

**United States Court of Appeals**  
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

---

Argued April 1, 2022

Decided May 10, 2022

No. 21-5282

CSL PLASMA INC., ET AL.,  
APPELLANTS

v.

U.S. CUSTOMS AND BORDER PROTECTION AND  
CHRIS MAGNUS, COMMISSIONER, U.S. CUSTOMS AND BORDER  
PROTECTION,  
APPELLEES

---

Appeal from the United States District Court  
for the District of Columbia  
(No. 1:21-cv-02360)

---

*Baruch Weiss* argued the cause for appellants. With him on the briefs were *R. Stanton Jones*, *Stephen K. Wirth*, and *John Swanson*.

*Lewis S. Yelin*, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, and *H. Thomas Byron III*, Attorney.

Before: ROGERS and RAO, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* RAO.

RAO, *Circuit Judge*: In June 2021, U.S. Customs and Border Protection (“CBP”) announced that aliens seeking to sell blood plasma could no longer enter the United States using “B-1” business visitor visas. Before this policy went into effect, a significant amount of the plasma used for medical treatments and research in this country came from Mexican nationals selling their plasma on the U.S. side of the southern border. CSL Plasma Inc., as well as other companies (“plasma companies”), had invested substantial resources to develop plasma collection facilities near the border to take advantage of this market.

The plasma companies sued, alleging that CBP’s policy runs afoul of the Administrative Procedure Act (“APA”) and unlawfully cuts off a major source of plasma that they use to manufacture therapies to treat a range of diseases. The district court concluded the plasma companies were not within the “zone of interests” of the B-1 business visitor classification set out in the Immigration and Nationality Act (“INA”) and sua sponte dismissed the suit for lack of subject matter jurisdiction.

We reverse. Whether the plasma companies are within the statutory zone of interests is a merits issue, not a jurisdictional one. *See Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014). Moreover, the plasma companies’ claims easily fit within the zone of interests of the B-1 classification, and therefore they have a cause of action under the APA.

# I.

CSL Plasma and the other plaintiffs “collect[] human blood plasma from individual donors for use in the development and manufacturing” of medical therapies.

According to their complaint,<sup>1</sup> the plasma companies have long depended on donations by “many thousands” of paid Mexican donors, who contribute a substantial portion of the plasma collected by the companies and whose donations make up some five to ten percent of all plasma collected nationwide. Until June of last year, Mexican donors would enter the United States and sell plasma at dozens of border area facilities in exchange for roughly \$50 per donation. They typically entered the country using “border crossing cards,” a combined B-1/B-2 (business and pleasure) visa that permits an alien to enter the United States for multiple limited stays.<sup>2</sup> See 22 C.F.R. § 41.32; 8 C.F.R. § 212.1(c)(1)(i).

For decades, CBP and its predecessor agencies allowed Mexicans with border crossing cards to enter the United States to sell plasma. Even at the peak of the COVID-19 pandemic, when B-1 visa holders were generally prohibited from entering the United States, the Department of Homeland Security “designated plasma donors as ‘essential’ and plasma collection a ‘critical infrastructure industry.’” That changed in June 2021, when CBP instructed its border agents not to allow aliens to enter with B-1 visas if they were planning to sell plasma.<sup>3</sup> To

---

<sup>1</sup> The district court dismissed the case on zone of interests grounds, which, as explained below, go to whether plaintiffs had a cause of action. We assume the truth of a complaint’s well-pled factual allegations when we review dismissals for failure to state a claim. See *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

<sup>2</sup> The term “B-1” comes from the regulations describing categories of nonimmigrants by reference to the relevant INA provisions. See 22 C.F.R. § 41.12 (citing Immigration and Nationality Act, Pub. L. No. 82-414, § 101(a)(15)(B), 66 Stat. 163, 167 (1952) (codified at 8 U.S.C. § 1101(a)(15)(B))).

<sup>3</sup> The parties dispute the nature of CBP’s decision. The plasma companies allege that CBP announced a substantive change in policy

justify this plasma policy, as we will call it, CBP explained in a memorandum that “selling plasma constitutes labor for hire in violation of B-1 nonimmigrant 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.” CBP said paid plasma donors were not proper B-1 visitors because that category excludes anyone coming to engage in “labor” within the meaning of the INA’s B-1 classification.<sup>4</sup>

After learning of CBP’s plasma policy and failing to secure a political solution, the plasma companies filed suit and sought a preliminary injunction ordering CBP not to implement the policy and to allow plasma donors to enter with B-1 visas. The plasma companies maintained that selling plasma is a legitimate B-1 business visitor activity and that they have relied on CBP’s prior longstanding practice of allowing B-1 visa holders to enter the United States to sell plasma. The companies alleged multiple violations of the APA, claiming CBP had adopted an erroneous interpretation of the INA’s B-1 business classification; changed its longstanding policy in an

---

through a press release, while CBP maintains that it clarified its established interpretation of the B-1 business visitor definition in an internal guidance document. We need not resolve this dispute for the purpose of this appeal, as it does not bear on the zone of interests analysis.

<sup>4</sup> The INA’s B-1 business visitor classification extends to

an alien (other than one coming for the purpose 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.

8 U.S.C. § 1101(a)(15)(B).

arbitrary and capricious way by failing to consider the plasma companies' reliance interests and the policy's public health effects; and implemented the policy change through an unofficial memorandum even though it was a legislative rule that required notice and comment.

After the parties briefed the preliminary injunction motion, the district court sua sponte dismissed the complaint "for lack of standing." *CSL Plasma Inc. v. U.S. Customs & Border Prot.*, 2021 WL 5869149, at \*1 (D.D.C. Dec. 3, 2021). The court explained that the APA's "zone of interests" requirement was a matter of prudential standing and jurisdictional. *Id.* at \*3. The plasma companies' interests were not within the zone of interests protected by the B-1 classification because the "B-1/B-2 program ... has always been intended to limit the influx of foreign workers to protect American labor." *Id.* at \*4 (cleaned up). Thus, only "workers affected by foreign labor," not businesses, could be proper plaintiffs to challenge the government's interpretation of the B-1 classification. *Id.* The plasma companies' interests were merely "coincidental" to the purpose of the statute and therefore outside the statutory zone of interests. *Id.* at \*5. The district court dismissed the entire complaint for lack of subject matter jurisdiction, and it denied the motion for a preliminary injunction as moot. *Id.* at \*6. The plasma companies appealed.

## II.

The district court erred in considering the zone of interests test a question of subject matter jurisdiction.

For the plasma companies to sue under the APA, they must have been "adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. To determine whether a plaintiff has a cause of action we consider whether a plaintiff's claims fall within the relevant statute's

“zone of interests” by “using traditional tools of statutory interpretation.” *Lexmark*, 572 U.S. at 127. The Supreme Court has made clear that the zone of interests test is a merits issue because it addresses whether the plaintiff “has a cause of action under the statute.” *Id.* at 128. That inquiry “does not implicate subject-matter jurisdiction.” *Id.* at 128 n.4 (cleaned up); *see also Bell v. Hood*, 327 U.S. 678, 682 (1946) (failure to plead a cause of action is not a jurisdictional defect). Our cases have repeatedly recognized the non-jurisdictional nature of the zone of interests test since *Lexmark* was decided in 2014. *See, e.g., Crossroads Grassroots Pol’y Strategies v. FEC*, 788 F.3d 312, 319 (D.C. Cir. 2015) (explaining the zone of interests test is neither a component of “prudential standing” nor a jurisdictional question); *Am. Inst. of Certified Pub. Accts. v. IRS*, 804 F.3d 1193, 1199 (D.C. Cir. 2015) (same).

The district court’s legal error resulted in a procedurally improper dismissal. A court may dismiss a case at any time for lack of subject matter jurisdiction. The zone of interests inquiry, however, is not jurisdictional, and therefore it could not be the basis for a sua sponte dismissal absent extraordinary circumstances. *Cf. Am. Inst. of Certified Pub. Accts.*, 804 F.3d at 1199 (explaining that the zone of interests test must be treated procedurally like any other “non-jurisdictional issue”); *see also Baker v. Dir., U.S. Parole Comm’n*, 916 F.2d 725, 726–27 (D.C. Cir. 1990) (per curiam) (explaining the narrow circumstances in which a non-jurisdictional sua sponte dismissal without notice is appropriate). The government did not file a motion to dismiss, and so the district court could not dismiss on zone of interests grounds without finding the required extraordinary circumstances. Therefore, the district court erred in dismissing for lack of subject matter jurisdiction.

## III.

The substantive question of whether the plasma companies fall within the B-1 classification's zone of interests is a purely legal question squarely before this court.<sup>5</sup> We thus address the zone of interests question and hold that the plasma companies are within the statute's zone of interests and therefore they have a cause of action to challenge the plasma policy. *Cf. Mendoza v. Perez*, 754 F.3d 1002, 1020 (D.C. Cir. 2014) (reaching a merits issue despite erroneous jurisdictional holding below because the issue was "purely legal" and "fully briefed" by both sides).

## A.

To determine whether the plasma companies have a cause of action, we consider whether their alleged injuries are "arguably within the zone of interests to be protected or regulated by the statute." *Match-E-Be-Nash-She-Wish Band of Pottawatomis Indians v. Patchak*, 567 U.S. 209, 224 (2012) (cleaned up). The zone of interests test does not require that the statute directly regulate the plaintiff, nor does it require specific congressional intent to benefit the plaintiff. *See Amgen Inc. v. Smith*, 357 F.3d 103, 108 (D.C. Cir. 2004). Instead "the salient consideration ... is whether the challenger's interests are such that they in practice can be expected to police the interests that the statute protects." *Id.* at 109 (cleaned up). Under this "lenient" test, "the benefit of any doubt goes to the plaintiff,"

---

<sup>5</sup> The government recognizes that the district court erred in treating the zone of interests test as jurisdictional but argues that we should nonetheless affirm the district court's dismissal under Rule 12(b)(6) for failure to state a claim because the plasma companies fall outside the B-1 classification's zone of interests. The plasma companies similarly address the merits of this issue, arguing that their interests are "incontrovertibl[y]" protected by the B-1 classification.

and “the test forecloses suit only when a plaintiff’s interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress authorized that plaintiff to sue.” *Lexmark*, 572 U.S. at 130 (cleaned up). When a claim arises under the APA, the zone of interests test requires considering the “substantive provisions” of the underlying statute, the “alleged violations of which serve as the gravamen of the complaint.” *Bennett v. Spear*, 520 U.S. 154, 175 (1997).

The gravamen of the plasma companies’ complaint is that CBP adopted an overly restrictive interpretation of the B-1 statutory classification in its plasma policy. The question we must answer is whether the plasma companies’ injuries are within the zone of interests of the INA’s B-1 business visitor classification. The INA creates a category of “nonimmigrant” temporary visitor that includes

an alien (other than one coming for the purpose 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.

8 U.S.C. § 1101(a)(15)(B). To ascertain the interests this classification protects, “we must consider [its] context and purpose” within the INA’s larger scheme. *Indian River Cnty. v. U.S. Dep’t of Transp.*, 945 F.3d 515, 530 (D.C. Cir. 2019) (cleaned up).

The B-1 provision creates a classification of nonimmigrant temporary visitors who may enter the United States in order to transact business. This business visitor classification imposes a lower barrier to enter the country than other nonimmigrant classifications, particularly the temporary worker

classifications.<sup>6</sup> With narrow exceptions, any alien coming to the United States to perform labor is presumptively inadmissible and must secure an affirmative determination from the Department of Labor that there are no Americans available to perform the same work. 8 U.S.C. § 1182(a)(5)(A). B-1 business visitors face no comparable burden. By regulation, an alien who meets the definition of a B-1 “nonimmigrant” presumptively can enter the country and, if he is a Mexican seeking to enter only the border area, can do so using a border crossing card. *See* 22 C.F.R. § 41.121 (“Nonimmigrant visa refusals must be based on legal grounds.”); *id.* § 41.32 (describing eligibility for border crossing cards).

In its plasma policy memorandum, CBP maintains that donors from Mexico who are “selling plasma” are engaged in “labor for hire” and therefore cannot use a B-1 nonimmigrant visa to enter the United States for that purpose. Because the plasma companies rely on Mexican plasma donors who enter this country using B-1 visas, the companies maintain that their interests are such that “in practice [they] can be expected to

---

<sup>6</sup> For example, the total number of H-visa temporary workers is capped, unlike the number of B-1 business visitors. *See* 8 U.S.C. § 1184(g)(1)(B). In addition, temporary non-agricultural laborers can enter only “if unemployed persons capable of performing [their] service or labor cannot be found in this country.” *Id.* § 1101(a)(15)(H)(ii)(b). This requires employer certification of the need for the workers. *Id.* § 1184(c)(1); *see also id.* § 1182(a)(5)(A) (prohibiting aliens from entering to perform labor unless the Department of Labor determines that they will not compete with American labor). As the plasma companies stated in their complaint, such certification would not be possible for plasma donors, whom the companies do not treat as employees.

police the interests that the statute protects.” *Amgen*, 357 F.3d at 109 (cleaned up). We agree.

The B-1 business visitor classification is designed to protect at least two classes of interests: American workers facing competition from immigrant labor and American businesses benefitting from transactions with B-1 business visitors. American workers are protected because the classification specifically excludes aliens coming “for the purpose of ... performing skilled or unskilled labor.” 8 U.S.C. § 1101(a)(15)(B). The advantages of the B-1 business visitor classification are denied to aliens coming for employment in competition with American workers. This court has held that labor unions, for instance, can sue to enjoin expansive readings of the B-1 classification to protect the interests of domestic workers. *See Int’l Union of Bricklayers & Allied Craftsmen v. Meese*, 761 F.2d 798, 804–05 (D.C. Cir. 1985). An overly expansive reading of the B-1 classification would allow an end run around the requirements for a work visa, and thus workers and their unions can fall within the statutory zone of interests.

The B-1 classification also affirmatively promotes American business interests. Congress provided a path for aliens to enter the United States for temporary business purposes, presumably because those visits would benefit the people and companies that do business with them. An excessively strict interpretation of the B-1 classification could therefore undermine the congressional policy of permitting temporary border crossings to facilitate business transactions.

Here, the plasma companies easily clear the low hurdle of pleading injuries within the zone of interests protected by the B-1 classification. The plasma companies depend heavily on B-1 visitors in the border region. They have invested hundreds of millions of dollars to construct and staff dozens of facilities

geared toward collecting plasma from Mexican donors. The plasma companies made these investments in reliance on the large number of Mexicans who cross the border to sell plasma: they allege Mexican B-1 visitors “comprise the majority of donors at most of the border centers” and that the domestic population of the border areas could not support the substantial plasma collection activities of these facilities. By denying plasma donors the benefit of the B-1 classification, CBP’s policy directly harms the companies’ businesses by depriving them of plasma they need to manufacture and develop their therapeutic products. Therefore, the companies may sue to vindicate the interests protected by the INA’s B-1 classification.

In reaching this conclusion, we note the fact-specific nature of the zone of interests test. That these plasma companies have a cause of action should not be read as providing either a floor or a ceiling for the type of business that is within the B-1 classification’s zone of interests. Some businesses may have interests so “marginally related to” the statute’s protected interests that it would be “unreasonable” to find that they have a cause of action. *Clarke v. Secs. Indus. Ass’n*, 479 U.S. 388, 399 (1987). On the other hand, a business with less at stake than the very substantial investments of the plasma companies may still meet the “lenient” standard of being within the statutory zone of interest. *Lexmark*, 572 U.S. at 130.

The companies bringing this suit established dozens of plasma collection facilities specifically relying on B-1 visitors for donations. CBP’s policy barred these visitors from entering to sell plasma on a B-1 visa. The district court erred in holding that the companies were not proper plaintiffs to challenge the policy.

12

B.

The government's arguments to the contrary do not place the plasma companies outside the zone of interests of the B-1 classification. The government maintains that plasma donation is not B-1 "business" because it is "purely domestic" and lacks "a connection to international trade or commerce." Therefore, the companies have no cause of action. We reject the government's unduly restrictive application of the zone of interests test and its narrow interpretation of the B-1 classification.

First, a party need not show it will prevail on the merits of its case to show its claim falls within the statute's zone of interests. *See Nat'l Coal Ass'n v. Hodel*, 825 F.2d 523, 527 (D.C. Cir. 1987) (per curiam) (plaintiffs "obviously need not prevail on all issues of statutory interpretation" to pass the zone of interests test). On the government's view, the plasma companies are not even in the class of plaintiffs able to challenge CBP's plasma policy unless they are correct that the transactions at issue are "business" within the meaning of the statute. This approach collapses the zone of interests question of whether the companies can sue into the ultimate merits question of whether the companies can win. As explained above, the plasma companies rely on Mexican donors, who enter the United States using their B-1 visas. CBP's plasma policy narrowly interprets the B-1 classification and prohibits using a B-1 visa to enter the United States for the purpose of selling plasma. Whether or not the plasma companies ultimately prevail on the merits, their allegations are sufficient to establish that they are "reasonable candidates" to challenge CBP's plasma policy. *Clarke*, 479 U.S. at 403.

Second, the government's zone of interests argument is without merit on its own terms. The government claims that an

activity is “business” within the meaning of the B-1 classification only if it has a “connection” to international commerce or is a “necessary incident” to international trade. Because the donors do not engage in the plasma business in Mexico, and the donation and compensation take place in the United States, the government claims the donors are not engaged in international business or commerce. According to the government, all B-1 “business” must be part of an international commercial operation.

The government’s limitation of the B-1 classification is found in neither the text of the statute nor longstanding judicial and agency interpretations. There is no international nexus requirement in the B-1 classification. The statutory definition simply includes aliens “visiting the United States temporarily for business” and specifically excludes aliens “coming for the purpose of study or of performing skilled or unskilled labor or as a representative of foreign press, radio, film, or other foreign information media coming to engage in such vocation.” 8 U.S.C. § 1101(a)(15)(B). These are the only statutory carve outs from the general “business” category, and nowhere does the B-1 classification use the term “international” or otherwise suggest that the “business” must be of a particular type.

Judicial decisions reinforce the plain meaning of the statute and include no international nexus requirement. The distinction between business and labor—as opposed to between international and domestic business—runs back to 1929 at least. When interpreting a similar classification in a predecessor statute, the Supreme Court addressed whether two Canadians who crossed “from Canada to the United States daily to labor for hire” were “visiting the United States ... temporarily for business.” *Karnuth v. United States ex rel. Albro*, 279 U.S. 231, 233, 235 (1929) (quoting Immigration Act of 1924, Pub. L. No. 68-139, § 3, 43 Stat. 153, 154). The

Canadians claimed they were just business visitors, but the Court held that “it cannot be supposed that Congress intended, by admitting aliens temporarily for business, to permit their coming to labor for hire in competition with American workmen.” *Id.* at 244. Instead, “business” “must be limited in application to intercourse of a commercial character.” *Id.* The touchstone for “business” was simply the “commercial character” of the activity and included no international nexus.

The distinction between local and international activity emerged in cases that defined the “labor” exception to “business” visits. These decisions addressed the practical reality that if business visitors could not engage in literally any work or “labor” while in the United States, the “business” classification would be an empty set. *See Garavito v. INS*, 901 F.2d 173, 175 (1st Cir. 1990) (noting that at least some work activities must be permissible under a B-1 visa in order to conduct “business”). The Third Circuit, for example, has explained that the Executive reasonably distinguishes between “local employment” that is outside the B-1 classification and “activities that are a necessary incident to international trade or commerce” and therefore permissible “business.” *Mwongera v. INS*, 187 F.3d 323, 329 (3d Cir. 1999) (cleaned up).

The cases from the Board of Immigration Appeals (“BIA”) cited by the government also rely on an international connection to distinguish business activity from “labor” within the meaning of the INA. *See, e.g., Matter of Camilleri*, 17 I. & N. Dec. 441, 444 (BIA 1980) (a truck driver crossing from Canada to the United States to deliver commodities was a business visitor); *Mwongera*, 187 F.3d at 329 (upholding the BIA’s determination that “extending a retail sales business that was incorporated in the United States” was “labor” and not proper B-1 “business”). The cases are concerned with the meaning of “labor” and, contrary to the government’s

assertions, do not impose an international nexus requirement on what constitutes “business.”

Department of State regulations have codified these principles: the fundamental distinction is between business and labor, and the international nexus matters only for understanding the B-1 restriction on “labor.” Under the principal regulation, “business ... refers to conventions, conferences, consultations and other legitimate activities of a commercial or professional nature. It does not include local employment or labor for hire.” 22 C.F.R. § 41.31(b)(1). The “local” designation applies only to “employment or labor for hire.” The term “international” appears nowhere in the regulatory definition of “business,” and the examples of “business” include activities that could easily involve only domestic commerce, such as business conventions or conferences. None of the examples requires or even implies an international nexus. In defending its plasma policy, the government cannot graft an international nexus requirement onto the statutory term “business.”

The plasma companies are within the statutory zone of interests because they have asserted an injury that bears a “plausible relationship to the policies” underlying the B-1 classification. *Clarke*, 479 U.S. at 403.<sup>7</sup>

---

<sup>7</sup> Although this decision on the zone of interests necessarily implicates the merits and although both parties ask us to resolve the underlying merits, we decline to reach issues not decided by the district court. See *Capitol Servs. Mgmt., Inc. v. Vesta Corp.*, 933 F.3d 784, 789 (D.C. Cir. 2019) (“[W]e are a court of review, not of first view.”) (cleaned up).

\* \* \*

The zone of interests test is a lenient one, not to be conflated with either the court's subject matter jurisdiction or the underlying merits of the case. The B-1 classification protects the interests of American businesses such as the plasma companies, so they have a cause of action under the APA to challenge CBP's plasma policy. We therefore reverse the judgment of the district court and remand the case for further proceedings consistent with this opinion.

*So ordered.*