In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 23-15V

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ANDREA HOROWITZ,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: June 26, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

Renee J. Gentry, Law Office of Renee J. Gentry, Washington, DC, for Petitioner.

Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

On January 5, 2023, Andrea Horowitz filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that a hepatitis B vaccine she received in Australia on February 4, 2020, caused her to experience transverse myelitis ("TM") and/or multiple sclerosis.

Respondent has raised a preliminary question about the claim's viability. *See* Respondent's Motion to Dismiss, dated Jan. 16, 2024 (ECF No. 30), and referenced Rule 4(c) Report, dated Jan. 16, 2024 (ECF No. 29) (collectively, "Mot."). Respondent contends that the claim is not cognizable under the Vaccine Act because it has not been demonstrated that the vaccine at issue (which

[1] As provided by 42 U.S.C. § 300aa-12(d)(4)(B), the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Order will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

Petitioner unquestionably received *outside* of the United States) was manufactured by a "vaccine manufacturer located in the United States," a phrase contained in Section 11(c)(1)(B)(i)(III) of the Vaccine Act—but not defined in the Act otherwise. Petitioner maintains Respondent's construction of that term is overly narrow. *See* Petitioner's Opposition Brief, dated Feb. 7, 2024 (ECF No. 35) ("Opp."). Now, for the reasons set forth below, I grant Respondent's Motion and dismiss the claim.

I. Fact History

The fact summary set forth below addresses only those matters relevant to the vaccine's administration, and not Petitioner's alleged vaccine injury.

In the fall of 2019, several months before the vaccination at issue, Petitioner was residing in the United States. She was at that time advised by primary care treaters to receive the hep B vaccine series. Ex. 3 at 12; Ex. 14 at 56. She subsequently relocated to Australia, and while there received medical treatment for a variety of ongoing issues. Ex. 7 at 30–38; Ex. 14 at 66, 69–76.

On February 4, 2020, Petitioner received the hep B vaccine in Melbourne, Australia. Ex. 1 at 1–2 (April 1, 2020 note and health insurance form from treater regarding administration of vaccine); Ex. 32 at ¶ 2 (Petitioner's affidavit). A handwritten record from the relevant treater (and evidently prepared on the same date as vaccination) states: "Living in Melbourne for [one year]. [First] Hep[atitis] B. ? never immunized in [New York City]. Engerix AHBVC857AA." Ex. 39 at 2. This refers to an Engerix-B hepatitis B vaccine batch number for vaccines sponsored by GlaxoSmithKline Australia Pty Ltd., a company located in Australia. *See* https://www.tga.gov.au/resources/lab-test-reports/engerix-b-hepatitis-b-surface-antigen-recombinant-yeast-20-microgram1ml-injection-syringe-glaxosmithkline-australia-pty-ltd-25 (last visited June 26, 2024). Petitioner has not established where this vaccine was actually manufactured.

Thereafter, Petitioner became ill and was treated for what initially appeared to be TM. By June 2020, she had relocated back to the United States, and continued to obtain treatment associated with her alleged vaccine injury. Ex. 37 at 1–19, 21.

II. Procedural History

The claim was filed in January 2023, and after it was released from "pre-assignment review" (a process utilized by the Office of Special Masters to ensure that sufficient records needed to analyze a claim have been filed), it was assigned to a different special master. The Rule 4(c) Report identifying issues with the claim's propriety was filed in January 2024, along with the present motion to dismiss. After Petitioner had reacted and Respondent had filed his reply on February 16, 2024 (*see* ECF No. 36 ("Reply")), the matter was reassigned to me.

III. Parties' Arguments

Petitioner

Petitioner maintains that although she did receive the subject covered vaccine in Australia, she can establish that "the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination." Section 11(c)(1)(B)(i)(III). She notes that the term "located" is undefined by the Act, and therefore should be given its ordinary understanding, which she represents would require only establishing that the manufacturer had a "significant presence" in the U.S. Opp. at 3. Here, the record suggests that she received a version of the hep B vaccine covered by the Table and manufactured by a global corporate entity, GlaxoSmithKline ("GSK"). *Id.* at 3–4. That entity, in turn, does substantial business in the U.S., even though its primary headquarters are in the U.K. *Id.* at 4. In particular, GSK sells and manufactures within the U.S. a large number of covered vaccines, and treats the U.S. as a "key market." *Id.*

Petitioner also argues that she is not obligated to prove that the vaccine she received was literally manufactured "in" the U.S., or that the manufacturer at issue has its principal place of business in the U.S. Opp. at 5. Thus, based upon her reading of the term "located," she can satisfy this requirement applicable to claimants who are vaccinated abroad. Notably, and despite a fair opportunity to brief the matter, Petitioner has not endeavored to establish the source or place of the vaccine's actual manufacture.

Respondent

Respondent's dismissal arguments are succinctly set forth in his initial motion, but greatly amplified in his Reply. Although Respondent does not dispute that Ms. Horowitz returned to the U.S. within six months of vaccination, he maintains that she cannot demonstrate that the vaccine she received "was manufactured by a vaccine manufacturer located in the United States." Reply at 4.

In so arguing, Respondent construes the term "manufacturer" (Section 33(3), but in conjunction with Section 11(c)(1)(B)(i)(III)) to mean that non-military individuals receiving covered vaccines abroad must show that the specific vaccine received was literally "manufactured, imported, processed, or distributed by a corporation . . . *located* in the United States." Reply at 6 (emphasis added). The record in this case, however, reveals that Petitioner received a version of the hep B vaccine that was either manufactured directly in, or imported into, Australia from elsewhere by "GSK Australia"—an entity that has *not* been shown to be located in the U.S. *Id.* at 6–7. And Petitioner otherwise has not explained the nature of the relationship between GSK Australia and GSK, conflating the two summarily. *Id.* at 8.

More broadly, Respondent observes that the Act's creation of a cause of action effectively against the U.S. amounts to a limited waiver of sovereign immunity—an especially important consideration, given that the claim arises from a vaccine administered outside of U.S. borders. Reply at 9. But the Act was intended to ensure primarily that *U.S.-based vaccine manufacturers* would not be discouraged from vaccine production due to the threat of widespread tort liability *Id.* at 9–10. Thus, in establishing the Act Congress sought to guarantee adequate vaccination supplies *within* the U.S., as opposed to globally. *Id.* at 10, *citing McGowan v. Sec'y of Health & Hum. Servs.,* 31 Fed. Cl. 734, 739 n.1 (Fed. Cl. 1994) (*citing* 132 Cong. Rec. H30760 (daily ed. Oct. 14, 1986) (statement of Rep. Waxman) (noting that the aim "is to protect the adequacy of the Nation's supply of vaccines"); H.R. Rep. No. 908, 99th Cong., 2d Sess., at 7 (1986), U.S. Code Cong. & Admin. News 1986, p. 348 (House Report stating that the purpose was "to ensure that the Nation is able to maintain safe and reliable childhood vaccination programs")).

It was for this reason that the Act sets limits on claims brought by petitioners who have been vaccinated abroad. *McGowan,* 31 Fed. Cl. at 739. Indeed, Respondent stresses that the Act should not be applied extraterritorially, as the Court of Federal Claims recently emphasized. *Dupuch-Carron v. Sec'y of Health & Hum. Servs*., 144 Fed. Cl. 659, 666 (2019), *aff'd,* 969 F.3d 1318 (Fed. Cir. 2020). Also relevant, Respondent argues, is the fact that the excise tax applied to covered vaccines and used to create the "Vaccine Fund" (the source for all Program compensation awards) applies only to vaccines directly manufactured within, or imported to (for use within) the U.S. Reply at 11. All of these secondary factors support construing the disputed phrase to mean that claims involving vaccines administered extraterritorially to non-military personnel must involve vaccines attributable to manufacturers literally located in the U.S. *Id.* at 11–12. Were it otherwise, Respondent reasons, then vaccines not subjected to the excise tax, and/or having nothing to do with U.S. vaccine supply or production, could also be the basis for claims. *Id.* at 12.

ANALYSIS

Respondent's motion to dismiss involves construction of a subset of the Act's "Petition content" section. *See generally* Section 11(c)(1)(B)(i). That section details the circumstances in which vaccines administered outside the United States can still be the basis for a Program claim. Although disputes have arisen in the past about the proper construction of this subset of Section 11, never before have they involved the issue framed by Respondent herein, tending instead to pose questions relating to a claimant's military status, or what constitutes a "return" to the U.S. *Compare Dupuch-Carron*, 144 Fed. Cl. at 667 (construing the phrase "returned to the United States" against reading favored by claimant).

Section 11(c)(1)(B)(i) identifies three "administration location" bases for a Program claim. First, the Act allows claims by individuals who received a covered vaccine "in the United States or in its trust territories," setting no additional elements that must be met under such circumstances.

Section 11(c)(1)(B)(i)(I). This category obviously covers the majority of claimants—but not Ms. Horowitz herein. Second, Section 11 addresses circumstances where a claimant who is both a U.S. citizen[3] and "serving abroad as a member of the Armed Forces," or in some other governmental capacity, received the vaccine outside the U.S., permitting such individuals to pursue a Vaccine Act claim. Section 11(c)(1)(B)(i)(II). This subsection also is inapplicable, since Petitioner does not contend she was a member of the Armed Forces or some other kind of government employee.

This leaves Section 11(c)(1)(B)(i)(III). And only one aspect of it is disputed: whether the hep B vaccine Petitioner received was "manufactured by a vaccine manufacturer located in the United States," since (a) Petitioner *did* receive the vaccine outside the U.S., and (b) she returned to the U.S. within six months after the vaccine's administration.

As the Court noted in *Dupuch-Carron*, interpretation of a disputed term from the Act should begin with its plain words. *Dupuch-Carron,* 144 Fed. Cl. at 664–65 (*citing Lewis v. U.S.,* 445 U.S. 55, 60 (1980)); *Sebelius v. Cloer,* 569 U.S. 369, 376–77 (2013) (statutory terms should be construed in light of ordinary meaning). "No single word or phrase should be wrenched from its context and interpreted in a vacuum." *Dupuch-Carron,* 144 Fed. Cl. at 665. And the Federal Circuit has emphasized the importance of avoiding "absurd results" from statutory construction. *Dupuch-Carron,* 969 F.3d at 1330–31 (citations omitted). In addition, because the Act creates a basis for a claim against the United States, it "operates as a limited waiver of sovereign immunity," such that "its provisions must be given a 'strict and narrow construction.'" *Dupuch-Carron,* 144 Fed. Cl. at 665, *citing Grice v. U.S.,* 36 Fed. Cl. 114, 120 (1996). Thus, statutory ambiguities must be resolved in the Government's favor. *Holihan v. Sec'y of Health & Hum. Servs.,* 45 Fed. Cl. 201, 208 (1999).

The parties offer competing constructions of the disputed phrase, and many aspects of their arguments are reasonable. Supporting Petitioner's construction is the fact that the Table itself, which sets forth the vaccines deemed to be "covered" under the Program, does not differentiate between vaccines literally prepared or manufactured within the U.S. versus those abroad. Instead, it focuses mainly on vaccine *formulation,* and whether a vaccine is "covered" by the Program. *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). In addition, the Act elsewhere defines "manufacturer" in a manner that is more consistent with Petitioner's construction. Section 33(3). The fact that a manufacturer can, for example, "import" a vaccine for administration in the U.S. and still be covered by the Act suggests that the originating location of manufacture is less of a critical consideration.

It is also definitely the case that many covered vaccines commonly administered in the U.S. are produced and sold by multinational pharmaceutical companies, like GSK. While such entities clearly "do business" in the U.S. (and therefore could be said to be "located" here), they

[3] This citizenship requirement is not included in Section 11(c)(1)(B)(i)(III).

are not necessarily *headquartered,* or even centrally managed, here, sufficient to meet general jurisdiction requirements. *Daimler AG v. Bauman*, 571 U.S. 117, 127 (2014) ("a court may assert [general] jurisdiction over a foreign corporation "to hear any and all claims against [it]" only when the corporation's affiliations with the State in which suit is brought are so constant and pervasive "as to render [it] essentially at home in the forum State" (*citing Goodyear Dunlop Tires Operations, S.A. v. Brown,* 564 U.S. ——, 131 S. Ct. 2846, 2851 (2011))). But multinational pharmaceutical companies who manufacture vaccines *used in the U.S.* would be able to avail themselves of the Act's liability shield if sued for a vaccine-related injury in a U.S. court. *Amendola v. Sec'y of Health & Hum. Servs.*, 989 F.2d 1180, 1186 (Fed. Cir. 1993).

At the same time, there are other relevant considerations suggesting that vaccines administered abroad should be viewed differently—and that the Act's provisions that are the subject of the present dispute *require* this. Indeed, the disputed language relevant to non-military personnel who receive a vaccine abroad may have been *intended* by Congress to create additional requirements for bringing a claim. For this aspect of Section 11(c)(1)(B)(i)(III) differs materially from the language used for military personnel who receive vaccines abroad in Section 11(c)(1)(B)(i)(II). Military personnel, for example, are not required to return to the U.S. in a defined time period post-vaccination (consistent with the likelihood that they may be posted to a duty station outside the U.S. for a long timeframe). By contrast, regular, non-military citizens *must* return to the U.S. not long after vaccination. Given the foregoing, there is logic to interpreting the phrase "manufacturer located in the United States" to constitute a condition separate from what applies to military personnel.

Although *Dupuch-Carron* involved a different question (what constituted "return" to the U.S.), both the Court's decision and the Federal Circuit's affirmance include relevant dicta commenting on this statutory subsection and how it should be understood in light of the Act's policy underpinnings—and they support Respondent's construction.

The Court's *Dupuch-Carron* decision relied on an exploration of different aspects of the Vaccine Act, underscoring the Act's focus (intended and incidental) on the *domestic market* for vaccines. In particular, the Court shined a light on the excise tax used to create the Vaccine Fund. That tax is levied only against vaccines "manufactured or produced in the United States," or otherwise entering the United States for use or storage—but *not* vaccines sold/re-sold for export. *Dupuch-Carron,* 144 Fed. Cl. at 666 (*citing* 26 U.S.C. § 4132, 4131(a)(1)). And it emphasized that the Act was not intended to establish a cause of action available to foreign individuals who lacked a domestic nexus (meaning only persons "returning" to the U.S. after receiving a vaccination abroad could file a claim). *Dupuch-Carron,* 144 Fed. Cl. at 666. Thus, Section 11(c)(1)(B)(i)(III) has some underlying policy purposes that require stronger evidence of a U.S. connection when a vaccine has been received (by non-military personnel) extra-territorially.

The Federal Circuit's subsequent *Dupuch-Carron* affirmance does not expressly embrace, or even discuss, this aspect of the Court's reasoning. Yet throughout its decision the Circuit panel suggested that it too understood Section 11(c)(1)(B)(i)(III) as requiring proof of a *U.S. association* when a vaccine was administered abroad. For example, the Circuit noted that one of the Act's purposes was providing compensation to those injured after their participation in "childhood vaccination programs"—but that because those programs were the product of *domestic* legal mandates, "[a]llowing those living outside the United States . . . who were not injured in connection with the United States vaccination programs" would frustrate one of the Act's legislative purposes. *Dupuch-Carron,* 969 F.3d at 1332. Similarly, the second policy goal of the Act—"stabilizing the vaccine market"—was to be effected by shielding manufacturers against some vaccine-related civil actions. *Id.* But permitting foreign individuals who "were not injured in connection with the United States vaccination programs" to file a claim in the U.S. would undermine the protections the Act was intended to confer on the domestic vaccine market. *Id.* (Such individuals were, of course, not prevented from bringing suit "in foreign courts." *Id.*).

None of the above directly resolves how the contested phrase from Section 11(c)(1)(B)(i)(III) should be construed. But it suggests that there is purpose behind the phrase, and that the purpose has something to do with the Act's focus on claimants having some territorial nexus with the U.S. When a claimant has received a vaccine abroad (and thus cannot demonstrate that vaccination was the result of a domestic program or U.S. vaccine mandate), they must *nevertheless* prove (in addition to their own relationship to the U.S.—by "returning" in six months of vaccination) that the source of the vaccine was domestic in some fashion—both to ensure the Act's funding tax process has not been circumvented, but also so that only those manufacturing entities intended to benefit from the Program's civil liability protections do so. A foreign manufacturer who has not paid the excise tax, and otherwise has no U.S. territorial association, is not included in that group.

Taken all of the foregoing into consideration, I find that Petitioner has not demonstrated that she likely received a vaccine manufactured by a U.S.-based manufacturer. On the contrary, the existing record establishes that a GSK foreign subsidiary was responsible for the vaccine. And other than its corporate relationship to GSK generally, it has not been shown that GSK Australia can be deemed (for purposes of the Act) to be "located" here—such that it would have been charged the excise tax that fills the Vaccine Fund, and from which any damages might putatively be paid to Petitioner. Indeed, it has not even been demonstrated (despite due opportunity) *where* the version of the hep B vaccine that Petitioner received was manufactured, further diminishing my ability to conclude the vaccine's manufacturer was located domestically.

This provision of the Act is entitled to some meaningful construction—and it suggests a limitation on claims arising from vaccines administered abroad. Here, that limit prohibits further pursuit of this matter.

CONCLUSION

Respondent's motion to dismiss is GRANTED. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[4]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[4] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.