

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

WUXI APPTec CO., LTD.,

Plaintiff,

v.

U.S. DEPARTMENT OF DEFENSE a/k/a
U.S. DEPARTMENT OF WAR, et al.,

Defendants.

Civ. Action No. 1:26-cv-02069-JEB

REDACTED

**REPLY MEMORANDUM IN SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY INJUNCTION**

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INTRODUCTION

The Department of War has provided three factual bases for its highly consequential designation. Each is demonstrably false. To support its finding that the Company is indirectly owned by SASAC, the Department distorts its own sources. It takes clear language detailing a small Chinese fund's 2019 open-market investment in the Company to the tune of 5.32% of the fund's portfolio and flips it as evidence showing the fund *owning 5.32% of the Company*. This error is not small. Instead of the 5.32% "ownership" stake found by the Department of War, the fund briefly held 0.001% of the Company—before divesting that stock on the open market in 2020.

The Department of War's factual basis in support of its findings that the Company is indirectly affiliated with SASTIND and the PLA is also flatly wrong. The Department points only to a handful of clinical studies, which were conducted at hospitals that the Department considers to be supervised by SASTIND or the PLA. The studies were sponsored by American, European, and other international pharmaceutical companies, and the Company's only role was that of a third-party research laboratory working on behalf of those sponsors, with no relationship whatsoever to SASTIND or the PLA. This definition of "indirect affiliation" would compel the same conclusion as to the sponsors in the center of that arrangement, with absurd results. According to the Department's own evidence, those at risk of being smeared as "affiliated with" SASTIND or the PLA and thus a "Chinese military company" under this logic include such entities as the University of Michigan. Such an overbroad construction of "affiliation" is unconstitutional.

The Department of War repeatedly rebuffed the Company's pleas for specific information about any concerns so that it could correct any factual misunderstandings. Such an opportunity—also known as due process of law—would have allowed the Company to point out the Department's math and reading errors and correct its other mistakes, leaving zero evidence

supporting designation. But the Department's decision was already made and communicated to Congress more than a month before its sham meeting with the Company, where Department officials declined to identify any of the concerns that it now uses to justify designating the Company. This is an ambush tactic that does not begin to satisfy due process.

The facts make abundantly clear that the Department of War started with a desired conclusion and then did a handful of internet searches for "evidence" to support that preordained result. This process subverts the Constitution and its guarantee of due process under law, and the result threatens to eviscerate a respected global company that aids in the discovery, development, and manufacture of life-saving and life-improving medicines for patients in the United States and worldwide; has deep American ties; and has operated lawfully in the United States for 19 years.

Undisputed evidence shows that the Company has sustained and will continue to suffer irreparable harm from the Department of War's unlawful 1260H designation, which automatically subjects the Company to the crushing restrictions of the BIOSECURE Act by virtue of its business as a biotechnology company. Those injuries, which are certain, significant, and unrecoverable, are multifaceted. They include concrete financial harms from canceled contracts, lost customers, and suspended relationships; severe reputational harm from being wrongly branded an arm of the Chinese military; interference with the constitutional liberty interest in contracting with other private parties, who must disengage from the Company or endure severe penalties from the Government under BIOSECURE; violation of the right to due process under law; and interference with the First Amendment right to petition the government through chosen representatives.

The unlawful 1260H designation has changed everything for the Company, and enjoining the Department of War's actions would cost it nothing. This Court should grant the Motion.

ARGUMENT

I. The Company Is Likely to Succeed on the Merits

A. The Decisional Memo Fails to Provide Evidence for the Department's Designation

The Opposition rests on the memorandum underlying the Department of War's decision to designate the Company as a Chinese military company, which the Government produced to the Company for the first time after this motion was filed. AR0055-77 (the "Decisional Memo"); *see* Supplemental Declaration of Steve Qing Yang ("Suppl. Yang Decl.") ¶ 36. The Decisional Memo, and thus the Opposition, is premised on fundamental factual errors and unsupported conclusions that could have been resolved had the Department conveyed its concerns to the Company in advance of the erroneous 1260H designation. "These errors do not inspire confidence in the fastidiousness of the agency's decisionmaking process." *Xiaomi Corp. v. U.S. Dep't of Def.*, 2021 WL 950144, at *5 (D.D.C. Mar. 12, 2021). The resulting decision is not the fruit of a "plausible alternative interpretation of the evidence," but an arbitrary and capricious government action lacking factual basis. *Archer W. Contractors, LLC v. U.S. Dep't of Transp.*, 45 F.4th 1, 6 (D.C. Cir. 2022). The Company does not ask this Court to "substitute its judgment" for that of the Department of War, or to raise the bar on what "substantial evidence" means. Opp. 11. The Department's evidence fails all on its own to survive judicial review, and the Company is likely to succeed on the merits.

1. There Is No Evidence That the Company Is Indirectly Owned By SASAC

The Department of War rests its primary determination on two internet sources, neither of which says what the Government represents them to say. This is not a matter of nuanced interpretation. The plain language of the Government's own sources unambiguously reports that a Chinese state-owned fund (the "AVIC Fund") held, in the second quarter of 2019, shares of the

Company that accounted for 5.32% of the fund’s net asset value. AR4582 (“WuXi AppTec was the sixth largest heavy stock in the product in the [second] quarter [of 2019], *accounting for 5.32% of the fund’s net asset value*”); AR4554 (“The latest fund report [Q2 2019] shows that the fund’s top holdings include ... WuXi AppTec (5.32%)”); *see also* Supplemental Declaration of Melissa Mills (“Suppl. Mills Decl.”), Exs. 1-2 (certified translations of Government’s sources). The Department of War misread that information to say the fund “*holds*” and “*owns a 5.32 percent stake in WuXi.*” Decisional Memo 6; Opp. 13. This twisting of language changes its meaning entirely. If a fund has \$100,000 in assets and invests \$5,000 in a multi-billion-dollar company, the fund has invested 5% of the fund’s assets in that company, but it does not hold 5% of the company.

Were the Government’s misreading accurate, the fund would have held, in 2019, approximately \$850 million¹ of the Company’s stock, over 40 times the AVIC Fund’s total asset value as of December 31, 2019. *See* Suppl. Mills Decl., Ex. 3; Suppl. Yang Decl. Ex. 1. Instead, the Government’s sources indicate that the fund purchased, on the public market, the Company’s publicly traded shares valued at approximately \$200,000, or *0.001% of the Company’s equity*. *See* Suppl. Yang Decl. ¶ 5, Exs. 1-2. This clearly falls far short of “ownership,” which requires “some level of control, not just mere possession of [] equity.” *SZ DJI Tech. Co. v. U.S. Dep’t of Def.*, 2025 WL 2761210, at *19-20 (D.D.C. Sept. 26, 2025); *see also* Mot. 21-22.

The Government’s warping of its two sources is not limited to the remarkable error of 5.32% versus 0.001%. Perhaps mindful of the requirement to use “the latest information available,” 1260H(b)(3)(A), and in an effort to cite to information more current than 2019, one of the Department’s two sources is a WeChat blog post from 2024. AR4580-85. According to the

¹ The RMB amounts have been converted to USD at a rate of RMB 1.00 to USD 0.16, the approximate exchange rate as of June 30, 2019. Converted figures are approximate.

Government, this source reported that the AVIC Fund had the purported “5.32% stake” in the Company in January 2024. This too is belied by the plain language. While the blog was *published* in January 2024, it clearly refers to a past investment “in the second quarter of 2019.” AR4582.

Compounding the problems with the Government’s misreading of its own sources, the Decisional Memo and the Government’s opposition engage in circular reporting. As noted above, both cite the same two internet sources, each referencing an AVIC Fund investment reported during the second quarter of 2019. For reasons that it does not explain, the Government implies that these are different investments with separate evidentiary value, when the sources make clear that this investment was one and the same. *See, e.g.,* Opp. 13 (“Underscoring that public evidence is further reporting...”); *see also* Decisional Memo 6.

A public investment by a Chinese-owned fund in 2019 of about \$200,000 in Company stock, which represented about 0.001% of the Company’s value, does not constitute “indirect ownership” by the Chinese government and fails to show any level of control. *See* Yang Decl. ¶¶ 30-31; Suppl. Yang Decl. ¶¶ 4-6. And public reporting confirms that, since 2020, the AVIC Fund has divested all holdings in the Company. *See* Suppl. Yang Decl. ¶ 5, Exs. 3-8 (translated excerpts of Fund’s annual reports). The Department of War’s stated reasoning for the finding that the Company is indirectly owned by SASAC by virtue of an infinitesimal holding of publicly traded shares seven years ago, long since divested, is a quintessential “inaccurate or unreasoned justification[] for a decision” that requires the decision to be vacated. *Env’t Def. Fund v. Env’t Protection Agency*, 922 F.3d 446, 454 (D.C. Cir. 2019).

The Department of War also casts shade on the Company’s inability to “disavow[] any certainty that there are *no* owners of WuXi equity with ‘a government affiliation.’” Opp. 14. At best, this reflects a basic misunderstanding of how public markets work. As with all publicly traded

companies, anyone with an eligible brokerage account can invest in the Company's stocks on the open market. No publicly traded company—Chinese, American, or otherwise—can preclude an individual or entity from trading in its stocks.

The Opposition repeatedly condemns the Company's motion for failing to refute the Department of War's specific evidence. *See, e.g., id.* (“Plaintiff fails ‘to point to a direct contradiction’ in the evidence before the agency” (internal citation omitted)). But when it filed its motion, the Company did not *have* the evidence before the agency, despite repeated requests for the opportunity to address any allegations against the Company. *See* Suppl. Yang Decl. ¶¶ 17, 36. And because the “evidence” ultimately offered by the Department of War is meritless and quoted for propositions it does not support, it is hard to see how the Company could have anticipated it.

2. There Is No Evidence That the Company Is Indirectly Affiliated with SASTIND or the PLA

The Government's argument that the Company is indirectly affiliated with SASTIND and the PLA is also groundless. The sole basis for this argument is a document detailing a series of clinical trials that *other* multinational companies conducted at university hospitals in China, and faulty assumptions about what the document means. Opp. 14-15; *see also* AR4799-4861.

This document details hundreds of clinical trials for which pharmaceutical companies obtained authorization in October 2022 to use human genetic material. From these, the Department of War notes that eleven applications were submitted by sponsors that listed the Company as their chosen third-party laboratory. For ten of these studies, the sponsors—among them the world's leading pharmaceutical companies headquartered in the United States and Europe—contracted with various university hospitals in China. AR4850-51, 4853. Because the Department of War considers these university hospitals to be overseen by SASTIND, it concludes that the Company is “indirectly affiliated with SASTIND.” Opp. 12. For the eleventh, the sponsor (a large

pharmaceutical company headquartered in Europe) contracted with the PLA General Hospital to conduct the study at that facility. AR4810. On that fact, the Department of War predicated its finding that the Company is “indirectly affiliated with the People’s Liberation Army.” Opp. 16. The Government’s sources fail to show any evidence of a “close formal or informal association” between the Company and either SASTIND or the PLA. Section 1260H(g)(1).

The Government’s argument reflects a fundamental misunderstanding of the global clinical drug testing process and the Company’s role in it. The errors are hard to square with the copious information that the Company provided on its business model and structure at every opportunity.

To ensure that medicines are safe and effective for use in humans, the companies that make them must test them. These clinical studies are regulated by the government of the country where they take place. In the United States, this work is overseen by the U.S. Food and Drug Administration. In China, aspects of certain clinical studies involving human genetic material required, until mid-2024, oversight by the Ministry of Science and Technology (MOST). *See* Suppl. Mills Decl., Exs. 4-6. Any non-Chinese or multinational company intending to conduct a human drug study in China that involves human genetic material—e.g., whole blood, tissues, cells—must obtain regulatory authorization. *See id.* The company conducting the study (known as the sponsor) chooses both the hospital where the study will be conducted and the third-party laboratory where the samples will be processed, and the sponsor enters into separate contracts with each. Suppl. Yang Decl. ¶¶ 20-22. As reflected in the document relied on by the Government, the role of the Company is to provide third-party laboratory services to the sponsor. *See, e.g.*, AR4809; AR4851.

SASTIND played no role in the Company’s work on these studies. Suppl. Yang Decl. ¶ 22. The sponsor, not the Company serving as a third-party laboratory, applied for the required authorization from MOST to use human genetic material. *Id.* MOST does not “approve” drug

studies but only regulates the use, collection, preservation, or export of human genetic material in studies controlled by the sponsors. *Id.* Nor does the Company “conduct” the study. *Id.* ¶¶ 21, 23. Nor is it a party to the sponsor’s contract with the hospital. *Id.* ¶¶ 20-21. Nor has the Company *ever* been the sponsor of a study involving any hospital or institution identified in the Department’s memorandum as affiliated with SASTIND or the PLA. *Id.* ¶ 20. The Opposition lays bare the Government’s fundamental misunderstanding of these central and concrete facts, which are opposite to and irreconcilable with the unsupported assumptions drawn in support of the Department of War’s findings. *See, e.g.*, Opp. 16 (erroneously asserting that the Company “received approval” from the Chinese government to “conduct” a drug study); Opp. 15 (erroneously stating that the Company “conducted” multiple drug studies); Opp. 14-15 (erroneously alleging that the Company conducted drug studies “in partnership with” various Chinese university hospitals).

The Department of War’s apparent theory that the Company’s alleged “indirect affiliation” with the Chinese government runs through multinational pharmaceutical companies, including those headquartered in the United States and Europe, is supported by zero evidence and patently farcical. Such a broad interpretation of affiliation “would have almost no limiting principle,” undermining its rationality. *See, e.g., Luokung v. Dep’t of Def.*, 538 F. Supp. 3d 174, 187 (D.D.C. 2021). For example, the Government’s source also lists the University of Michigan as the sponsor for a study at a Peking University-affiliated hospital, the same SASTIND-supervised university the Department of War points to in support of the Company’s designation for its role as a sponsor’s third-party laboratory—meaning that the Company is *one step further removed from an “affiliation with SASTIND” than the University of Michigan*. AR4817; Opp. 15. The Government offers no “reasoned explanation” for distinguishing between such a relationship and the

Company's. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

B. The Department of War Violated Due Process by Failing to Provide the Company Notice or An Opportunity to be Heard

It is undisputed that the Department of War provided the Company with no factual basis whatsoever until it produced, during the pendency of this Motion, the Decisional Memo. It is clear that its “factual” basis is entirely erroneous. *See supra* § I.A. The Department violated the Company's due process rights by failing to provide “the opportunity to tailor its submission to the [Government's] concerns or rebut the factual premises underlying the [Government's] action.” *Ralls Corp. v. Comm. on Foreign Inv. in U.S.*, 758 F.3d 296, 320 (D.C. Cir. 2014).

1. The Company Has a Constitutionally Protected Interest

The Company has a due process liberty right to enter into contracts. *Susman Godfrey LLP v. Exec. Off. of President*, 789 F. Supp. 3d 15, 51 (D.D.C. 2025) (penalizing firm clients with preclusion from government contracts “violates the firm's interest in being able to contract with clients”); *Anthropic PBC v. U.S. Dep't of War*, 825 F. Supp. 3d 1101, 1127 (N.D. Cal. 2026) (Department of War government contracting ban “threaten[ed] to cripple Anthropic by... ending its ability to have *any commercial relationship* with any company that might want to do business with DoW”) (emphasis in original). The Opposition's strawman argument that the Due Process Clause protects only the liberty interest in “*government contract bidding*” is incorrect on the facts and the law. Opp. 20-21.

By designating the Company under 1260H, the Department effectively “impos[ed] a broad preclusion that seriously affects, if not destroys, [the Company's] ability to obtain contracts in its chosen field of business,” *Anthropic PBC*, 825 F. Supp. 3d at 1126-27 (quoting *Trifax Corp. v. District of Columbia*, 314 F.3d 641, 644 (D.C. Cir. 2003) (internal quotation marks omitted), because government contractors must—under threat of losing their own government contracts—

cut ties with the Company once BIOSECURE restrictions take effect. *See* Mot. 31; *see also* Damond Decl. ¶ 37. The Department’s actions violated the Company’s constitutionally protected interest to enter into contracts.

The Opposition’s failure to recognize this constitutional interest causes it to misread *SZ DJI*. Opp. 21. There, only after finding that the plaintiff had failed to show a direct deprivation of a protected interest did the Court proceed to consider whether it had made an alternative showing of sufficiently severe “consequential” injury. *SZ DJI*, 2025 WL 2761210, at *21-22. Unlike that plaintiff, the Company has sustained a direct deprivation from the BIOSECURE Act, which interferes with the Company’s contracting relationships by creating a regime that will strip government contracts from its business partners. Damond Decl. ¶¶ 37-40. The BIOSECURE Act is the functional equivalent of the Executive Order in *Susman Godfrey LLP* that violated a law firm’s constitutional right to enter into private contracts by threatening its clients with debarment. 789 F. Supp. 3d at 20. That BIOSECURE has passed but not yet taken full effect does not cure the deprivation. The Company’s contracts are long-term, covering multi-year clinical trials, and cannot be terminated midstream without endangering patient safety or disrupting critical medical studies. But business partners know that the Company will be subject to these restrictions, so they are—right now—making plans to offramp and engage other partners that will not cost them their ability to contract with the Government. Damond Decl. ¶¶ 37-40. The Government’s 1260H determination also infringed the Company’s First Amendment rights by forcing lobbying firms to choose between representing the Company and representing other clients that want to continue doing business with the Government. *See* 10 U.S.C. § 4663; *infra* § II.C.4.

2. The Company Was Not Afforded Pre-Deprivation Due Process

a) *There Was No “Special Need For Very Prompt Action”*

The Government misunderstands the three factors required to support a deprivation of due

process before an action is taken. The first factor does not, as the Opposition implies, merely require that the underlying action “further[] the compelling government interest[.]” Opp. 23. Rather, *the deprivation of due process* must have been “necessary to secure an important government interest.” *López Bello v. Smith*, 651 F. Supp. 3d 20, 39 (D.D.C. 2022) (citation omitted). The Opposition does not explain how depriving the Company of notice of the Department of War’s specific concerns and a meaningful opportunity to address them was necessary to the stated governmental interest of “protecting the U.S. military supply chain by preventing infiltration from foreign actors.” Opp. 23.

As to the second factor, the Government’s professed “special need for very prompt action” is belied by the evidence. *Id.* As noted above, it relies entirely on an incorrect reading of evidence from 2019 and 2022. *See supra* § I.A.1-2. Setting aside the glaring defects in that evidence, the 2019 investment was divested in 2020, and in most of the cited clinical drug trials for which the Company provided third-party laboratory services to multinational corporations in 2022, the Company’s participation has concluded. *See supra* § I.A.2. Absent from the Opposition is any explanation of why that information compelled, in June 2026, a “special need for very prompt action” that precluded the Government from providing due process. The Government’s claim that it could not provide advance notification of the 1260H designation is further undermined by the fact that the Department engaged in years of on-again-off-again discussions with the Company, revealed its intentions to Congress in a widely reported letter, and published (then quickly withdrew) a 1260H list including the Company five months ago. *See* Suppl. Yang Decl. ¶¶ 7-17, 24-36; AR0078-3608.

Moreover, the suggestion that the Company might react to notice by “spinning off assets” or “creating new entities while obscuring their true ownership” is not credible. Opp. 23. This is a

\$50 billion international company with deep ties to the United States and a known name in the global life sciences industry. It is not, contrary to the Government’s stated fears, a potential player in “a constant game of whack-a-mole” that could secretly compete for government contracts under a new name. *Id.* The Government’s final theory, that “very prompt action is required to ensure that [the Company] *cannot spoliage relevant evidence*,” is both unexplained and entirely inexplicable, and it merits no further discussion. *Id.* (emphasis added).

As to the third and ministerial factor, the Company agrees that the party initiating the deprivation was a governmental official. *Id.* 23-24. That does nothing to justify the deprivation.

b) The Department of War Did Not Provide Pre-Deprivation Process

Plaintiff’s purported opportunity to “present its argument” to Department officials pre-deprivation is not adequate process. *Id.* 24. The Company had no meaningful opportunity to “tailor its submission[s] to [the Department’s] concerns.” *Ralls*, 758 F.3d at 319-20; *see also Nat’l Council of Resistance of Iran v. Dep’t of State*, 251 F.3d 192, 209 (D.C. Cir. 2001) (requiring advance notice and opportunity “to rebut the [non-classified] administrative record” for foreign-terrorist-organization designation). The Department’s conduct in this matter highlights why: the alleged pre-deprivation process was an empty “gesture.” *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 315 (1950).

The Company repeatedly asked to review and respond to the evidence supporting any designation and explicitly expressed concern that it would be denied due process by being designated without an opportunity to respond to unknown allegations:

[W]e are concerned ... that a decision about WuXi AppTec might be made without allowing WuXi AppTec to respond to allegations against it. Due process requires that opportunity. ... We ... respectfully request an opportunity to hear and respond to any DoW views to the contrary. AR0513, 3602, 3606.

Rebuffing the Company’s repeated requests, the Department never disclosed the evidence or the

grounds on which it ultimately relied. Suppl. Yang Decl. ¶¶ 32-36; AR3602-3608. In particular, the Department never told the Company: (1) it believed that the AVIC Fund held a 5.32% stake in the Company that the Department perceived as amounting to SASAC ownership, or (2) it was concerned about the 2022 clinical studies underlying its SASTIND and PLA-affiliation findings. *See supra* § I.A. The Company was thus afforded no opportunity to “include evidence in the record” that “would have affected the outcome,” rendering years of engagement a sham. *Hesai Tech. Co., Ltd. v. Dep’t of Def.*, 792 F. Supp. 3d 22, 48 (D.D.C. 2025) (citation omitted); *Ralls*, 758 F.3d at 319-20.

The Department’s decision was made long before it was published, and indeed weeks before it entertained a November 2025 meeting with the Company for the ostensible purpose of gathering information for the decision-making process. This is evidenced by a Bloomberg article reporting that, in October 2025, the Deputy Secretary of War sent a letter to Congress indicating an intent to list the Company. Mills Decl., Ex. 4. The sham nature of the November 2025 meeting is further shown by the Government’s inexplicable refusal to provide, despite requests before and during this litigation (and a FOIA request months ago), this October 2025 letter. From this conduct among other facts, the Court should infer that the meeting did not provide good-faith due process.

c) Deprivation Is Not Cured by Post-Deprivation Process

Nor is due process satisfied by the opportunity to seek reconsideration and pursue judicial review. Opp. 24-25; *Perkins Coie LLP v. U.S. Dep’t of Justice*, 783 F. Supp. 3d 105, 173-74 (D.D.C. 2025) (due process violated by failure to provide pre-deprivation notice despite opportunity to seek later judicial relief). All of Defendants’ supporting cases are either inapposite or undermine their position. Opp. 24-25; *see, e.g., First Nat’l Bank & Tr., Wibaux v. Dep’t of Treasury*, 63 F.3d 894, 898-99 (9th Cir. 1995) (Plaintiff was “given the opportunity to respond to

the [government’s] findings” pre-deprivation); *Memphis Light, Gas & Water Division v. Craft*, 436 U.S. 1, 16 (1978) (“some kind of hearing is required at some time before a person is finally deprived of his property interests.”); *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 595, 598 (1950) (requisite hearing must be held before the final administrative order becomes effective).

3. The Failure to Provide Due Process Was Not Harmless

Defendants’ failure to provide sufficient process was not harmless. Error is harmless only when it “clearly had no bearing on the procedure used or the substance of decision reached.” *Ctr. For Biological Diversity v. U.S. Int’l Dev. Fin. Corp.*, 77 F.4th 679, 690 (D.C. Cir. 2023). The Department’s numerous mistakes absolutely “affected the outcome,” *supra* § I.A, because if the Company had been afforded the opportunity to clear up the many plain mistakes and inaccuracies in the Government’s conclusions, the Department of War would—in good faith—have reached a different conclusion. *PDK Lab’y Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (finding error not harmless because agency would have reached a different conclusion absent its mistake).

C. **The Affiliation Clause of Section 1260H Is Void for Vagueness**

The Opposition and Decisional Memo confirm that Section 1260H’s “affiliated with” clause is unconstitutionally vague. *See supra* § I.A.2; Mot. 29. As the Government has interpreted and applied that provision, *any* pharmaceutical company, American public university, or other entity—no matter how far removed from the Chinese government—conducting a drug trial at a Chinese university hospital would be considered a “Chinese military company.” From the Government’s source document alone, AR4799-4861, several leading U.S. and European pharmaceutical companies—and indeed American universities—would be subject to designation as a “Chinese military company” pursuant to the sweeping void of Section 1260H’s “affiliation” language. It thus fails to provide any “explicit standards” for determining whether there is an “affiliation,” as it is impossible to know ahead of time whether the Government will deem a

company's relationship with another entity sufficiently "close" to constitute a prohibited association. *See Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). The definition has no meaningful limiting principle and thus would allow for "arbitrary and discriminatory enforcement," rendering it unconstitutionally vague. *Hill v. Colorado*, 530 U.S. 703, 732 (2000).

II. The Department of War's Designation Is Inflicting, and Will Continue to Inflict, Irreparable Harm on the Company

Defendants' arguments to rebut the Company's showing of irreparable harm rest on the wrong legal standard, mischaracterize completed and ongoing business losses as speculative possibilities, and discount evidence of a few weeks of losses by comparing them with the Company's annual global revenue. The undisputed evidence demonstrates present, substantial, and irreparable harm. And since the Company filed its motion, the irreparable harm caused by the Defendants' erroneous designation has only increased.

A. The Company Need Not Show That the Designation Threatens Its Existence

Economic losses need not threaten a company's existence to be irreparable where, as here, sovereign immunity makes them unrecoverable. There are "at least two circumstances" in which economic loss may constitute irreparable harm: where the loss "threatens the very existence" of the business, or where the loss is unrecoverable because of sovereign immunity and is "great, certain and imminent." *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 211 (D.D.C. 2012). In the latter circumstance, this Court has recognized that "a lesser showing is permissible" and asks whether substantial economic losses are "certain, imminent and unrecoverable," "even if [the loss] would not wipe the business out." *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 58-59 (D.D.C. 2020) (Boasberg, C.J.) (cleaned up). The relevant question is therefore whether the designation is causing unrecoverable losses that are serious in their practical effect—not whether the Company is on the brink of collapse. And on that score, the Opposition does not

seriously dispute the Company’s showing. As explained in the Declaration of Steve Yang, within ten days of the designation, approximately [REDACTED]—[REDACTED]—[REDACTED]—had raised concerns, while customers across multiple business lines had already suspended, terminated, or withheld work. Yang Decl. ¶¶ 42-43. And as further discussed below, those harms have increased as news of the Company’s erroneous designation continues to spread. *See infra* § II.C.

B. The BIOSECURE Act Harms Are Immediate and Ongoing

Because of Defendants’ unlawful actions, the Company will be subject to the devastating effects of the BIOSECURE Act, absent judicial intervention. This is not theoretical. The BIOSECURE Act has two prerequisites for subjecting a company on the 1260H list to its punitive regime for “biotechnology companies of concern” (“BCC”): (1) the Department of War must include the company on the 1260H list, and (2) the Office of Management and Budget (OMB) must determine that it is “to any extent involved in the manufacturing, distribution, provision, or procurement of any biotechnology equipment or service.” Pub. L. No. 119-60, § 851(f)(2)(A)(i). The first criterion has now been satisfied. As to the second, the Company is a biotechnology service company. That is its entire business. Notwithstanding the Government’s insistence that the 1260H designation is only “the first step” toward designation under the BIOSECURE Act, it does not, and cannot, credibly dispute that OMB will fulfill its ministerial duty and affirm that the Company is indeed a biotechnology company.

The BIOSECURE Act explains why customers are acting *now*, and full implementation of the BIOSECURE Act regime is not a prerequisite to the harm being inflicted on the Company today. The Government’s authorities do not support treating these present injuries as speculative. *Wisconsin Gas* rejected predictions about third-party conduct where no supplier had “stated an intention to cease contracting” and the petitioners had not shown that customer reductions were

“presently a real possibility.” *Wis. Gas Co. v. FERC*, 758 F.2d 669, 675 (D.C. Cir. 1985). Here, by contrast, customers and business partners have already taken the very actions the Government calls speculative: halting contracts, suspending ongoing work, and terminating relationships. Yang Decl. ¶¶ 42-43; Suppl. Yang Decl. ¶¶ 39-42. The Opposition diminishes these harms in ways that the evidence does not support. *Compare, e.g.*, Opp. 37 (citing customer’s “‘wait and see’ posture” in suggesting the relationship would suffer no harm), *with* Yang Decl. ¶ 43 (making clear that “wait and see” posture related to “*further* cooperation,” and that the customer had “urgently halted contracts across multiple clinical stage projects and suspended ongoing work”).

The rationale of *Sonderling* does not apply here. There, this Court denied preliminary relief because the asserted injury had not yet occurred, and because the Court expected to decide the merits before it arose. *AFL-CIO v. Sonderling*, 2026 WL 1906727, at *6 (D.D.C. July 2, 2026). By contrast, the injury here is already underway and even an expedited merits ruling cannot precede losses the Company has already suffered and continues to suffer.

C. The Designation Is Causing Concrete, Substantial, and Irreparable Harm

The Department of War’s remaining arguments likewise fail. First, they minimize concrete and escalating disruption by reducing it to a narrow snapshot of immediately quantifiable revenue. This oversimplification disregards the practical consequences of customers shifting work to alternative providers in an industry where long-term contracts span lengthy clinical drug trials and complex relationships take time to build and to unwind. Critically, the Opposition does not address the fact that major law firms are openly advising their clients and other industry participants to reevaluate their relationships with the Company in light of its 1260H designation. Second, the Government incorrectly assumes that a later judgment can restore projects, relationships, opportunities, and goodwill lost in the meantime. Third, the Government ignores the designation’s ongoing constitutional harms.

1. The Designation Has Already Caused Serious and Growing Harm

The Department of War reduces the Company's evidence to customer "concerns," "pauses," and "reassessments." Opp. 35-36. In fact, immediately following the designation, concrete harms materialized. The Company's customers withheld new work, suspended active projects, placed entire collaborations on hold, reassessed more than ██████ in existing commitments, and terminated ongoing programs to preserve access to government funding. Mot. 24-25; Yang Decl. ¶¶ 42-43. The designation has already cost or interrupted existing business for the Company, and its impacts cannot be trivialized to mere apprehension about uncertain future possibilities.

The Government also treats those early examples as isolated, but developments since the motion was filed show that the disruption continues to spread. Since then, more customers have adopted prohibitions on working with the Company, cancelled planned collaborations, declined to award new programs, and begun redirecting existing and future work to competitors. *See* Suppl. Yang Decl. ¶ 40 (█████ eliminated all business with the Company after adopting a policy barring further work with it); *id.* ¶ 41 (█████ cancelled a planned collaboration and halted discussions across multiple business lines, and ██████ declined to award the Company a new program and intends to move existing business to another supplier); *id.* ¶ 42 (█████ ██████ advised that it expects to route its next order to a competing supplier because of designation-related restrictions and a relationship with ██████ has ceased). These developments illustrate that the harms identified in the motion continue to spread.

And these adverse customer reactions reported to the Company are the tip of the iceberg. They do not capture the full extent of the disruption already underway. Relationships between pharmaceutical companies and service providers are complex, and customers have every incentive to begin qualifying alternative providers before formally terminating an existing agreement. Damond Decl. ¶¶ 41-44. Although the Company can quantify the value of a cancelled contract, it

is impossible to calculate the future work lost when a repeat customer moves to a competitor—often for many years—or the business of prospective customers is deterred before they ever engage the Company. Suppl. Yang Decl. ¶ 43. The losses identified to date therefore reflect the designation’s most immediate and observable effects, not the full extent of customer migration.

Industry alerts—which the Government does not address at all—confirm that customers are being urged to take precisely these steps *now*. *See, e.g.*, Mills Decl., Ex. 16 (“Companies should review their existing agreements with entities named on the 1260H list,” specifically including “WuXi AppTec”); *Id.*, Ex. 17 (“industry participants should carefully evaluate the impact [of the Company’s 1260H designation] on their current and future arrangements”); *see also* Mot. 34; Damond Decl. ¶¶ 58-60 (explaining that advisers are recommending that prospective customers select alternative providers, and that existing customers shift work away from the Company). Customers are thus already reducing the scope or duration of planned agreements and looking for alternative providers. Damond Decl. ¶ 51. The Government does not dispute this evidence, nor does it explain why it is unreasonable to conclude that the Company’s business partners are following this chorus of explicit advice from a host of trusted industry sources.

Nor is the harm limited to decisions by individual customers. [REDACTED]—an online marketplace through which pharmaceutical and biotechnology companies source and purchase outsourced research services—has restricted the Company on its platform because of the designation. Suppl. Yang Decl. ¶ 38. The designation is also affecting other relationships necessary to the Company’s operations. It has subjected supplier relationships to heightened scrutiny and new conditions. Mot. 35; Yang Decl. ¶ 45. This is not a “brief interruption.” Opp. 37. The consequences are metastasizing with each passing day.

2. Defendants Understate the Magnitude of Harm.

Defendants try to minimize the harm by pinning known losses from the designation’s first

weeks to a percentage of the Company’s annual worldwide revenue. Opp. 35-36. But irreparability is “not a mathematical judgment.” *See District of Columbia v. U.S. Dep’t of Agric.*, 444 F. Supp. 3d 1, 38-39 (D.D.C. 2020). Rather, the inquiry considers the injury’s practical effect, and whether evidence of its nature and likely consequences is sufficient to establish harm. *See id.* (finding declarations and representative cost estimates “enough proof” for irreparable harm).

Here, the injury extends far beyond revenue attached to the projects formally cancelled during the designation’s first weeks. Drug development is a years-long, multi-stage process, and once a customer begins the process of qualifying an alternative supplier, its relationship with the Company is, as a practical matter, over. Damond Decl. ¶¶ 42-43. Defendants’ efforts to cabin the harms to reported final losses fails to account for the lost future projects and follow-on work, and the durable customer losses already set in motion.

Defendants’ authorities, involving injuries that were unsupported by concrete evidence of loss, do not support minimizing the Company’s losses by reference to its overall size. *See Alcresta Therapeutics, Inc. v. Azar*, 318 F. Supp. 3d 321, 327 n.4 (D.D.C. 2018) (finding projected losses “far from certain” because the underlying methodology—and the losses’ significance to the company—were unclear); *Air Transp. Ass’n of Am., Inc. v. Export-Import Bank of the U.S.*, 840 F. Supp. 2d 327, 337-38 (D.D.C. 2012) (finding alleged harm speculative where plaintiffs had not shown that challenged conduct would cause them “to lose revenue or lay off employees” and thus had not “adequately described and quantified the level of harm”). Defendants’ remaining authority—*Cardinal Health*—does not support Defendants’ comparison either. Although the court considered Cardinal’s overall financial health in evaluating irreparable harm, it did so because the challenged conduct caused a discrete interruption at one facility that Cardinal could mitigate by shipping through its other facilities, and Cardinal offered “no concrete estimates regarding lost

revenues, customers, or market share” attributable to that suspension. *Cardinal Health*, 846 F. Supp. 2d at 211-13. Here, the designation reaches the Company as a whole, there are no comparable means of mitigation, customer decisions across multiple business lines are impacted, and identifiable work has already been suspended, terminated, and withheld. Those effects cannot be assessed by comparing known losses quantified during the designation’s first weeks to annual worldwide revenue.

Nor is the Company required to wait until customer flight has fully run its course. Preliminary relief requires a showing that irreparable injury is “likely in the absence of an injunction,” not that the injury has already been completed. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Companies that regularly do business with federal agencies do not wait for a prohibition to take effect before moving work away from a supplier the government has identified as a national-security risk. Damond Decl. ¶ 50; *see also TikTok Inc. v. Trump*, 490 F. Supp. 3d 73, 84 (D.D.C. 2020) (finding irreparable harm where uncertainty had driven users to competing platforms and made those users unlikely to return); *Luokung Tech. Corp.*, 538 F. Supp. 3d at 192-93 (finding significant unrecoverable harm after two key customers terminated contracts and crediting “high likelihood” of further market share decline as customers shifted to competitors).

That progression is already occurring: the number and scope of adverse customer actions have increased since the motion was filed. Suppl. Yang Decl. ¶¶ 39-42. Those escalating reactions confirm both that the Company faces the loss of a substantial portion of its U.S. customer base and that losses quantified to date capture only the earliest, and most visible, effects.

3. A Later Merits Judgment Cannot Restore the Projects, Relationships, and Opportunities Being Lost Now

Once a customer transfers work or begins qualifying an alternative provider, a later judgment cannot restore the lost development time, recover projects awarded elsewhere, or unwind

the validation, method-transfer, and regulatory investments that make switching back commercially unlikely. Damond Decl. ¶¶ 42-44; Suppl. Yang Decl. ¶ 43. Courts recognize that such customer migration causes irreparable harm even if the challenged government action is later reversed. *See Nalco Co. v. U.S. Env't Prot. Agency*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) (finding irreparable harm where government action drove major customer to a competitor, costs of switching made customers unlikely to return, and plaintiff faced further loss of longstanding clients and goodwill); *TikTok*, 490 F. Supp. 3d at 84 (finding irreparable harm where government action drove users to competing platforms). The designation also damages goodwill and causes lost profits that cannot later be recaptured. *See Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962) (finding irreparable harm where government action would damage the plaintiff's good name and force it either to market a misbranded product or withdraw from the market and lose profits).

4. The Designation's Ongoing Constitutional Injuries Independently Support Preliminary Relief

Defendants argue that the Company's constitutional injury cannot support preliminary relief because they dispute its due process claim, Opp. 38-39, but that simply repackages their incorrect merits arguments. As explained above, the Company is likely to succeed on its claim that Defendants imposed a property-impairing and stigmatizing national-security designation without constitutionally adequate process. *See supra* § I.B. The resulting deprivation is independently irreparable. *See Mills v. District of Columbia*, 571 F.3d 1304, 1312 (D.C. Cir. 2009) ("[T]he loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" (citation omitted)); *Simms v. District of Columbia*, 872 F. Supp. 2d 90, 104-05 (D.D.C. 2012) (finding irreparable harm where the plaintiff was likely to succeed on a procedural-due-process claim). Each day the designation remains in effect perpetuates that

deprivation, regardless of how Defendants minimize the magnitude of the economic losses.

That is not the designation's only constitutional consequence. It has also impaired the Company's First Amendment right to petition the U.S. government through professional representatives. On July 1, [REDACTED]—the Company's only U.S. lobbying firm—terminated its engagement following the designation, and to date the Company has been unable to retain a replacement firm due to the designation. Suppl. Yang Decl. ¶ 44. The Government's claim that the Company "forfeited" its right to raise this First Amendment violation by not addressing it in the opening motion, Opp. 39-40, omits the key fact that, as the Company advised Government counsel in advance of the Government's opposition, the Company lost the lobbyist *after* filing its opening motion.

Defendants' suggestion that the Company can simply hire another firm or lobby on its own, Opp. 40, is both factually refuted and legally beside the point. The right to petition includes the right to urge one's claims through professional representatives before the government. *See Autor v. Pritzker*, 740 F.3d 176, 182-83 (D.C. Cir. 2014) ("[R]egistered lobbyists are protected by the First Amendment right to petition" and the availability of other ways to petition "is no answer" to the loss of "an especially effective way to affect government policy"); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565-66 (2011) ("Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content."). By causing the Company's only lobbying firm in the U.S. to withdraw and deterring potential replacement firms, the designation is materially impairing the Company's ability to seek relief from the very government action causing its injuries at a time when the Company desperately needs to communicate to lawmakers the harm that is being caused not only to the Company but to American patients and other American interests (for instance, the risk of skilled job loss at the Company's current and forthcoming U.S. facilities).

III. The Balance of Equities and the Public Interest Support a Preliminary Injunction

The Opposition does nothing to show that the balance of the equities favors the Government. Instead, it fails to confront a simple reality: designating the Company under section 1260H has changed everything for the Company, while granting the injunction and de-designating the Company during the pendency of this litigation would change nothing for the Department of War. The Company has operated in the United States since 2007. *See* Mot. 24. The Government has not explained how or why *preserving the status quo of the past 19 years* until the Court can fully evaluate the Company's claims will harm them or the public.

The Department of War will be unaffected if the Court grants the Motion and the Company is de-designated. Indeed, its conduct in waiting months after deciding to designate the Company before publishing and withdrawing the 1260H List in February and re-publishing the List in June makes clear that the Department will not suffer if it is enjoined from including the Company on the list until this litigation resolves. *See* Mot. 11. Defendants' Opposition ignores this fatal flaw and rests on the general principle that courts afford the government deference in matters of national security. Opp. 41-42. But the Opposition does nothing to establish that national security interests are actually at stake with respect to the Company's designation, offering only the circular justification that the 1260H list serves an important purpose because the government decided there should be a 1260H list. *Id.* But the Company does not seek to enjoin the government from creating and publishing the 1260H list; it seeks to enjoin its own designation until the Court has had the opportunity to evaluate the merits of its claims.

Because the Government has failed to establish how it will be harmed if the requested relief is granted, the balance of the equities and public interest support entry of a preliminary injunction.

IV. No Stay or Bond is Warranted

If the Court grants the Motion, the injunction should not be stayed, and no bond should be

required. The Government cites Fed. R. App. P. 8(a) to support its assertion that any injunction should be stayed pending appeal. Opp. 42. But Rule 8(a) contemplates a motion in the district court, and as the Government's own authority confirms, "[t]he party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009). The Government's single conclusory sentence that "[f]or the reasons explained above" they have shown those circumstances falls far short, and no stay is warranted. Opp. 42. Further, its own authority makes clear that the factors to determine whether a stay is warranted overlap with the factors for a preliminary injunction. *See Nken*, 556 U.S. at 434. Having already applied those factors to grant the injunction, applying the same factors again to stay that injunction would be contradictory.

Likewise, as the Motion established, no bond is warranted because the Department of War faces no risk of monetary harm from the requested relief. Mot. 44. The Opposition attempts to conjure monetary harm by asserting that an injunction may result in a "mandate" that the Government "spend money on unwanted uses of goods or services from WuXi or its subsidiaries." Opp. 43. But the Department of War has not contracted and does not contract with the Company, and de-designating it would not create a "mandate" to start doing so. The single sentence regarding the deterrent effect of a bond is also inapposite; the Company was forced to seek relief to prevent irreparable harm, and the injunction will not inflict any injury on the Government.

CONCLUSION

The Company respectfully requests that the Court grant the Motion and enter a preliminary injunction enjoining the Department of War and its officers, employees, and agents from enforcing, implementing, applying, or taking any action whatsoever under, or in reliance on, the designation of the Company as a Chinese military company under Section 1260H.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI, P.C.

Dated: July 20, 2026

/s/ Melissa Mills
Melissa Mills (D.C. Bar No. 90033390)
953 East Third Street, Suite 100
Los Angeles, CA 90013-1955
(323) 210-2991
mmills@wsgr.com

Michael S. Sommer
(pro hac vice forthcoming)
Morris Fodeman
(pro hac vice)
Sheryl Shapiro Bassin (N.Y. Bar No.
4662797)
(admitted to practice before this court)
31 West 52nd Street, Fifth Floor
New York, NY 10019-6118
(212) 999-5800
msommer@wsgr.com
mfodeman@wsgr.com
sbassin@wsgr.com

Timothy M. Broas (D.C. Bar No. 391145)
1700 K Street NW, Fifth Floor
Washington, DC 20006-3814
(202) 973-8846
tbroas@wsgr.com

Counsel for Plaintiff WuXi AppTec Co., Ltd.