describe a direct causal link between the Guidance and their complained-of injuries: the Guidance has caused a drop-off in plasma donations at collection centers, forcing the plasma companies to reduce Employee Plaintiffs’ hours and wages. *Amaya* Compl. ¶ 79; *see also Amaya* Mot. for PI, Angulo Decl. ¶ 6, Cavanaugh Decl. ¶ 6, Felix Decl. ¶ 4, McCrimmon Decl. ¶ 4, Miranda Decl. ¶ 6, Wolsing Decl. ¶ 5.

Defendants first respond that any reduction in plasma collection volume is not because of the Guidance, but instead because of the “upheavals of the COVID-19 pandemic.” *Amaya* PI Opp. at 12. Plaintiffs themselves proffer compelling evidence that the pandemic has had a profound impact on the plasma collection industry. *See, e.g., Amaya* Mot. for PI, Efantis Decl. ¶ 6 (“[J]ust as many Americans have limited their visits to restaurants and retail stores, many have limited their visits to plasma centers.”). But the Guidance is a significant, traceable cause of that downturn as well—Plaintiffs have shown a precipitous decline in collections after the Guidance was issued. *Id.*, Cavanaugh Decl. ¶ 5, Procaccio Decl. ¶ 5 & Ex. A, Slide 7 (third-party research showing near zeroing-out of donation volume in Texas following Guidance issuance).

Defendants also contend that any reduction in employee hours were the result of the plasma companies’ independent business decisions and were unrelated to the decline in collection volume. *Amaya* Defs.’ Opp. at 12-14. They argue that because the plasma companies could have taken alternative measures, such as increasing compensation for American donors or relocating their collection centers, Employee Plaintiffs’ injuries cannot be traced to the Guidance

or redressed by enjoining it. *Id.* at 12. But Employee Plaintiffs claim their employers have already tried some of these measures, and their hours were still reduced. *See Amaya* Mot. for PI, Cavanaugh Decl. ¶ 6, Wolsing Decl. ¶ 6 (“To mitigate these losses, Grifols increased its marketing efforts dramatically . . . [and] increased the monetary reimbursements to donors that continued to donate. . .”).

Employee Plaintiffs have offered sufficient factual allegations that “embrace those specific facts necessary to support the claim” that their reduction in hours is traceable to the Guidance and redressable by enjoining it. *Defenders of Wildlife*, 504 U.S. at 561. The court thus finds that the Employee Plaintiffs have standing to pursue their claims.

B. Preliminary Injunction Factors

i. Likelihood of Success on the Merits

Company and Employee Plaintiffs both contend the Plasma Guidance is contrary to law, arbitrary and capricious, and impermissibly promulgated without notice and comment procedures.

a. Contrary to Law

The INA provides that foreign nationals may visit the United States on a B-1/B-2 visa “temporarily for business,” but not to perform “skilled or unskilled labor.” 8 U.S.C. § 1101(a)(15)(B). The State Department—which administers and enforces visa issuance, *Id.* § 1104(a)—has clarified via regulation that business “refers to conventions, conferences, consultations and other legitimate activities of a commercial or professional nature.” 22 C.F.R. § 41.31(b)(1). The State Department has also adopted the following “significant considerations” to determine if an activity is a B-1 visa-eligible business activity:

[1] A clear intent on the part of the alien to continue their foreign residence and not to abandon the existing domicile;

[2] that the principal place of business and the actual place of eventual accrual of profits, at least predominantly, remains in the foreign country;

[3] the business activity itself need not be temporary, and indeed may long continue; [and]

[4] the various entries into the United States made in the course thereof must be individually or separately of a plainly temporary nature. . . .

Matter of Hira, 11 I. & N. Dec. 824, 827 (BIA 1966); *see also* 9 Foreign Aff. Manual § 402.2-5(A)(b) (characterizing *Hira* as the “clearest legal definition” of the distinction between business and labor for B-1 visa purposes.). The Department of Homeland Security, which enforces the immigration laws, 8 C.F.R. §2.1, also considers the *Hira* factors to be of “great utility” in differentiating between business and labor. *See* Nonimmigrant Classes; B Visitor for Business or Pleasure, 58 Fed. Reg. 58982, 58983 (Nov. 5, 1993) (codified at 8 C.F.R. §§ 214, 274a).

Plaintiffs cite the *Hira* factors in support of their contention that plasma donation is business, not labor. They argue that because plasma donation “takes just a few hours” and the donors return to their overseas residences, plasma donation fits under the *Hira* definition of business. *CSL Plasma* Mot. for PI at 20. They also contend that despite receiving payment in the United States, Mexican national donors’ principal place of business and the place where they accrue their profits is in Mexico. *CSL Plasma* Mot. for PI at 20. In support, they offer two Board of Immigration Appeals (“BIA”) decisions and an Immigration and Naturalization Service (“INS”)⁶ general counsel’s opinion in which nonimmigrant aliens paid in the United States were allowed entry under B-1 visas. *CSL Plasma* Mot. for PI at 20.

⁶ The Immigration and Naturalization Service is the predecessor organization to Customs and Border Patrol. *See generally* Homeland Security Act of 2002, Pub. L. 107-296, 116 Stat. 2135 (2002).

These arguments do not clearly show that the Plasma Guidance is contrary to law. Certainly, as Plaintiffs observe, the BIA is “entitled to deference in interpreting ambiguous provisions of the INA.” *Negusie v. Holder*, 555 U.S. 511, 516 (2009) (citing *Chevron U.S.A. Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842-43 (1984)). But the cases upon which both sets of Plaintiffs rely are all factually distinguishable; none clearly shows that plasma donation should be considered a business activity, rather than labor.

First, in *Matter of Camilleri*, the BIA held that a Canadian truck driver who transported agricultural equipment from Canada to the United States and was paid in the United States in United States dollars was admissible under a B-1 visa. 171 I. & N. Dec. 441, 442 (B.I.A. 1980). But the BIA based this decision on the fact that “the second contention set forth in *Matter of Hira* . . . is not applicable to employees of common carriers who are engaged in international trade or commerce.” *Id.* at 443. Plaintiffs here are not common carrier employees. Plaintiffs’ second case, *Matter of Duckett*, concerned a Canadian employee who completed and was paid for the “bulk of his work” in Canada; his visits to the United States involved “only a few hours of his shift.” 19 I. & N. Dec. 493, 497 (B.I.A. 1987). By contrast, plasma donors completed and were paid for all of their work in the United States.

The INS general counsel opinion involved couriers who transported laboratory samples from Mexico to a laboratory in the United States, and medical reports back across the border. Genco Op. No. 93-95, HQ 235-C, 1993 WL 1504042 (Dec. 28, 1993). Plaintiffs contend that “like the couriers, plasma donors are carrying a substance that ‘originates in Mexico.’” Pls.’ Reply to *CSL Plasma* Defs.’ Opp. (“*CSL Plasma* Pls.’ Reply”) at 12, ECF No. 20 (quoting Genco Op. No. 93-95). They argue that—like couriers—donors simply deliver their product in the United States after transporting it across the border. *See CSL Plasma* Compl. ¶ 56.

The comparison is unpersuasive. A person is more than just a shopping cart of biological products to be bought and sold at a later date. While a market for those products might exist, their production and sale implicate the “inviolability of the human personality,” whereas delivering a couriered package would not. *Cf. Schmerber v. California*, 384 U.S. 757, 762 (1966). Plasma donation, as Plaintiffs note, is a “closely regulated” medical process; donors must meet FDA eligibility requirements and may only donate a limited number of times per week. *CSL Plasma* Mot. for PI ¶ 23. Package delivery may require physical effort, but, unlike plasma donation, the act of delivering a package carries no health risks. *See, e.g., Potential Long-Term Effects of Donating Plasma*, CSL Plasma, <https://www.csplasma.com/become-a-donor/effects-of-donating-plasma> (last accessed July 15, 2022) (“For donors who donate frequently or for an extended amount of time, there is a risk for depleting immunoglobulin levels, which can lower the ability to fight off infections.”). And while a delivery person who delivers a package suffers no physiological effects, let alone ones that continue for several days, scientific literature shows that a plasma donor might. *See, e.g.,* David W. Hill, Jakob L. Vingren, & Samantha D. Burdette, *Effect of Plasma Donation and Blood Donation on Aerobic and Anaerobic Responses in Exhaustive, Severe-Intensity Exercise*, 2 INT’L J. EXERCISE SCI. 22 (describing study finding plasma donation increased time to exhaustion and decreased measures of anaerobic capacity up to one week after donation); *see also* Jeffrey L. Winters, *Complications of Donor Apheresis*, 21 J. CLINIC APHERESIS 132 (2006) (discussing potential negative long-term effects of apheresis donation).

Plaintiffs also contend that the definitions of the words “business” and “labor,” as well as other judicial opinions related to plasma collection centers support their contention that plasma donation is labor. Dictionary definitions may assist the court when a statute is not clear. *See,*

e.g., Mohamad v. Palestinian Auth., 566 U.S. 449, 454 (2012) (considering dictionary definition of “individual”). But the court cannot simply “tally the dictionary definitions” in order to resolve a statutory ambiguity. *Competitive Enter. Inst. v. United States Dep’t of Transp.*, 863 F.3d 911, 916 (D.C. Cir.2017); *see also Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir. 1945) (“[A] mature and developed jurisprudence [does] not . . . make a fortress out of the dictionary.”) (opinion of Hand, J.). Plaintiffs’ multiple dictionary definitions clarifying the broad meaning of the word “business” are helpful, but not dispositive.

Plaintiffs also cite cases on the issue of whether plasma collection centers should be considered service establishments under the Americans with Disabilities Act (“ADA”). CSL Plasma Mot. for PI at 17. Two Circuits—the Third and Tenth—have held that plasma collection centers are service establishments subject to the ADA’s anti-discrimination provisions. *Id.* (citing *Matheis v. CSL Plasma Inc.*, 936 F.3d 171, 178 (3d Cir. 2019); *Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1234 (10th Cir. 2016)). The Fifth Circuit has concluded otherwise. *Id.* (citing *Silguero v. CSL Plasma Inc.*, 907 F.3d 323, 328 (5th Cir. 2018)). The Department of Justice filed a Statement of Interest in a case in the Northern District of Illinois arguing that the Fifth Circuit’s position is incorrect and supporting the Third and Tenth Circuits’ conclusions. *Id.* (citing Statement of Interest of the United States at 6-10, ECF No. 50, *Gomez v. CSL Plasma Inc.*, No. 20-cv-2488 (N.D. Ill. July 14, 2021) (“Gomez SOP”); *see generally* Lucy Richman, Note, *Equal Access to Donate: Plasma Donation Centers and the ADA*, 70 CLEV. ST. L. REV. 631, 643-45 (2022) (describing Circuit split and key cases).

The ADA cases turned on whether donor compensation is a benefit that transformed plasma collection centers into service establishments, that is, whether donors receive a benefit for their donations. *See Matheis*, 936 F.3d at 177. In holding that they did, the Third and Tenth

Circuits referred to a plasma collection center as a “place of business.” *Id.*; *Levorsen*, 828 F.3d at 1231. Thus, Plaintiffs urge the court to reach the “inescapable conclusion [that] . . . plasma donation is not akin to employment or contract work . . . and donation thus cannot be considered labor for hire.” *CSL Plasma* Mot. for PI at 18 (citing *Gomez* SOI) (internal quotation marks omitted).

Although Plaintiffs’ ADA cases refer to a plasma collection center as a “place of business,” the courts in those cases were not tasked with determining whether plasma donation is business or labor, just the “narrow[]” question of “whether a plasma donation facility is an ‘other service establishment’” for ADA purposes. *Matheis*, 936 F.3d at 176 (quoting ADA, 42 U.S.C. § 12181(7)(F)). In fact, the Tenth Circuit concluded that a service establishment could include an institution that “provides useful labor without producing a tangible good for a customer or client.” *Levorsen*, 828 F.3d at 1231.

The fact that the word “business” appears in the term “place of business” does not support the “inescapable conclusion” that plasma donation is business and not labor. *Cf. Weaver v. U.S. Info. Agency*, 87 F.3d 1429, 1437 (D.C. Cir. 1996) (quoting *Atl. Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932)) (“Identical words may have different meanings where . . . the conditions are different.”). Thus, Plaintiffs’ citation to these ADA cases is informative, but not dispositive as to whether plasma donation is business or labor.

b. Arbitrary and Capricious

Plaintiffs also argue that the Plasma Guidance is arbitrary and capricious; they contend that it has been “longstanding practice” for B-1/B-2 visa holders to enter the United States to donate plasma, even if there was no formal policy allowing them to do so. *CSL Plasma* Mot. for PI at 23. Employee Plaintiffs’ employers thus—relying on this practice—“invested millions of

dollars in establishing collection centers, . . . advertising to Mexican nationals, . . . to maintain and grow such operations.” *Id.* at 24. Consequently, Plaintiffs argue, the Guidance is arbitrary and capricious because it neither acknowledges nor explains the change in CBP’s position and its impact on the plasma industry’s serious reliance interests. *Id.* at 23-26.

Defendants counter that because “CBP never had a formal policy that selling plasma was an appropriate B-1 visa activity,” the Guidance is not a policy shift, and therefore cannot be arbitrary and capricious. *CSL Plasma Defs.’ Opp.* at 16 (quoting Davies Decl. ¶ 10). Moreover, they argue, the Guidance’s statement that “CBP understands the role of the plasma donation business in cross border commerce” is sufficient acknowledgment of whatever reliance interests might exist. *Id.* at 18.

Under the APA, a reviewing court must hold unlawful and set aside agency actions, findings, and conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). There is no difference in the standard of review “between initial agency action and subsequent agency action undoing or revising that action.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). But an agency changing position must “display awareness that it *is* changing position . . . [and] that there are good reasons for the new policy.” *Id.* (emphasis in original). An agency must be especially “cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.” *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020) (citations omitted).

The agency thus must provide “a more detailed justification than what would suffice for a new policy created on a blank slate . . . when its prior policy has engendered serious reliance interests.” *Fox Television Stations*, 566 U.S. at 515 (citing *Smiley v. Citibank (South Dakota)*,

N.A., 517 U.S. 735, 742 (1996)). When serious reliance interests are at play, the agency must “determine whether they were significant, and weigh any such interests against competing policy concerns.” *Regents*, 140 S. Ct. at 1915. “It would be arbitrary and capricious to ignore such matters.” *Id.* at 1913 (internal quotation marks omitted).

An agency remains obligated to weigh reliance interests against policy concerns even if the policy or practice in question was never formally implemented. The court must still evaluate whether an agency’s new practice is an arbitrary and capricious deviation from prior practice and precedent, even if there had been no previous formal policy. *See, e.g., American Wild Horse Preservation Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017) (an “established pattern of agency conduct and formalized positions” creates a general practice of established conduct that can implicate a policy shift); *ANR Pipeline Co. v. F.E.R.C.*, 71 F.3d 897, 901 (D.C. Cir. 1995) (“[W]here an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious.”).

Applied to the Guidance, this analysis raises three questions: (1) was the Guidance a shift in practice, (2) that engendered serious reliance interests, (3) which CBP failed to appropriately consider? *See MediNatura, Inc. v. Food & Drug Admin.*, 998 F.3d 931, 940-41 (D.C. Cir. 2021) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)) (internal quotation marks and citation omitted). The court finds the answer to each question is yes.

First, the Guidance was a shift in CBP’s practice. While there may not have been an official policy allowing B-1/B-2 visa holders to enter the U.S. to donate plasma, Plaintiffs have sufficiently shown that CBP was at least aware that B-1/B-2 visa holders had been allowed to cross the border to donate plasma. In his declaration, CBP’s Executive Director of Admissibility and Passenger Programs admits that he was “aware of reports, . . . [and] news media articles

dating back to 2019” discussing the practice of B-1/B-2 visa holders entering the U.S. to donate their plasma. *CSL Plasma Defs.’ Opp.*, Davies Decl. ¶ 10. Plaintiffs attest that CBP officials—aware that B-1/B-2 visa holders were crossing the border to donate plasma—worked with plasma donation centers to facilitate donations during the COVID-19 pandemic. *Id.*, Mercado Decl. ¶¶ 6-7 (describing CBP involvement with safe passage letter process), Sanchez Decl. ¶ 7 (same). Plaintiffs have also provided declarations stating that CBP has allowed this practice for at least 3 decades. *Id.*, Cavanaugh Decl. ¶ 2, Wolsing Decl. ¶ 7, Procaccio Decl. ¶ 2.

Plaintiffs argue that it “strains credulity” that CBP has been unaware of a multi-million-dollar industry requiring tens of thousands of people to cross the U.S.-Mexico border annually for over thirty years. *CSL Plasma Pls.’ Reply* at 15; *see also id.*, Efantis Decl., Slides 5, 8-9 (quantifying volume of Mexican national plasma donors at border collection centers). Although Plaintiffs have not clearly shown that CBP was aware of the extent of the industry that had developed at the border, the court agrees that it would be unusual for the agency charged with protecting the country’s borders to be unaware that its agents had been facilitating thousands of donor border crossings for decades. Plaintiffs’ assertion comports with CBP’s own press statement on the Guidance, in which it stated that B-1/B-2 visa holders would “*no longer* be permitted” to cross the border to donate plasma, indicating that it knew that B-1/B-2 visa holders were previously being admitted to donate plasma, even if the practice was not officially sanctioned. *CSL Plasma Mot. for PI* at 3. (emphasis added). Consequently, Plaintiffs have clearly shown that a general practice existed allowing B-1/B-2 visa holders to enter the United States, and that the Plasma Guidance therefore was a shift in practice.

As to the second question—whether that shift in practice engendered serious reliance interests—employee Plaintiffs allege that their employers—Company Plaintiffs—relying on

CBP’s practice of allowing B-1/B-2 visa holders to donate plasma “for over three decades . . . invest[ed] millions of dollars in establishing collection centers . . . [and] significant sums to maintain and grow such operations.” *Amaya* Mot. for PI at 24-25. These centers rely heavily on Mexican donors, who “comprise the majority of donors at most of the border centers.” *CSL Plasma* Compl. ¶ 63. Company Plaintiffs claim that since the Guidance was issued, their border collection centers have lost anywhere between 20 and 94% of their collection volumes. *CSL Plasma* Mot. for PI, *Efantis* Decl. ¶ 14-15.

In response, Defendants argue first that reliance interests cannot exist where—in the absence of an official policy—there was nothing on which to rely. *CSL Plasma* PI Opp. at 17-18. In the alternative, Defendants argue that while some individual border agents may have mistakenly approved some donor entries throughout the years, those grants do not create a “binding precedent or consistent pattern” that might engender any reliance interests. *Id.* at 18 (internal quotation marks omitted).

Agencies must still consider potential reliance interests even if they are not legally cognizable. *Regents*, 140 S. Ct. at 1913. Defendants correctly note that the D.C. Circuit has declined to quantify the number of erroneous visa grants that might “grant[] an obligation to explain a break in that pattern.” *Open Soc’y Inst. v. U.S. Citizenship & Immigr. Servs.*, 573 F. Supp. 3d 294, 321 (D.D.C. 2021), *dismissed sub nom. Open Soc’y Inst. v. United States Citizenship & Immigr. Servs.*, No. 21-5251, 2022 WL 4002149 (D.C. Cir. Aug. 29, 2022) (citing *Fogo de Chao v. DHS*, 769 F.3d 1127, 1144 (D.C. Cir. 2014)). But the Circuit also noted that “a pattern of visa grants of sufficient magnitude could obligate the agency to provide a reasoned explanation for treating similar situations differently. . . .” *Fogo de Chao*, 769 F.3d at 1144 (quoting *ANR Pipeline*, 71 F.3d at 901 (internal citations and punctuation omitted)). Here,

Plaintiffs have alleged tens of thousands of visa grants for plasma donors over three decades. While there is no hard line, thousands of cases over an extended time are “of sufficient magnitude” to require a fully reasoned explanation from CBP. *Doe v. Mayorkas*, No. 22-2521, 2022 WL 424978 at * 8-9 (D.D.C. Feb. 11, 2022) (eight cases required the agency “to acknowledge and explain its apparent change in position”); *see also Guam Contractors Ass’n v. Sessions*, No. 16-00075, 2018 WL 525697 at *7-8 (D. Guam Jan. 24, 2018) (“decades of approvals on the same facts and statutory and regulatory language” obligated a more reasoned explanation from the agency).

Finally, the third question: was CBP’s stated justification for the Guidance sufficient? When serious reliance interests are imperiled by an agency’s change of course, the agency is “required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns.” *Regents*, 140 S. Ct. at 1915.

The Guidance acknowledged Plaintiffs’ serious reliance interests: “CBP understands the role of the plasma donation business in cross border commerce, specifically along the U.S./Mexico border.” Guidance at 1. Defendants contend that though brief, this acknowledgment shows that the agency assessed and weighed the reliance interests at issue and is “similar to other acknowledgments that the courts have found sufficient” when an agency changes course to correct an erroneous pattern of visa grants. *CSL Plasma Defs.’ Opp.* at 18 (quoting *Open Society Inst.*, 573 F. Supp. 3d at 309-310).

Certainly, a brief explanation is not arbitrary and capricious just because of its brevity. *See, e.g., Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007) (finding no “significant legal problem” with an agency’s “reasonable, albeit brief” explanation clarifying a

regulatory term’s meaning) (internal quotations and citations omitted). But it must at least address why the policy shift outweighs the alleged reliance interests and “explain[] its ‘good reasons’ for concluding those interests were insufficient to hold off” the policy shift.

MediNatura, 998 F.3d at 943 (quoting *Encino Motorcars*, 136 S. Ct. at 2126) (internal quotations omitted). That burden is not satisfied by a one-sentence acknowledgement that CBP “understands the role of the plasma donation business.” Guidance at 1. Plaintiffs, therefore, have shown that they are likely to succeed on the merits of their claim that the Guidance was arbitrary and capricious.

c. Notice and Comment

Plaintiffs also argue that the Guidance was not promulgated with the requisite notice-and-comment procedures. See *CSL Plasma Compl.* ¶¶ 92-97 (citing 5 U.S.C. § 553). Notice-and-comment procedures only apply to legislative, not interpretive rules. 5 U.S.C. § 553(b)(3)(A). Interpretive rules “clarify a statutory or regulatory term, remind parties of existing statutory regulatory duties, or ‘merely track[]’ preexisting requirements and explain something the statute or regulation already required.” *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (quoting *Nat’l Family Planning & Reprod. Health Ass’n, Inc. v. Sullivan*, 979 F.2d 227, 236-37 (D.C. Cir. 1992)). They “must derive a proposition from an existing document whose meaning compels or logically justifies the proposition.” *Id.* (quoting *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 494 (D.C. Cir. 2010)). A legislative rule, by contrast, “supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy.” *Id.*

The difference between these two types of rule has long been “‘enshrouded in considerable smog.’” *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir.

1984) (en banc) (quoting *American Bus. Ass'n v. ICC*, 627 F. 2d 525, 529 (D.C. Cir. 1980)). Essentially, in determining whether a rule is legislative or interpretive, the court must consider whether “the new rule effects ‘a substantive regulatory change’ to the statutory or regulatory regime.” *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.* 653 F.3d 1, 6–7 (D.C. Cir. 2011) (quoting *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 35 (D.C. Cir. 2005)). If so, the rule is legislative.

This is inherently a fact-driven inquiry, in which courts consider the impact of the new agency action on the duties or burdens of the regulated parties. *See, e.g., id.* (new TSA policy “substantially chang[ing] the experience of airline passengers . . . [was] not merely ‘interpretive’”); *U.S. Telecom Ass'n*, 400 F.3d at 35 (FCC policy change imposing a “requirement that [an earlier order] had foresworn” was legislative).

Plaintiffs allege that before the Guidance, their donation centers received thousands of donations per week. *See, e.g., CSL Plasma Mot. for PI*, Efantis Decl. ¶ 15. After the Guidance, that number rapidly declined between 20 and 90%. *Id.* ¶ 14. Although this decline may not be entirely attributable to the Guidance—donors may have chosen not to travel due to the pandemic or for other reasons—it is plausible that a substantial number of Mexican national donors—the regulated parties—who once would have crossed the border to donate plasma were no longer able to do so because of the Guidance. That fundamental change of experience—staying in Mexico and not donating instead of crossing the border to donate—is the sort of “substantive change [to] the experience of” a regulated party that makes a rule legislative, not interpretive. And since the Guidance was issued without the notice and comment required for a legislative rule change, Plaintiffs have also made a clear showing that they are likely to succeed on their notice and comment claim.

ii. Irreparable Harm

a. *Employee Plaintiffs*

Employee Plaintiffs allege that they will suffer “substantial unrecoverable economic losses” because if the Guidance “remains in force, [the plasma collection] centers will be shut down” and they will lose their source of income. *Amaya* Mot. for PI at 32. In the alternative, Employee Plaintiffs also allege irreparable harm to their “notice-and-comment rights.” *Id.* at 34. Neither argument is availing.

Preliminary injunctions are intended to prevent “actual and not theoretical harm” that is “beyond remediation.” *League of Women Voters of United States v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016) (citations omitted). Economic loss can qualify as irreparable harm when the Government is a defendant because sovereign immunity would otherwise bar recovery. *See, e.g., Whitman-Walker Clinic, Inc. v. U.S. Dep’t of Health and Hum. Servs.*, 485 F. Supp. 3d 1, 58 (D.D.C. 2020) (collecting cases supporting the proposition). But economic loss caused by potential job loss does not automatically amount to irreparable harm; a prospective injury must still “be both certain and great; it must be actual and not theoretical.” *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam).

Employee Plaintiffs have not shown a direct causal chain connecting the Guidance to the irreparable harm they claim they will suffer. They contend that because “CSL Behring centers have reduced hours by 40%,” they are likely to suffer irreparable harm. *Amaya* Mot. for PI at 32. But Employee Plaintiffs’ declarations merely speculate that the donation centers may close. *See, e.g., Id., Amaya* Decl. ¶ 4 (“[I]f CPB’s [sic] ban remains in effect, the center *may* close”); Angulo Decl. ¶ 3 (“[i]f CBP’s ban remains in effect, the center *may* close”); Felix Decl. ¶ 3 (“[i]f CBP’s ban remains in effect, the center *may* close”); McCrimmon Decl. ¶ 3 (“[i]f CBP’s ban remains in effect, the center *may* close”); Miranda Decl. ¶ 3 (“[i]f CBP’s ban remains in effect, the center

may close”). And while reduced hours may lead to reduced income, it is well-settled that loss of income, even if a plaintiff has insufficient savings, does not constitute irreparable harm meriting injunctive relief because of “the possibility that adequate compensatory or other corrective relief will be available at a later date.” *Sampson v. Murray*, 415 U.S. 61, 89-90 & 92 n.68 (1974).

Employee Plaintiffs’ financial worries are legitimate and understandable, but their “[b]are allegations of what is likely to occur are of no value since the court must decide whether the harm will *in fact* occur.” *Wis. Gas Co.*, 758 F.2d at 674 (emphasis in original). Moreover, declarations from executives at the plasma companies indicate that—at least for Employee Plaintiffs—irreparable economic harm may be avoided, despite the Guidance. *See Amaya* Mot. for PI, Cavanaugh Decl. ¶ 6 (“In response to the drop in collections . . . , we have reduced operating hours at various centers and are working to retain jobs by moving employees to other collection centers not affected by the Plasma Ban. CSL Plasma has paid travel costs for the reassigned employees.”); Wolsing Decl. ¶ 5 (“As a result of the border closing in Arizona and California . . . staff in some cases were redeployed to other facilities”). Employee Plaintiffs have therefore failed to clearly show a risk of irreparable economic harm.

Employee Plaintiffs also claim irreparable harm to their notice-and-comment rights. But, as a preliminary matter, Plaintiffs do not provide—and the court is unaware of—any case conferring a due process right to participate in notice-and-comment procedures. The two cases Employee Plaintiffs cite for this proposition only conclude that plaintiffs injured by agency action taken without notice-and-comment procedures had standing to challenge that action. *See Fund Democracy, LLC v. S.E.C.*, 278 F.3d 21, 27 (D.C. Cir. 2002) (“A party has standing to challenge an agency's failure to abide by a procedural requirement only if the government act performed without the procedure in question will cause a distinct risk to a particularized interest

of the plaintiff.”); *Nat’l Fed. of the Blind v. United States Dep’t of Ed.*, 407 F. Supp. 3d 524, 533 (D. Md. 2019) (“Deprivation of a procedural right. . . can constitute an injury for purposes of standing when it is tied to a specific resultant harm.”).

Plaintiffs also cite a Northern District of California case which held that being “deprived of the opportunity to offer comments on [a] Rule . . . may constitute irreparable injury, provided that plaintiffs suffer some additional concrete harm as well.” *E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 866 (N.D. Cal. 2018), *aff’d sub nom. E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640 (9th Cir. 2021), *aff’d*, 950 F.3d 1242 (9th Cir. 2020), and *aff’d sub nom. E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640 (9th Cir. 2021). But the court in *East Bay* also required plaintiffs to adduce that this “additional concrete harm” flowed directly from the agency’s failure to conduct notice-and-comment procedures. *E. Bay*, 349 F. Supp. at 865. The same is true in this Circuit; Plaintiffs are only entitled to an injunction if the harm they will suffer flows directly from the agency action. *See Wis. Gas Co.*, 758 F.2d at 674 (Plaintiffs “must show that the alleged harm will directly result from the action which [they] seek to enjoin.”); *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009) (“to justify the issuance of a preliminary injunction, . . . [plaintiffs] must show that unless the rule is enjoined, [they are] likely to experience not just some injury, but irreparable harm that cannot be cured by ultimate success on the merits in this case.”). As with their alleged financial harm, Employee Plaintiffs have failed to allege concrete harm or a direct causal link to the Guidance. There is, therefore, no risk of irreparable harm to their notice-and-comment rights.

b. Company Plaintiffs

Company Plaintiffs claim that the decrease in total donations caused by the Guidance will necessarily lead to an unrecoverable decline in sales revenue and market share. *CSL Plasma*

Mot. for PI at 29-30. Defendants respond first that Company Plaintiffs' alleged losses may be mitigated by paying American donors more for their blood plasma, and second, that Company Plaintiffs have failed to show that the harm they will suffer is sufficiently large enough to warrant injunctive relief. *CSL Plasma Defs.' Opp.* at 23-24.

Defendants construe Company Plaintiffs' harm too narrowly. Economic harm need not be measured purely in dollars and cents; a plaintiff need only allege "certain and great," "actual and not theoretical" harm. *Wis. Gas Co.*, 758 F.2d at 674. Company Plaintiffs claim they increased compensation for American donors over the last two years and still suffered a decline in donations and a corresponding drop in revenue. *CSL Plasma Reply* at 20; *see also CSL Plasma Mot. for PI*, Procaccio Decl. ¶ 5 (discussing doubled fees), Barber Decl. ¶ 6 (discussing fee increase of 70%). They state that even if higher fees and more marketing attract some new donors, "the border communities in which Plaintiffs built their centers do not have sufficient U.S. population to be independently viable without donations from Mexican donors." *CSL Plasma Reply* at 20. Thus, they argue, they "will have to build new donation centers in other parts of the country to try to make up the shortfall—a process that would take many years and cost millions of dollars." *Id.* (quoting *CSL Plasma Mot. for PI*, Procaccio Decl. ¶ 7). They allege that a new facility costs anywhere between \$2.5 and \$4.0 million to build and open. *CSL Plasma*, Mot. for PI, Procaccio Decl. ¶ 4.

A party is entitled to a preliminary injunction if it can "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Nat. Res. Def. Council*, 555 U.S. at 22 (emphasis in original). Company Plaintiffs have demonstrated a likelihood of success on the merits, and that they are likely to incur certain and great expense—anywhere between \$2.5 and \$4.0 million—if they are forced to build new collection facilities throughout the country to sustain their business.

They have therefore made a sufficient showing that a preservation of the status quo is needed to prevent them from incurring significant expense while this case is litigated. *Cf. Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (“The primary purpose of a preliminary injunction is . . . to preserve the status quo.”) (internal quotation marks and citation omitted).

iii. Balance of the Equities and The Public Interest

The balance of the equities weighs the relative harms against the parties—the harm that the Government would suffer if an injunction were to issue against the harm the Plaintiffs would suffer absent an injunction. *See Pursuing Am.’s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016). Here, CBP’s interest is the same as the public interest, “because the government’s interest *is* the public interest.” *Id.* (citing *Nken*, 556 U.S. at 435) (emphasis in original).

Company and Employee Plaintiffs argue that an injunction would protect patients and public health at a time of greatly reduced blood plasma supplies. *CSL Plasma* Mot for PI at 32-33; *see generally* Br. of Amicus GBS/CIDP Found. Int’l, Inc. and Immune Deficiency Found., ECF No. 23, *CSL Plasma* (describing negative impact of current blood plasma shortage on availability of patient therapies for people diagnosed Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, and primary immunodeficiency). They claim that Mexican-national blood plasma donors account for 5% of U.S. total blood plasma donations. *CSL Plasma* Mot. for PI, Efantis Decl. ¶ 21. And they point to a new campaign seeking additional blood and plasma donors from the U.S. Department of Health and Human Services in response to the “nation’s blood and plasma supply dropp[ing] to historic lows” as evidence that this shortage is already being acutely felt. Not. of Supp. Auth, Press Release, U.S. Dep’t of Health and Hum. Servs., *HHS Announces New Campaign to Increase U.S. Blood and Plasma Donations* at 1 (Aug. 4, 2022), ECF No.43.

The Government proffers the public interest in ensuring the “consistent and uniform application of regulations,” balancing “international business against Congress’s strong interests in protecting domestic workers from foreign competition,” and preserving “the careful balance that Congress struck in crafting the INA’s interrelated provisions.” Defs.’ Opp. at 24-26 (quoting *Allina Health Servs. v. Sebelius*, 756 F. Supp. 2d 61, 71 (D.D.C. 2010)).

Company Plaintiffs have demonstrated how the absence of a preliminary injunction would specifically harm them, while the Government has failed to make an argument beyond an appeal to statutory consistency. And Plaintiffs’ point that constraining the supply of blood plasma at a time when national public health—and the supply chains that undergird it—is particularly imperiled is a compelling one. Therefore, the balance of the equities and the public interest, taken together, tilts towards Plaintiffs.

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Injunctive relief is an extraordinary remedy; the court “is not mechanically obligated to grant an injunction for every violation of law.” *Id.* (citing *TVA v. Hill*, 437 U.S. 153, 193 (1978)). However, the court finds that Company and Employee Plaintiffs have clearly shown a likelihood of success on the merits. And while Employee Plaintiffs have not shown that they would suffer irreparable harm absent an injunction, Company Plaintiffs have. Given that the balance of the equities and public interest weigh equally in this matter, the court finds that Company Plaintiffs are entitled to the extraordinary remedy of injunctive relief.

IV. CONCLUSION

For the foregoing reasons, the *Amaya* motion for a preliminary injunction, ECF No. 3, *Amaya*, will be **DENIED**, and the *CSL Plasma* motion for a preliminary injunction, ECF No. 7, *CSL Plasma*, will be **GRANTED**. A corresponding order will issue contemporaneously with this memorandum opinion.

Date: September 16, 2022

Tanya S. Chutkan

TANYA S. CHUTKAN
United States District Judge