In the United States Court of Federal Claims

No. 20-313V
Filed[1]: January 11, 2021

ROSA SOTO GALVAN,

***Plaintiff*,**

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Keywords: National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012); Motion for Review; Arthrocentesis; Severity Requirement.

Kristina K. Green, Kralovec, Jambois, & Schwartz, Chicago, IL, for Plaintiff.

Mary E. Holmes, Trial Attorney, *Darryl R. Wishard,* Assistant Director, *Catherine E. Reeves,* Deputy Director, *C. Salvatore D'Allessio,* Acting Director, and *Ethan P. Davis,* Acting Assistant Attorney General, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Defendant.

MEMORANDUM OPINION AND ORDER

TAPP, Judge.

In this vaccine case, Petitioner, Rosa Soto Galvan ("Galvan"), petitioned for compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012) ("Vaccine Act"), alleging that she suffered complications following the administration of various vaccinations. (Compl., ECF No. 1). Regarding the Vaccine Act's severity requirement for remedies, Galvan alleged she experienced inpatient hospitalization and surgical intervention, specifically arthrocentesis—a procedure in which accumulated fluid is removed from a joint cavity by a needle. (*Id.* at 5). The Special Master reviewed Galvan's claim, ultimately concluding that Galvan "cannot meet the statutory severity requirements pursuant to

[1] This Order was originally filed under seal on December 17, 2020, (ECF No. 25). The Court provided parties the opportunity to review this opinion for any proprietary, confidential, or other protected information and submit proposed redactions no later than January 6, 2021. The parties did not file a status report indicating proposed redactions. In accordance with RCFC, App. B, Vaccine Rule 18(b)(2), "an objecting party must provide the court with a proposed redacted version of the decision. In the absence of an objection, the entire decision will be made public." Thus, the sealed and public versions of this Order are identical, except for the publication date and this footnote.

the Vaccine Act at § 300aa-11(c)(1)(D)" because "arthrocentesis, though an intervention, is not a surgical procedure." (*Galvan v. Sec'y of Health & Human Servs.*, No. 20-313V 2020 WL 4593163 (Fed. Cl. Spec. Mstr. July 6, 2020) at *1, *18, "Decision", ECF No. 20). Consequently, on July 6, 2020, the Special Master granted Respondent, the Secretary of Health and Human Services' ("the Secretary"), motion to dismiss pursuant to RCFC 12(b)(6).

On August 3, 2020, Galvan filed a Motion for Review, (ECF No. 22), before this Court arguing that the Special Master's legal conclusions and attendant factual findings should be set aside as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. (Pet.'s Mot. for Rev., ECF No. 22-1 at 20). The sole issue before the Court is whether the Special Master's conclusion is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B); RCFC, App. B, Vaccine Rule 27(b). As explained below, the Court finds that the Special Master's decision was not arbitrary, capricious, or otherwise not in accordance with law. Therefore, the Court **DENIES** Galvan's Motion for Review and **AFFIRMS** the Special Master's decision.

I. Background

On September 26, 2018, Galvan received vaccines for Hepatitis A, Hepatitis B, Influenza, and Pneumococcal Conjugate (PVC 13). (Compl. at 2). Within one hour of the administration of these vaccines, Galvan experienced abdominal pain and chills, and within four hours, she experienced headache, nausea, vomiting, dizziness, chest pain and tightness, and tachycardia. (*Id*. at 2). The same day, Galvan presented at and was admitted to the Emergency Department at MacNeal Hospital in Berwyn, Illinois, where she would remain hospitalized until October 1, 2018. (*Id*. at 2). Shortly after arrival, Galvan developed a fever and an abnormal rhythm of sinus tachycardia. (*Id.* at 2–3). Thereafter, Galvan experienced swelling in her right knee and effusion, along with redness and blistering on the right arm at the site of the vaccine injection. (Compl. at 3, Ex. 4 at 220). Upon intake, Galvan was diagnosed with "other complications following immunization, not elsewhere classified" and her discharge diagnosis was "post-vaccination fever." (*Id*. at 220, 222). During hospitalization, Galvan underwent arthrocentesis of her right knee, a procedure where a needle is injected into the knee to drain excess synovial fluid (*i.e.*, effusion), thereby reducing swelling and pressure contributing to pain. (Compl. at 3; *see* Compl., Ex. 4 at 220; Pet.'s Mot. for Rev. at 6). A rheumatologist performed the arthrocentesis. (Pet.'s Ex. 5 at 3, ECF No. 17-1).

Galvan petitioned for vaccine compensation on March 20, 2020, claiming that arthrocentesis constitutes a surgical procedure caused by her vaccine injury and that she was entitled to compensation under the Vaccine Act. (*See generally* Compl.). The Secretary moved for dismissal pursuant to RCFC 12(b)(6), arguing that Galvan's claim failed to satisfy the Vaccine Act's severity requirement. (Mot. to Dismiss, ECF No. 13). The Special Master found that arthrocentesis, though an intervention, is not a *surgical* intervention and granted the Secretary's Motion to Dismiss. (Decision at *1).

In 1986, Congress passed the Vaccine Act, establishing a program administered by the Secretary of Health and Human Services to increase the safety and availability of vaccines. 42 U.S.C. § 300aa-1; *Terran v. HHS*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). The Vaccine Act created the National Vaccine Injury Compensation Program, through which claimants could

petition for compensation due to alleged vaccine-related injuries or death. 42 U.S.C. § 300aa-10(a). Under the Vaccine Act, there are two methods by which a petitioner may demonstrate eligibility for an award. A petitioner may demonstrate with reliable medical evidence that an injury listed on the Vaccine Injury Table occurred within the requisite period or that an unlisted injury was caused-in-fact by a vaccine listed on the Table. 42 C.F.R. § 100.3; 42 U.S.C. § 300aa-11(c)(1)(C). In either instance, the Vaccine Act imposes a "severity requirement" on petitioners. A petitioner must prove that the individual experiencing the alleged vaccine-related injury:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

42 U.S.C. § 300aa-11(c)(1)(D) (severity requirement). The underlying Motion to Dismiss was predicated on whether Galvan met the requirement for "surgical intervention," as it applies to the severity requirement. To determine whether Galvan's arthrocentesis constitutes a "surgical intervention," the Special Master considered: (1) Galvan's "proffered evidence regarding the correct understanding of 'surgery;'" and (2) whether arthrocentesis should be considered surgical in light of prior Vaccine Program case law ("Program case law"), interpreting the relevant statutory language. (*Id*. at 11).[2]

Galvan cited the definition of "surgery" adopted by the American Medical Association ("AMA") based on a statement from the American College of Surgeons, which provides:

> **Surgery** is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. **Surgery** also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be **surgery** (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are

[2] The Special Master also addressed whether Galvan's arthrocentesis constituted an "intervention" and whether it was the result of her alleged vaccine reaction, finding that Galvan's arthrocentesis likely constituted an "intervention" but that additional evidence was necessary to determine whether the arthrocentesis was in treatment of her vaccine reaction. (Decision at 16–18). This issue is not before the Court.

> performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.
>
> Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of **surgery** are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

(Pet.'s Ex. 8, ECF No. 16-4) (emphasis added; bolding in original). Galvan further cited an article describing how knee arthrocentesis is performed.[3] (Halleh Akbarnia & Elise Zahn, *Knee Arthrocentesis*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (NCBI) BOOKSHELF, Feb. 10, 2020; Pet.'s Ex. 7, ECF No. 16-3). Drawing all inferences in favor of Galvan, and accepting the AMA definition and article, the Special Master concluded that arthrocentesis did not fall within any of the three AMA descriptions of what constitutes surgery. (Decision at *9).

In relevant part, the Special Master found that the inclusion of the specific term "needle" in the second description was not dispositive, as the description was "limited to the context of 'localized alteration or transposition of live human tissue.'" (*Id.* at *10). The Special Master also noted a distinction between drawing or removing fluid and injecting diagnostic and therapeutic substances and agreed with the Secretary that Galvan's proposed interpretation "fails to meaningfully distinguish between a surgical procedure and a routine blood draw[.]" (*Id.*). In response to Galvan's argument that penetration of the skin by a needle constitutes "manipulation of live tissue with an instrument," the Special Master explained that "the AMA definition does not discuss manipulation of tissue broadly . . . [r]ather, it discusses the specific procedure of manipulation by closed reduction of major dislocations or fractures." (*Id*. (internal quotations omitted)).

The Special Master determined that the AMA definition *as a whole* makes clear that arthrocentesis lacks the requisite gravity to constitute surgery, pointing to the AMA's statement that "[p]atients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards." (Decision at *11; Pet.'s Resp. Ex. 8 at 1). The Special Master highlighted that arthrocentesis may be performed by a healthcare worker who has knowledge of the anatomy of joints, thus it is distinguishable from the procedures included in the AMA definition that are reserved for execution by licensed physicians. (*Id.*).

After finding that arthrocentesis did not constitute "surgery" under the AMA definition, the Special Master analyzed prior Program case law that interpreted the term "surgical intervention" and reached the same conclusion. (*Id*. at *11–14). The Special Master considered

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[3] The article describes knee arthrocentesis as a procedure performed to aspirate synovial fluid from a joint cavity. (Pet.'s Ex. 7, at 1). Knee arthrocentesis can be performed by a clinician or other medical care professional or healthcare worker and typically does not require assistance. (*Id.*). The patient is placed in a comfortable position with the knee extended at 15–20 degrees and a local anesthetic is used. (*Id.*). Knee arthrocentesis is normally performed as an outpatient procedure. (*Id.*).

four prior Program decisions that address whether certain needle-based procedures performed during hospitalization constituted "surgical interventions" under the Vaccine Act. (*Id.* at *11–13 (citing *Stavridis v. Sec'y of Health & Human Servs.*, No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009); *Spooner v. Sec'y of Health & Human Servs.*, No. 12-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); *Ivanchuk v. Sec'y of Health & Human Servs.*, No. 15-357V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. Sept. 18, 2015); and *Leming v. Sec'y of Health & Human Servs.*, No. 18-232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019)).

Stavridis examined whether treatment with blood transfusion and intravenous steroids constituted surgical interventions. 2009 WL 3837479, at *2. Ultimately, the *Stavridis* Special Master rejected the petitioner's proposed broad definition, finding that classifying intravenous steroid injections or blood transfusions as surgical interventions would be overly inclusive. *Id.* at *6. In 2014, *Spooner* considered whether a lumbar puncture and intravenous immunoglobulin treatment were surgical interventions within the meaning of the Act. 2014 WL 504728, at *5. *Spooner* deemed "surgery" to mean "the treatment of an injury with instruments or by the hands of a surgeon." *Id.* at *11. Using that definition, the Special Master in *Spooner* concluded that neither a lumbar puncture nor intravenous immunoglobulin treatment constitutes surgical interventions, explaining that "[a]lthough the scope of the phrase 'surgical intervention' is broader than merely the surgery performed to correct intussusception, it is not so broad as to exceed the common meaning of its component terms in the medical community." *Id*. at *11. Applying the *Spooner* definition, *Ivanchuk* yielded a different result. *Ivanchuk*, 2015 WL 6157016. There, the Special Master concluded that bone marrow aspiration and biopsy were surgical interventions because, while not a treatment itself, it was performed as part of a protocol for administering steroid treatment. *Id.* at *2–3. The Special Master in *Leming* likewise agreed that a bone marrow biopsy constitutes a surgical intervention. 2019 WL 5290838.

Galvan argued that arthrocentesis is similar to both lumbar punctures and bone marrow aspiration and biopsy, which were found to be "surgical" in *Ivanchuk* and *Leming*. (Pet.'s Resp. at 13). Galvan further argued arthrocentesis is akin to these procedures because arthrocentesis, lumbar punctures, as well as bone marrow aspiration and biopsy involve a needle penetrating the cutaneous and subcutaneous tissue and some type of microbiologic analysis being performed after extraction. (*Id*. at 13). The Special Master disagreed, finding that the "key characteristic" of lumbar punctures and bone marrow aspirations is that they penetrate beyond the cutaneous and subcutaneous tissue. (Decision at *11). Further, the Special Master distinguished Galvan's arthrocentesis from the facts in *Ivanchuk* and *Leming* on the basis that MacNeal Hospital—where Galvan was treated—did not take steps to classify the arthrocentesis as "surgical," namely that arthrocentesis at MacNeal Hospital did not require general anesthesia, was conducted bedside rather than in an operating room, and did not require written consent. (*Id*.). The Special Master also relied on the fact that arthrocentesis does not require a physician at all and found the fact that a physician performed Galvan's procedure was not dispositive. (*Id*. at *13).

In addition, the Special Master partially relied upon the legislative history of the Vaccine Act's severity requirement, noting that the addition of surgical interventions in the statutory language was not intended to diminish the Vaccine Act's severity requirement and that any surgical intervention at issue should be understood as an equivalent stand-in for six months of sequela or residual effects. (*Id*. at *12 (citing *Stavridis*, 2009 WL 3837479 at *5–6; *Spooner*, 2014 WL 504728 at *11)). Galvan challenges these conclusions.

II. ANALYSIS

Under the Vaccine Act, the Court reviews a decision of the Special Master upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2) (2018). In reviewing such decisions, the Court may:

> (A) uphold the findings of fact and conclusions of law . . . , (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or, (C) remand the petition to the Special Master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)–(C). Findings of fact and discretionary rulings are reviewed under the arbitrary and capricious standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Dep't of Health and Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). This Court cannot "substitute its judgment for that of the Special Master merely because it might have reached a different conclusion." *Snyder v. Sec'y of Health and Human Servs.*, 88 Fed. Cl. 706, 718 (2009). Rather, "[r]eversal is appropriate only when the Special Master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Id.* Under this "highly deferential" standard, a Special Master's decision need only "articulate a rational connection between the facts found and the choice made" in order to be upheld. *Cucuras v. Sec'y of Dep't of Health and Human Servs.*, 26 Cl. Ct. 537, 541 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). As such, if the Special Master "has considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id.* at 541–42 (quoting *Hines ex rel. Sevior v. Sec'y of Dep't of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Galvan's Motion for Review raises three objections to the Special Master's decision. (Pet.'s Mot. for Rev. at 3). Namely, Galvan objects to the Special Master's application of the AMA definition, his analysis of case law, and the characterization of arthrocentesis as a nursing function. (*Id.*). Galvan requests that "this Court set aside the Special Master's legal conclusion that Petitioner's arthrocentesis was not a surgical procedure and attendant factual findings and issue its own finding that Petitioner's arthrocentesis was in fact surgical within the meaning of Vaccine Act, . . .[and] reinstate the Petition for further proceedings." (*Id.* at 20). In the alternative, Galvan requests that "this Court set aside the Special Master's legal conclusion that Galvan's arthrocentesis is not a surgical procedure and attendant factual findings," reinstate the Petition and remand this matter back to the Special Master for an opportunity to obtain an expert medical opinion as to whether arthrocentesis is surgical in nature. (*Id*. at 20–21). The Court will address Galvan's arguments in turn.

Principally, Galvan argues that the Special Master erred by "mischaracterizing" the "precedent" in prior Program cases. (Pet.'s Mot. for Rev. at 3–4, 9–12). Galvan further asserts that the Special Master's decision is contrary to the plain meaning of the statutory language and, in effect, creates new limitations and conditions on the severity requirement that the legislature did not intend to create. (*Id.* at 4). That assertion is incorrect. Citing *Stavridis* and *Spooner*, the Special Master determined that "the addition of surgical interventions in the statutory language

was not intended to diminish the [severity requirement] and that any surgical intervention at issue should be understood as an equivalent stand-in for six months of sequela or residual effects." (Decision at *12 (citing prior Program cases)). Galvan argues that this statement creates an incorrect bright-line rule that surgical interventions "which are minor, low-risk, minimally invasive or relatively simple are insufficient to satisfy the [severity requirement]," and that this proposition is both unsupported by case law and the plain meaning of the Vaccine Act statutory language. (Pet.'s Mot. for Rev. at 10). (*Id.*).[4]

In reaching his conclusion, the Special Master relied upon Program case law, the surrounding statutory language, and legislative history of the Vaccine Act in concluding that arthrocentesis did not satisfy the Vaccine Act's severity requirement. Though prior Program case law is not binding upon Special Masters, it may be used as an analytical tool. Other Special Masters have followed this framework in interpreting the severity requirement. (Decision at *11 (citing *Stavridis*, 2009 WL 3837479; *Spooner*, 2014 WL 504728)). Further, the statute must be interpreted as a unified whole. *See Spooner*, 2014 WL 504728, at *10 (citing *Saunders v. HHS,* 25 F.3d 1031, 1035 (Fed. Cir. 1994) ("[I]t is a settled rule of statutory interpretation that a statute is to be construed in a way which gives meaning and effect to all of its parts.) "It is a principle of statutory interpretation . . . that a court should seek to avoid construing a statute in a way which yields an absurd result and should try to construe a statute in a way which is consistent with the intent of Congress." *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1570–71 (Fed. Cir. 1993). Following that logic, prior Program case law has held that "a court should 'construe a statute in a way which is consistent with the intent of Congress,' [thus] it is also appropriate to consider the Act's legislative history." *Spooner*, 2014 WL 504728, at *10 (quoting *Hellebrand*, 999 F.2d at 1570–71). Galvan presents no reason why this framework, followed by other Special Masters in analyzing an issue similar to that presented here, is contrary to law.

Following this analysis, the Special Master correctly considered case law and the Vaccine Act's legislative history. The Special Master concluded that Galvan's proposed definition of "surgical" did not comport with the section of the statute where the term appears. (Decision at *12). This argument is facially inconsistent with other provisions of the statute and was properly rejected by the Special Master through his analysis of *Spooner* and *Stavridis*. (*Id.* ("[B]oth *Stavridis* and *Spooner* [explain] that the addition of surgical interventions in the statutory language was not intended to diminish the Vaccine Act's severity requirement and that any surgical intervention at issue should be understood as an equivalent stand-in for six months of sequela or residual effects.")). The Special Master appropriately considered petitioner's knee arthrocentesis in the context of 42 U.S.C. § 300aa-11(c)(1)(D) as a whole and concluded the severity requirement was not met, and it cannot be said that this conclusion is arbitrary, capricious, or otherwise not in accordance with the law.

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[4] Galvan points to *Leming*, where the Special Master refused to consider the legislative history of the severity requirement. *Leming v. Sec'y of Health & Human Servs.*, No. 18-232V, 2019 WL 5290838 at *6 (Fed. Cl. Spec. Mstr. July 12, 2019). As previously noted, prior Program cases are not binding on Special Masters, thus the Special Master's analysis in *Leming* is not dispositive. *See Hanlon*, 40 Fed. Cl. at 630.

In reference to the Special Master's finding that arthrocentesis did not fit any of the three AMA descriptions of "surgery," (Decision at *9–12), Galvan presents two arguments to the contrary. (Pet.'s Mot. for Rev. at 13–14). First, Galvan argues that the Special Master's interpretation of the AMA definition is too narrow. (*Id*. at 14). Galvan posits that the AMA definition discusses the manipulation of tissue more broadly, including both the manipulation of tissue "by closed reduction for major dislocations . . ." or "otherwise altered by mechanical . . . means." (*Id*. at 14). Second, Galvan argues that the alteration of tissue in arthrocentesis is more extensive than the Special Master considered. (*Id.*). Galvan explains that the needle utilized during arthrocentesis does not merely penetrate the skin and remove bodily fluid, but also penetrates the tissue, joint cavity, and synovial membrane. (*Id.*). Thus, Galvan argues that the Special Master's finding that arthrocentesis does not fit the AMA definition should be set aside. Because the Vaccine Act does not define "surgical intervention," standard medical definitions are informative as to the meaning of Section 11(c)(1)(D)(iii). *See Spooner*, 2014 WL 504728 at *10 (citing *Abbot v. Sec'y of Health & Human Servs.*, No. 93-5129V, 19 F.3d 39, slip. op. at *6 (Fed. Cir. 1994)). The Special Master accepted Galvan's proposed AMA definition and thoroughly detailed his conclusion that arthrocentesis did not fit within that definition. (Decision at *9–12). The Special Master accepted and analyzed whether arthrocentesis is "surgical" in the context of the AMA definition but ultimately relied upon case law, the surrounding statutory language, and the legislative history of the Vaccine Act. (*See id*.). Special masters may consider definitions from other sources, such as the AMA, but they are not bound to apply them. Medical dictionary definitions are informative, but the relevant statutory language is controlling on term interpretation. *Hellebrand*, 999 F.2d at 1570–71 (citing *Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940)). Galvan's arguments to this point have not presented any reason to abandon this fundamental principle. Here, the Special Master considered the AMA definition of arthrocentesis but ultimately found the procedure did not satisfy the severity requirement. (Decision at *9–12). Although Galvan disagrees with the Special Master's analysis, it is supported by substantial evidence and not contrary to law, thus the Court will not substitute its own judgment for that of the Special Master. *Snyder*, 88 Fed. Cl. at 718.

Lastly, in an effort to argue that arthrocentesis is not a nursing function akin to blood draws, Galvan points to various medical articles that indicate arthrocentesis cannot be performed by *any healthcare worker*, as suggested by the Special Master's decision. (Pet.'s Mot. for Rev. at 15–20). Specifically, Galvan objects to the Special Master's finding that "there are no distinctions between Petitioner's knee arthrocentesis and IVIG treatment, blood transfusions or blood draws[.]" (Pet.'s Mot. for Rev. at 15–20; Decision at *10). Galvan asserts that these findings were merely an adoption of the Respondent's lay arguments and were not reasonably based on medical opinion. (Pet.'s Mot. for Rev. at 3–4, 15–20). The United States argues that the Decision did not rest solely upon the identity or qualifications of persons able to perform arthrocentesis. (Respondent's Resp. at 12). The Court finds that this argument mischaracterizes the Special Master's findings and ultimately agrees with the Secretary. The underlying decision states, "the mere fact that petitioner's arthrocentesis was performed in this instance by a physician does not alter the overall character of the procedure as one that is so low-risk and minimally invasive as to not necessarily require a physician." (Decision at *13). This statement indicates that the identity of the person performing the procedure was ancillary to the character of the procedure itself. In reference to the character of the procedure, the Special Master accepted Galvan's proffered AMA definition and after careful analysis, found that arthrocentesis did not fit any of the three descriptions, showing that the Special Master conducted a detailed

review of the AMA definition as a whole as well as considering the three discrete definitions of surgery. (*Id.* at *9–12). As such, the identity of the person who performs the arthrocentesis, while it was considered, was merely a single element in a host of other factors considered by the Special Master and not dispositive to the decision. Based on the foregoing, the evidence presented in Galvan's Motion for Review regarding the qualifications needed to perform arthrocentesis does not constitute grounds for reversal.

As an alternative, Galvan summarily requests a remand to present expert testimony on whether her procedure was "surgical." (Pet.'s Mot. for Rev. at 20). Galvan's argument is largely predicated on *Stavridis* where the Special Master relied on the unrebutted medical testimony from the respondent's expert who testified that blood transfusions and intravenous delivery of medications are considered non-operative. (*Id.* (citing 2009 WL 3837479, at *5)). The Secretary disagrees that *Stavridis* stands for the premise that expert testimony is necessary when considering surgical intervention and argues that courts may reasonably use resources such as medical dictionaries and treating physician records to determine whether a procedure is "surgical." (Respondent's Resp. at 14).

The Court of Federal Claims may remand a vaccine case to the Special Master "for further development of the evidentiary record, as well as additional fact-finding." *See Hokkanen v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 300, 302 (2010); 42 U.S.C. § 300aa–12(e)(2). In keeping with the "inquisitorial format" of Vaccine Program proceedings, Special Masters exercise unique control over the evidence to be adduced and considered. *Snyder ex rel. Snyder*, 88 Fed. Cl. at 738 (citing H.R.Rep. No. 101-386, at 87). This Court sees no need for additional proceedings in this case, as the Special Master was perfectly capable of gatekeeping and consideration of evidence before him. Before the Special Master were Primary Care Associates records (Compl., Ex. 1), an Affidavit by Galvan (Compl., Ex. 2), Jen Care Senior Center records (Compl., Ex 3), and MacNeal Hospital records (Compl., Ex. 4), totaling 929 pages of records. In reference to the Secretary's Motion to Dismiss, Galvan produced 91 pages of additional exhibits. (*See* Pet.'s Ex. 5–16, ECF Nos. 16, 21). The development of a more profuse record is unlikely to alter the result of the Special Master's findings. Thus, remand for the admittance of expert testimony would be futile. The Court finds that the record before Special Master was appropriate to make the requisite findings of fact and conclusions of law and prepare its decision dismissing Galvan's petition. As such, remand is unwarranted.

III. Conclusion

Based on the foregoing, the Court finds that the Special Master considered the relevant evidence of record, drew plausible inferences, and articulated a rational basis for the decision. the Special Master's July 6, 2020 decision was not arbitrary, capricious, an abuse of discretion, or contrary to law. Thus, the Court hereby **DENIES** Galvan's Motion for Review, (ECF No. 22), and **AFFIRMS** the Special Master's July 6, 2020 decision. The Clerk is directed to enter judgment accordingly.

The Court has filed this ruling under seal. The parties shall confer to determine proposed redactions to which all the parties agree. Per Vaccine Rule 18(b), no later than January 4, 2021, the parties shall file a joint status report indicating their agreement with the proposed redactions,

attaching a copy of those pages of the Court's ruling containing proposed redactions, with all proposed redactions clearly indicated.

IT IS SO ORDERED.

s/ David A. Tapp
DAVID A. TAPP, Judge