UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CSL PLASMA INC., *et al*	)	
Plaintiffs,	)	
v.	)	Civil Action No. 21-cv-02360 (TSC)
UNITED STATES CUSTOMS AND BORDER PROTECTION, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs CSL Behring L.L.C., CSL Plasma Inc. (collectively, "CSL Behring" or "CSL"), Biomat USA Inc., GCAM, Inc., and Talecris Plasma Resources, Inc. (collectively, "Grifols") filed suit on September 7, 2021 against Defendants United States Customs and Border Protection ("CBP") and Troy A. Miller, in his official capacity as Senior Official performing the duties of CBP Commissioner. ECF No. 1. Plaintiffs also moved for a preliminary injunction to enjoin CBP from preventing B-1/B-2 visa holders from crossing the U.S.-Mexico border to donate blood plasma. ECF No. 7.[1] The court heard oral argument on the issue of standing on October 20, 2021.

For the reasons set forth below, Plaintiffs' Complaint will be DISMISSED for lack of standing, and their Motion for a Preliminary Injunction will therefore be DENIED as moot.

[1] The GBS/CIDP Foundation International, Inc. and the Immune Deficiency Foundation jointly filed a brief as amicus curiae in support of Plaintiffs' Motion for a Preliminary Injunction. ECF No. 17.

I. BACKGROUND

A. Parties

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. operate hundreds of plasma collection centers. *See* Compl. at 7-8.

Defendants CBP and Troy A. Miller are the federal agency responsible for the enforcement of immigration laws, and its Senior Official, respectively.

B. Statutory and Regulatory Framework

The Immigration and Nationality Act of 1952 ("INA") [2] created the modern statutory framework governing immigration, naturalization, and nationality of aliens to the United States. Pub. L. No. 82-414, 66 Stat. 163 (1952) (codified at 8 U.S.C. ch. 12). While the INA is primarily concerned with the immigration process, it also includes entry and removal considerations for "certain nonimmigrants," *id.* at § 102, 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." 8 U.S.C. § 1101(a)(15)(B).

Under the INA, visa categories are regulated by the Department of State, *id.* § 1104(a), which has issued regulations allowing nonimmigrants to enter the United States for business under a "B-1" visa, and for pleasure under a "B-2" visa. *See* 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). Pleasure refers to "legitimate activities of a recreational character." *Id.*

[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.

§ 41.31(b)(2)(i). State Department consular officers are instructed to issue B-1/B-2 visas if a visa 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).

Mexican nationals may be either issued a B-1/B-2 visa for each trip, or a "Border Crossing Card" ("BCC") that allows multiple B-1/B-2 entries for a 10-year period. *See* 21 C.F.R. § 41.32. Mexican national BCC holders are limited to trips no longer than 72 hours and are restricted to a zone 25-75 miles from the border. *See* 8 C.F.R. § 235.1(h)(iii)-(v).

C. Factual Background

Human blood plasma is a valuable element of many medical therapies and treatments. Compl. at ¶ 22; *see generally* Br. of Amicus GBS/CIDP Found. Int'l, Inc. and the Immune Deficiency Found, ECF No. 23 ("Amicus Br."). In some cases, a plasma-derived treatment is the only FDA-approved treatment for a particular disorder or condition. Compl. at ¶ 22, 24. This combined with the amount of plasma required for a treatment makes demand for plasma particularly high. *Id ¶ 22.*

Plasma is collected through "plasmapheresis," a process in which a donor's blood is drawn, the plasma separated out, and the remainder (red cells, white cells, and platelets) returned to the donor. Compl. ¶ 23. Donors must wait 48 hours between donations and may donate no more than twice within a seven-day period. *Id*. Donors in the United States receive approximately $50 for each donation.

A large source of the U.S. plasma supply comes from donations made by Mexican nationals. *Id.* ¶ 26. Starting in the late 1980's or early 1990's, CBP border patrol agents in Texas, Arizona, and California permitted Mexican nationals to cross the border on B-1/B-2 visas to donate plasma. *Id.*¶ 34. Defendants claim that such entries were always contrary to B-1/B-2

visa regulations, but CBP officers allowed the entries because they were unable to reliably ascertain whether visitors were entering to sell plasma. Def. Opp. at 4-5, ECF No. 23.

To facilitate these donations, Plaintiffs opened or acquired 39 collection centers along the southern border in Texas, Arizona, and California within the port-of-entry distance limitations. Compl. at ¶ 30. Plaintiffs have also spent "several million dollars in the last several years" on advertising to encourage Mexican citizens to donate plasma in exchange for payment at the centers located along the border. *Id.* ¶¶ 31–32. Plaintiffs assert that they made these investments "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." *Id.* ¶ 31.

Following the onset of the COVID-19 pandemic, land border crossings were restricted to "essential travel," precluding most BCC holders from entering the United States. Davies Decl. at 5, ECF No. 16-1. During this time, CBP officials in Texas allowed some Mexican nationals to enter the United States to donate plasma. Compl. ¶ 35. After this came to the attention of CBP leadership, an internal guidance memorandum was issued on June 14, 2021 stating that donating blood plasma was not an acceptable reason for entry under a B-1/B-2 visa. Davies Decl. at 6; *Id.* Ex. 1. On June 15, 2021, 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.

Compl. ¶ 37. After this statement was issued, Plaintiffs began contacting members of the executive and legislative branch to "resolve the situation." *Id.* ¶ *41.* When those efforts proved unsuccessful, Plaintiffs filed this action.

II. LEGAL STANDARD

Federal courts must decide the "threshold" issue of their own jurisdiction, including standing. *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 94-95 (1998). Standing is a jurisdictional matter, and a court may raise the issue at any time, including before addressing the merits. *See, e.g.*, *Steffan v. Perry*, 41 F.3d 677, 697 n.20 (D.C. Cir. 1994). This preliminary requirement includes "prudential standing;" a showing that the interest a party seeks to protect is arguably within the zone of interests to be protected or regulated by the statute. *Grocery Mfrs. Ass'n v. E.P.A.*, 693 F.3d 169, 179-80 (D.C. Cir. 2012). Lack of prudential standing is grounds for dismissal for lack of jurisdiction. *Id.* at 180.

III. ANALYSIS

Plaintiffs assert prudential standing on two grounds.[3] First, that they are "best positioned to vindicate" the B-1/B-2 visa program's zone of interests. *See* Pls. Rep. at 5, ECF No. 20. Second, that they have third-party standing derived from Mexican national plasma donors and patients who benefit from plasma-derived therapies. Neither serve to confer standing upon Plaintiffs.

A. Plaintiffs' Independent Standing

To have prudential standing, a plaintiff must fall within the class of persons that Congress intended to protect in enacting a statute, or its "zone of interests." *Mendoza v. Perez*, 754 F.3d 1002, 1016 (D.C. Cir. 2014) (citing *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345-48 (1984)).

[3] Only prudential standing is controverted; Defendants do not challenge constitutional standing.

This is not an "especially demanding" requirement. *Clarke v. Securities Indus. Ass'n.*, 479 U.S. 388, 399 (1987)). Indeed, when a plaintiff's placement in the zone of interests is unclear or at least "arguabl[e]," the plaintiff gets the benefit of the doubt. *Match-E-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012).

But a plaintiff must, at a minimum, show that they could "be expected to police the interests that the statute protects." *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998). A plaintiff's own interests must bear "more than a marginal relationship to the statutory purposes." *Fed'n for Am. Immigr. Reform, Inc. v. Reno*, 93 F.3d 897, 900 (D.C. Cir. 1996) (cleaned up). Courts look to the "act itself and to its legislative history" to identify its purpose and the associated zone of interests that the statute intends to protect. *Int'l Union of Bricklayers and Allied Craftsmen v. Meese*, 761 F.2d 798, 804 (D.C. Cir. 1985) ("*Meese I*") (citing *Copper & Brass Fabricators Council v. Dep't of the Treas.*, 679 F.2d 951 (1982)).

a. <u>The B-1/B-2 Visa Program's Zone of Interests</u>

The B-1/B-2 visa program developed from statutes prohibiting the entry of contract laborers in the late 19th century. *See, e.g.*, *Int'l Union of Bricklayers and Allied Craftsmen v. Meese*, 616 F. Supp. 1387, 1400 (N.D. Cal. 1985) ("*Meese II*") (providing historical background). These early laws were intended to "protect American labor against the influx of foreign labor" who, by virtue of lower wages and higher populations, could outcompete the American worker. *See, e.g.*, *Karnuth v. United States*, 279 U.S. 231, 243 (1929). While the statutes were also motivated by xenophobia and racism,[4] their purpose was to regulate entry of

[4] *See, e.g.*, Enid Trucios-Gaynes, *The Legacy of Racially Restrictive Immigration Laws and Policies and the Construction of the American National Identity*, 76 ORE. L. REV. 369, 375-90 (1997) (outlining nationalist and racially identarian threads in early immigration laws).

foreign nonimmigrant laborers in a way that would keep the American workforce "stalwart" in the face of competition. *Meese I*, 761 F.2d at 805.

The clear legislative history and subsequent interpretation of the B-1/B-2 program and its predecessors show that it has always been intended to limit the influx of foreign workers to "protect[] American labor." *See, e.g.*, *Karnuth*, 279 U.S. at 243 (interpreting predecessor of INA's B-1/B-2 provisions as "protect[ing] American labor against the influx of foreign labor."); *see also Meese I*, 761 F.2d at 804 (citing cases that "clearly established that Congress intended to protect American labor from an influx of cheaper foreign competition"); *Pai v. U.S. Citizenship and Immigration Services*, 810 F. Supp. 2d 102, 110-111 (D.D.C. 2011). The legislative history is unambiguous: the zone of interests is limited to those who seek to protect American laborers from competing with foreign laborers. That zone does not include employers and businesses affected by B-1/B-2 visa-related agency action.

There is scant judicial analysis of the B-1/B-2 visa program, but where it exists, it is clear—workers affected by foreign labor, not their employers, are the parties "expected to police" the program's interests. A statute designed to protect American workers places those workers in its zone of interest and confers upon them "a proper ground for standing." *Meese I*, 761 F.2d 798 at 805 (citing *Autolog Corp. v. Regan*, 731 F.2d 25, 29-31 (D.C. Cir. 1984)).

This narrowed interpretation of the zone of interests aligns with the statutory purpose: the American workers displaced by foreign labor are best positioned to police their own interests through enforcement of the B-1/B-2 visa program. Thus, plaintiffs who are employees or employees' unions have been found to have standing when challenging B-1/B-2 visa determinations. *See, e.g.*, *Mendoza*, 754 F.3d at 1007 (unemployed herders); *Meese I*, 761 F.2d at 799 ("international union. . . , a local union. . . , and three members of the local"); *United*

Ass'n of Journeymen and Apprentices of Plumbing and Pipe Fitting Industry, AFL-CIO v. Reno, 73 F.3d 1134, 1136 (D.C. Cir. 1996) ("two labor unions representing American construction workers") ("*United Ass'n*"); *United States ex rel. Krawitt v. Infosys Technologies Limited, Incorporated*, 372 F. Supp. 3d 1078 (N.D. Cal. 2019) (employee) ("*Krawitt*"); *Meese II*, 616 F. Supp. at 1389 ("international union. . . , a local union. . . , and three members of the local"). The rare cases in which an employer had standing to challenge B-1/B-2 visa actions typically involved a visa petitioner-company seeking to reverse the denial or nonrenewal of one of their employees' B-1 visas where those employees lacked standing themselves. *See, e.g.*, *Pai*, 810 F. Supp. 2d at 111 (because plaintiff B-1 visa recipient's interests are so "marginally related" to the B-1/B-2 visa statute, "it is the employer . . . that has standing in this case.").

Admittedly, this precedent does not map to the instant case perfectly. Most B-1/B-2 agency action challenges have been brought by American workers seeking to halt the entry of B-1/B-2 visa holders. This case is the opposite–Plaintiffs seek injunctive relief to continue to allow Mexican nationals to enter the United States under B-1/B-2 visas. Similarly, most B-1/B-2 agency action cases involve employees and employers at odds regarding the entry of foreign workers. *See, e.g.*, *United Ass'n*, 73 F.3 1134 (construction union challenging hiring non-citizen employees to work on off-shore oil rigs); *Krawitt*, 342 F. Supp. 3d. 958 (employee suit against employer challenging B-1 visas for non-citizen technology trainers); *Palmer v. Infosys Technologies Ltd. Inc.*, 888 F. Supp 2d 1248 (M.D. Ala. 2012) (employee suit alleging B-1 visa fraud by employer). Despite these differences, the case law is clear: the zone of interests of the B-1/B-2 program is meant to protect the American worker.

b. Plaintiffs' Standing

Plaintiffs argue that they have standing because they too are "adversely affected or aggrieved" by the B-1/B-2 agency action. Pls Rep. at 3. This, they claim, makes them "best positioned to vindicate the relevant interests" at play for the B-1/B-2 visa program. *See Id.* at 5. D.C. Circuit precedent, however, says otherwise: coincidental interests, such as the ones here, do not confer standing.

The Circuit has explained that "when we grant standing to a party with only an oblique relation to the statutory goal, we run the risk that the outcome could . . . thwart the congressional goal." *Hazardous Waste Treatment Council v. U.S. E.P.A.*, 861 F.2d 277, 283-84 (D.C. Cir. 1988). Such a tangential relation includes when a company's "pecuniary interests" aligns with the statutory goals. *White Stallion Energy Ctr., LLC v. E.P.A.*, 748 F.3d 1222, 1257 (D.C. Cir. 2014), *rev'd on other grounds*, *Michigan v. E.P.A.*, 576 U.S. 743 (2015). Judicial intervention to grant standing in such cases may actually defeat statutory goals if they "proceed[] at the behest of interests that coincide only accidentally with those goals." *Hazardous Waste Treatment Council*, 861 F.2d at 283.

Plaintiffs' standing here is coincidental. As they admit in their briefing, the American workers potentially imperiled by CBP's revised guidance are Plaintiffs' own employees, who might lose their jobs if Plaintiffs reduce their blood plasma collections. *See* Pls. Mot. at 5, 29. Plaintiffs claim that their own business interests align with their employees', but Circuit precedent is clear: coincidental alignment does not confer standing. *See, e.g.*, *White Stallion Energy Ctr.*, 748 F.3d at 1257 (quoting *Hazardous Waste Treatment Council*, 861 F.2d at 283) ("If Congress authorized bank regulators to mandate physical security measures for banks, for example, a shoal of security services firms might enjoy a profit potential. . . , [but] no one would

suppose them to have standing to attack regulatory laxity."). To hold otherwise would be to "destroy the requirement of prudential standing; any party with constitutional standing could sue." *Hazardous Waste Treatment Council*, 861 F.2d at 283. Thus, although Plaintiffs may argue they are "best positioned to vindicate the relevant interests," the Circuit has made clear that mere coincidental alignment with the zone of interests cannot confer standing.

B. Third-Party Standing

In the alternative, Plaintiffs seek to assert the third-party interests of Mexican plasma donors and patients who benefit from plasma-derived therapies. But Plaintiffs' own lack of standing under the zone of interests test precludes them from acquiring third-party standing. *See, e.g.*, *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 100 & n.6 (1979) (listing among the "nonconstitutional limitations on standing to be applied in appropriate circumstances" the requirements that plaintiffs assert their own legal interests as determined by the zone of interests test, rather than those of third parties,); *see also Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 39 n.19 (1976) (quoting *Data Processing Serv. v. Camp*, 397 U.S. 150, 153 (1969) ("the interest of the plaintiff, regardless of its nature in the absolute, [must] at least be 'arguably within the zone of interests to be protected or regulated' by the statutory framework within which [the] claim arises."); *Warth v. Seldin*, 422 U.S. 490, 499 (1975) ("[T]he plaintiff generally must assert [their] own legal rights and interests, and cannot rest [their] claim to relief on the legal rights or interests of third parties."); *see* discussion § II.A.b *supra*.

Plaintiffs have not met the zone of interests test, and thus cannot assume third-party standing for Mexican national plasma donors or patients benefitting from plasma-derived therapies. One of the reasons for limitations on third-party standing is to "ensure 'that the most effective advocate of the rights at issue is present to champion them." *LaRoque v. Holder*, 650

F.3d 777, 781-82 (D.C. Cir. 2011) (quoting *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 80 (1978)). As the zone of interests test shows, the most effective advocate here would be the group that Congress intended to protect through the B-1/B-2 visa program: the American worker.

IV. CONCLUSION

For the reasons explained above, Defendants lack standing to pursue this action. Pursuant to the Federal Rules of Civil Procedure, this court must dismiss the Complaint without prejudice.[5] The Motion for a Preliminary Injunction will therefore be denied as moot.

Date: December 3, 2021

Tanya S. Chutkan
TANYA S. CHUTKAN
United States District Judge

[5] *See, e.g.*, *Rudder v. Williams*, 666 F.3d 790, 794 (D.C. Cir. 2012) ("Dismissal with prejudice is the exception, not the rule in federal practice because it 'operates as a rejection of the plaintiff's claims on the merits and precludes further litigation of them") (internal citations and quotations omitted).