In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-313V
Filed: July 6, 2020
PUBLISHED

ROSA SOTO GALVAN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Dismissal; Motion to Dismiss; Severity Requirement; Surgical Intervention; Arthrocentesis

Kristina Kay Green, Kravolec, Jambois & Schwartz, Chicago, IL, for petitioner.
Mary Eileen Holmes, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On March 20, 2020, petitioner, Rosa Soto Galvan, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012)[2], alleging that she suffered anaphylaxis and related complications, including serum sickness-like syndrome, following administration of hepatitis A, hepatitis B, influenza, and pneumococcal conjugate vaccinations on September 26, 2018. (ECF No. 1, p. 1.) To satisfy the Vaccine Act's severity requirement (§300aa-11(c)(1)(D)), petitioner alleged that she experienced inpatient hospitalization and surgical intervention, specifically arthrocentesis of her right knee, a procedure in which accumulated fluid is removed from a joint cavity by needle. (ECF No. 1, p. 5.) Respondent now moves to dismiss, arguing that petitioner's arthrocentesis was not related to her alleged vaccine reaction and does not constitute a surgical intervention within the meaning of the Vaccine Act. For all the reasons discussed below, I conclude that petitioner's arthrocentesis, though an intervention, is not a surgical procedure. Accordingly, respondent's motion is granted and this petition is dismissed.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Hereinafter, all references to "§300aa" refer to sections of the Vaccine Act.

I. Procedural History

As noted above, this case was filed on March 20, 2020. (ECF No. 1.) Along with her petition, petitioner filed medical records and an affidavit marked as Exhibits 1-4. She filed a Statement of Completion on March 25, 2020. (ECF No. 8.) Following a Pre-Assignment Review ("PAR"), the case was assigned to me on April 13, 2020. (ECF Nos. 9-10.)

On May 12, 2020, respondent filed his motion to dismiss pursuant to RCFC 12(b)(6). (ECF No. 13.) He indicated that "[f]ollowing a review of the records, respondent has determined that petitioner's claim does not satisfy the Vaccine Act severity requirement . . . [and] the petition must be dismissed for failure to state a claim upon which relief may be granted, pursuant to RCFC 12(b)(6)." (*Id.* at 1)

Petitioner filed a response to the motion on June 3, 2020. (ECF No. 15.) In her response, petitioner explained that "[a]s petitioner does not contend or allege her vaccine injury symptoms persisted for more than six months, and respondent does not dispute petitioner required inpatient hospitalization for her vaccine injury, the only issues to be decided are: (1) whether petitioner's right knee arthrocentesis was performed as a result of her vaccine injury; and (2) whether petitioner's right knee arthrocentesis constitutes surgical intervention within the meaning of the Vaccine Act." (*Id.* at 3.)

Along with her response, petitioner filed additional exhibits marked as Exhibits 5-8. (ECF Nos. 15-16.) These exhibits include an affidavit by petitioner's adult son accompanied by photographs of petitioner's arthrocentesis procedure being performed (Ex. 5),[3] as well as internet-sourced materials defining serum sickness, surgery, and arthrocentesis (Exs. 6-8).

Respondent filed his reply on June 9, 2020. (ECF No. 18.) This issue is now ripe for resolution.

II. Factual History

On September 26, 2018, petitioner received hepatitis A, hepatitis B, influenza, and pneumococcal vaccinations from her primary care doctor. (Ex. 1, p. 62.) Petitioner avers that she was previously in good health; however, relevant to respondent's motion, she did have a history of osteoarthritis. (Ex. 2, p. 2; Ex. 4, p. 220.) Later that day, she reportedly developed nausea, vomiting, abdominal pain, chest pain, headache and dizziness. (Ex. 4, p. 247.) She also developed swelling of the right hand, dorsum, and joints of the right hand and right knee. (*Id.* at 220.) She developed a right knee effusion and a cellulitis of the right forearm. (*Id.*)

[3] Initially petitioner filed an unsigned copy of the affidavit marked as Exhibit 5. (ECF No. 16-1.) Subsequently, a signed copy was filed as "Amended Exhibit 5." (ECF No. 17-1.) For purposes of this decision, the unsigned affidavit will not be referenced and the executed affidavit will be referenced as Exhibit 5.

Petitioner was hospitalized from September 26 to October 1. (*Id*. at 220.) Her intake diagnosis was "other complications following immunization, not elsewhere classified" and her discharge diagnosis was "post vaccination fever." (*Id*. at 220, 222.) However, she also had 23 secondary diagnoses considered during her hospitalization. (*Id*. at 219.) Petitioner was discharged with instructions to follow up with her primary care physician. (Ex. 4, p. 221.) That primary care physician in turn recorded a history of "serum sickness-like reaction" and recorded an impression of "adverse reaction to mixed bacteria vaccine." (Ex. 1, pp. 33, 35.) However, it was noted that petitioner "feels better and right shoulder is healing." (*Id*. at 33.) She does not contend that she experienced residual effects lasting six months. (ECF No. 15, p. 3.)

During her hospitalization, petitioner was observed to have had right knee swelling and pain significant enough that she could not bend her right knee. (Ex. 4, p. 52.) This was specifically identified as a "right knee effusion" and rheumatology was consulted. (*Id*. at 53.) The reason for that rheumatology consult was "painful swollen joint" and the assessment/plan indicated "[p]ainful swollen joint, possible septic arthritis versus inflammatory arthritis versus crystal arthropathy. I will perform arthrocentesis of the right knee." (*Id*. at 249-50.) The records indicate that 30ml of fluid was removed from petitioner's knee. (*Id*. at 250.)

Petitioner confirms that the procedure was done bedside and that only oral consent was obtained. (ECF No. 15, p. 13, n.3.) Petitioner filed an affidavit by her adult son that included photographs of petitioner's arthrocentesis being performed. (Ex. 5.) The photographs show petitioner gowned and laying supine in a hospital bed without guardrails with her legs fully extended and somewhat spread. Petitioner's rheumatologist, dressed in plain clothes and not surgical scrubs, reached over petitioner's left leg to reach her right leg. A needle of indeterminate size was inserted into petitioner's joint and two syringes of fluid were extracted. (*Id.*) Petitioner described the arthrocentesis procedure as painful (Ex. 2, p. 1); however, Dr. Syed W. Rizvi indicated that petitioner tolerated the procedure well and no further follow up was recorded. (Ex. 4, p. 250.) Petitioner's discharge summary indicates that her right knee joint effusion had resolved by the time of discharge. (Ex. 4, p. 220.)

III. The Vaccine Act Severity Requirement and Surgical Intervention

In order to state a claim for a vaccine-related injury under the Vaccine Act, a vaccinee must have either:

> (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.

§300aa-11(c)(1)(D).

There is no definition of "surgical intervention" within the Vaccine Act. *See* §300aa-33 (Definitions). Nor is there any Federal Circuit decision interpreting that term. As described in prior decisions by special masters, the "surgical intervention" language was added to the Vaccine Act in the year 2000 to allow for recovery for intussusception, which is an intestinal prolapse that is often severe enough to require surgery but which typically does not include significant residual effects after surgery. *See, e.g.*, *Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); *Stavridis v. Sec'y of Health & Human Servs.,* No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009).

The first case to address in detail the meaning of "surgical intervention" within the context of the Vaccine Act was *Stavridis v. Secretary of Health & Human Services*.[4] 2009 WL 3837479. In that case, petitioner argued that treatment with intravenous steroids and blood transfusions constituted surgical interventions. *Id.* at *2. Petitioner urged application of combined dictionary definitions of surgical and intervention respectively. *Id.* at *4. Specifically, petitioner contended that a "surgery," akin to an "operation," is defined as "any methodical action of the hand, or of the hand with instruments, on the human body, to produce a curative or remedial effect, as in amputation, etc." while an intervention is "the act or fact of interfering so as to modify." *Id.* at n.8.

However, the *Stavridis* special master was concerned that "[i]f petitioner's cobbled-together definition were accepted, it seems a great number of minor procedures would qualify as surgical intervention." *Id.* at *4. Moreover, respondent provided evidence from a hematologist explaining that blood transfusions and intravenous delivery of medications are considered non-operative by the International Classification of Disease. *Id.* at *5.

Ultimately, the *Stavridis* special master rejected petitioner's proposed definition, stressing that the addition of the surgical intervention language into the Vaccine Act was meant to allow additional serious injuries to be compensated, not to diminish the severity requirement itself. *Id.* at *5. He found that "petitioner's definition casts too wide a net even though it is taken from a medical dictionary." *Id.* at *6. Moreover, he rejected the specific contention that either intravenous steroid injections or blood transfusions represent surgical interventions. He further explained:

> It is foreseeable that numerous cases will present before this court, challenging the breadth of procedures that constitute "surgical intervention." One can imagine a potentially large gray area between treatments that are definitively considered "surgical intervention" and those that are not.

[4] In a prior case, a petitioner was found entitled to compensation based in part on the idea that a lumbar puncture constituted a surgical intervention, but the meaning of surgical intervention was not actually analyzed. *Hocraffer v. Sec'y of Health & Human Servs*., 63 Fed. Cl. 765 (2005). The Court requested supplemental briefs addressing that very question; however, respondent did not object to petitioner's characterization of a lumbar puncture as constituting a surgical intervention and the issue was therefore treated as conceded. *Id.* at n.4.

> Support from medical treatises or doctors will be needed to determine the appropriate boundaries of what constitutes surgical intervention.

Id. at *6.

Subsequently, in 2014, the definition of "surgical intervention" was again examined in *Spooner v. Secretary of Health & Human Services*. 2014 WL 504728. In *Spooner*, petitioner contended that a lumbar puncture[5] and IVIG[6] treatment were surgical interventions within the meaning of the Vaccine Act. *Id*. at *4-5. As in *Stavridis*, the petitioner urged a broad, dictionary-based definition combining the respective definitions of surgery and intervention. *Id*. at *8. Specifically, the petitioner urged the special master to consider a surgery "[a] procedure to remove or repair part of the body or to find out whether disease is present" and an intervention "a treatment or action taken to prevent or treat disease, or improve health in other ways." *Id*.

As in *Stavridis*, the special master considered the fact that the legislative history showed intussusception to be the specific injury for which the Vaccine Act's severity requirement was amended; however, he also stressed that the language of the amendment was not limited to surgeries to correct intussusception. *Id*. at *11. Citing prior Federal Circuit cases that allowed for the use of medical dictionaries to define medical terms, he also explored such definitions.[7] *Id*. at *10 (citing *Abbott v. Sec'y of Health & Human Servs.*, No. 93-5129V, 19 F.3d 39, slip op. at *6 (Fed. Cir. 1994). He ultimately concluded that:

> Congress indicated that, for an injury to be compensable, it must meet a severity threshold. In amending the Act to include the "inpatient hospitalization and surgical intervention" alternative, Congress indicated that certain medical procedures are so traumatic as to serve as a suitable statutory proxy for a serious injury equivalent to more than six months of pain and suffering. An intervention of the magnitude contemplated by

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[5] A "lumbar puncture," also known as a "spinal tap," is "the withdrawal of fluid from the subarachnoid space in the lumbar region, usually between the third and fourth lumbar vertebrae, for diagnostic or therapeutic purposes. *Dorland's Illustrated Medical Dictionary*, p. 1532, 1842 (33rd ed. 2019).

[6] "IVIG" stands for intravenous immunoglobulin. Neil M. Davis, *Medical Abbreviations*, p. 317.

[7] Specifically, the special master explained that at the time the Vaccine Act was amended, the 29th Edition of Dorland's Medical Dictionary defined "surgical" as "the branch of medicine that treats diseases, injuries, and deformities by manual or operative methods." He noted the 27th edition of Stedman's Medical Dictionary then in publication provided a nearly identical definition. *Spooner,* 2014 WL 504728, at *10. "Operative methods," in turn, are defined as "any act performed with instruments or by the hands of a surgeon." Using the same sources, the special master noted that "intervention" is defined by Dorland's 29th edition as either "the act or fact of interfering so as to modify" or "specifically, any measure whose purpose is to improve health or to alter the course of a disease." Stedman's 27th Edition defines intervention as "an action or ministration that produces an effect or that is intended to alter the course of a pathological process." *Id*. Accordingly, the special master concluded the definition of "surgical intervention" is "the treatment of a disease, injury, and deformity with instruments or by the hands of a surgeon to improve health or alter the course of a disease." *Id*.

Congress and akin to that undertaken to treat severe cases of intussusception is consistent with the definition of "surgery" as the treatment of an injury with instruments or by the hands of a surgeon.

Id. at *11.

In applying that definition, however, the special master in *Spooner* concluded that neither a lumbar puncture nor IVIG treatment constitute surgical interventions. He explained 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.*

With regard to lumbar punctures, the special master explained that such procedures are not always performed by a surgeon and may not be performed under general anesthesia; however, when performed under general anesthesia in an operating room, he concluded that a lumbar puncture is surgical in nature. *Id*. at *11-12. Nonetheless, because lumbar punctures are generally considered diagnostic, he concluded that they do not improve or alter the course of a disease or condition and therefore are not "interventions." *Id*. at *12.

Conversely, the special master concluded that IVIG treatments are interventions because they have a curative or therapeutic purpose and effect. *Id*. at *12. However, unlike the lumbar puncture, IVIG treatments are a nursing function and are therefore not surgical. *Id*. The special master stressed that in amending the severity requirement, the legislative history showed that Congress distinguished between intussusceptions reduced by surgery under general anesthesia and those reduced by other, less invasive means, such as hydrostatic or pneumatic reductions which are not performed with general anesthesia. He concluded that IVIG, as an intravenous treatment, was more akin to the less severe type of intussusception treatment that was not included in the newly amended statutory language.[8] *Id*.

Subsequent decisions by other special masters have followed the definition of "surgical intervention" described in *Spooner* and reached different results based upon the fact pattern. In *Uetz v. Secretary of Health & Human Services*, the parties again presented the question of whether a lumbar puncture constitutes a surgical intervention; however, because the procedure was conducted on an out-patient basis, the special master did not determine whether a surgical intervention occurred. No. 14-29V, 2014 WL 7139803 (Fed. Cl. Spec. Mstr. Nov. 21, 2014). In *Ivanchuk v. Secretary of Health & Human Services*, the special master concluded that a bone marrow aspiration[9] and

[8] Notably, special masters have repeatedly held that barium enemas to reduce intussusceptions do not constitute surgical interventions. *E.g.*, *Green v. Sec'y of Health & Human Servs*., No. 19-1295V, 2020 WL 1845325 (Fed. Cl. Spec. Mstr. Mar. 18, 2020); *Carda v. Sec'y of Health & Human Servs.*, No. 14-191V, 2017 WL 6887368 (Fed. Cl. Spec. Mstr. Nov. 16, 2017).

[9] A bone marrow biopsy or aspiration is a procedure in which the bone is punctured with a needle attached to a syringe to remove soft bone marrow tissue for testing. *Aspiration biopsy,* DORLAND'S

biopsy *did* constitute a surgical intervention consistent with the *Spooner* definition. No. 15-357V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. Sept. 18, 2015). As in *Spooner*, the special master stressed that the procedure occurred in accordance with hospital policies for a surgical procedure (written consent, post-operative recovery) and occurred under general anesthesia. In contrast to *Spooner*, the special master concluded the bone marrow aspiration and biopsy at issue was an intervention, because, while not a treatment itself, it was performed as part of a protocol for administering steroid treatment. *Id.* at *2-3.

Most recently, in *Leming v. Secretary of Health & Human Services*, a second decision issued that followed *Ivanchuk* in determining that a bone marrow biopsy constitutes a surgical intervention. No. 18-232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019). As in *Ivanchuk*, the *Leming* child was placed under general anesthesia and the hospital followed surgical protocols including consent and post-op recovery. *Id.* at *6. Notably, that decision rejected respondent's invitation to examine the Congressional intent behind the "surgical intervention" amendment. Rather, the special master concluded that she "does not agree that the statutory language is sufficiently ambiguous to allow consideration of Congressional intent." *Id.* at *6. The special master noted that the prior *Spooner* decision did examine legislative intent, but also found the *Spooner* definition persuasive based on the fact that "surgical intervention" is adequately defined by the appropriate discipline. *Id.*

IV. Party Contentions

a. Respondent's Motion

As a starting point, respondent notes that petitioner's medical records do not reflect six months of residual symptoms following her alleged vaccine reaction. Accordingly, the question of whether petitioner experienced "inpatient hospitalization and surgical intervention" as pleaded by petitioner (arthrocentesis) is dispositive. (ECF No. 13, p. 6, n.2.) Respondent does not dispute that petitioner experienced inpatient hospitalization but does dispute that arthrocentesis constitutes a surgical intervention. (*Id.*)

Regarding petitioner's arthrocentesis, respondent cites approvingly to the above-discussed *Spooner* decision, arguing that "[t]he insertion of a needle, in and of itself, is not considered 'surgical.'" (*Id.* at 7.) Respondent notes that the procedure did not involve general anesthesia, was conducted bedside rather than in an operating room, and the medical records contain no consent forms. In sum, respondent argues that "[t]he hospital did not treat this procedure as if it were surgical," a point which respondent indicates was stressed in *Spooner*. (*Id.* at 8.)

MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=60555 (last visited July 2, 2020).

Noting that arthrocentesis can be either diagnostic or therapeutic, respondent also disputes that petitioner's procedure was an intervention. Respondent explains that in petitioner's own case, her medical records reflect that the procedure was performed to rule out septic arthritis and was therefore diagnostic and did not alter the overall course of her alleged injury. (*Id.* at 8.)

Finally, respondent also disputes that petitioner's arthrocentesis was related to the serum sickness-like syndrome that forms the basis of her petition. (*Id.* at 8-9.) Respondent contends that petitioner's medical records reflect her joint swelling to have been related to osteoarthritis and none of petitioner's treating physicians attributed her joint swelling to the possible vaccine reaction for which she was hospitalized.[10] (*Id.* at 9.)

b. Petitioner's Response

In her response, petitioner confirmed that she does not allege her injury to have persisted for more than six months and that she agrees that the question of whether she had a surgical intervention is at issue. (ECF No. 15, p. 3.) Petitioner argues that, when her medical record is considered as a whole, it is evident that her arthrocentesis was performed in connection with her alleged vaccine reaction. (*Id.* at 9-11.)

Petitioner approves of the *Spooner* decision's reliance on medical dictionaries to define "surgical intervention," but proposes a different, more detailed definition as instructive based on a definition of "surgery" proposed by a statement from the American College of Surgeons subsequently adopted by the American Medical Association ("AMA"), which is discussed in detail further below. (*Id.* at 12 (citing Ex. 8).)

Petitioner argues that the finding in *Spooner* that a lumbar puncture was surgical, as well as the findings in both *Leming* and *Ivanchuk* that bone marrow aspiration and biopsy were surgical interventions, support petitioner's position that arthrocentesis is a surgical intervention. (*Id.* at 13.) Specifically, "[p]etitioner's right knee arthrocentesis is very similar to both lumbar puncture and bone marrow aspiration and biopsy in that all three procedures involve puncturing or penetrating the cutaneous and subcutaneous tissue with a needle by a physician; removal, draining or aspiration of bodily fluid, and typically some type of microbiologic analysis of the fluid extracted." (*Id.*)

Petitioner acknowledges the distinctions raised by respondent – petitioner had local instead of general anesthesia, her procedure was conducted bedside rather than in an operating room, and consent was obtained only orally. (*Id.*) However, petitioner argues that none of these factors are contained in the statutory language, the definition followed by *Spooner*, or petitioner's preferred definition by the AMA, "because they are not defining characteristics of surgery." (*Id.* at 14.) Petitioner argues that a finding that

[10] Respondent also argues that this petition lacks a reasonable basis. (ECF No. 13, pp. 9-10.) However, in the absence of any application for attorneys' fees and costs, I am not reaching that question at this time.

petitioner's arthrocentesis does not constitute a surgery based on these factors "would be inserting requirements not present in the statutory language itself or any of the definitions of surgery discussed above." (*Id.* at 15.)

With regard to whether arthrocentesis constitutes an intervention, petitioner agrees with respondent that the procedure can be both diagnostic and therapeutic. (*Id.*) Petitioner stresses, however, that 30 ml of fluid was extracted from petitioner's knee whereas only 3 ml of fluid was required for the laboratory analysis. Accordingly, petitioner argues that it is "nonsensical" to argue that such a substantial amount of excess fluid was drained for no medical purpose and without any therapeutic effect. (*Id.* at 15-16.) Moreover, petitioner argues that draining an effusion necessarily constitutes an intervention because it altered the course of petitioner's condition. (*Id.* at 16.)

c. Respondent's Reply

In his reply, respondent contends that petitioner is proposing a "novel" interpretation of surgical intervention. (ECF No. 18, p. 1.) Respondent argues that petitioner's proposed interpretation of surgical intervention "would broaden the Act's narrow waiver of sovereign immunity to a point of absurdity." (*Id.* at 7.) Specifically, respondent contends that "petitioner's arthrocentesis procedure lacks the traumatic aspect necessary to serve as a proxy for six months of pain and suffering" and, moreover, that since the severity requirement constitutes a waiver of sovereign immunity, it must be construed narrowly. (*Id.* at 10.) Respondent notes, for example, that petitioner's proposed interpretation would fail to distinguish between a surgical intervention and a routine blood draw. (*Id.* at 11.)

Respondent also argues that petitioner misconstrues the prior precedents of *Spooner*, *Leming* and *Ivanchuk*. Respondent stresses that these prior decisions "based their finding of whether a surgery occurred from the perspective of the hospital performing the surgery," explaining that in those prior cases the hospital "took notable steps to classify the questioned procedure as a surgery" and respondent "argues that the hospital is in the best position to define a surgery." (*Id.* at 8.)

Respondent also reiterated his position that petitioner's arthrocentesis does not constitute an intervention. Additionally, he explained further why he does not believe petitioner's arthrocentesis was performed in treatment of her alleged vaccine injury. (*Id.* at 2-6.)

V. Applicable Legal Standard for Motions to Dismiss

Although the Vaccine Act and the Vaccine Rules contemplate case dispositive motions (*see* §300aa-12(d)(2)(C-D); Vaccine Rule 8(d)), the dismissal procedures included within the Vaccine Rules do not specifically include a mechanism for a motion to dismiss (*see* Vaccine Rule 21). However, Vaccine Rule 1 provides that for any matter not specifically addressed by the Vaccine Rules the special master may regulate applicable practice consistent with the rules and the purpose of the Vaccine Act.

(Vaccine Rule 1(b).) Vaccine Rule 1 also provides that the Rules of the Court of Federal Claims ("RCFC") may apply to the extent they are consistent with the Vaccine Rules. (Vaccine Rule 1(c).)

Accordingly, there is a well-established practice of special masters entertaining motions to dismiss in the context of RCFC 12(b)(6), which allows the defense of "failure to state a claim upon which relief can be granted" to be presented via motion.[11] *See, e.g.*, *Herren v. Sec'y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070 (Fed. Cl. Spec. Mstr. July 18, 2014); *Bass v. Sec'y of Health & Human Servs.*, No. 12-135V, 2012 WL 3031505 (Fed. Cl. Spec. Mstr. June 22, 2012); *Guilliams v. Sec'y of Health & Human Servs.*, No. 11-716V, 2012 WL 1145003 (Fed. Cl. Spec. Mstr. Mar. 14, 2012); *Warfle v. Sec'y of Health & Human Servs.*, No. 05-1399V, 2007 WL 760508 (Fed. Cl. Spec. Mstr. Feb. 22, 2007). And, significant to this case, this practice has included decisions by special masters specifically addressing whether a petitioner's alleged injury has satisfied the Vaccine Act's severity requirement. *E.g.*, *supra,* at *Herren*; *Spooner*, 2014 WL 504728; *Uetz*, 2014 WL 7139803.

Under RCFC 12(b)(6), a case should be dismissed "when the facts asserted by the claimant do not entitle him to a legal remedy." *Extreme Coatings, Inc. v. United States*, 109 Fed Cl. 450, 453 (2013) (quoting *Lindsay v. United States*, 294 F.3d 1252, 1257 (Fed Cir. 2002)). In considering a motion to dismiss under RCFC 12(b)(6), allegations must be construed favorably to the pleader. *Id*. However, the pleading must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Golden v. United States*, 137 Fed. Cl. 155, 169 (2018) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

"To determine whether a complaint states a plausible claim for relief, the court must engage in a context-specific analysis and 'draw on its judicial experience and common sense.'" *Id*. (quoting *Iqbal*, 556 U.S. at 679). However, "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." *Bell Atlantic Corp.*, 550 U.S. at 555 (quoting *Neitzke v. Williams*, 490 U.S. 319, 327 (1989)). Nonetheless, on a motion to dismiss courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Id*. (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). In assessing motions to dismiss in the Vaccine Program, special masters have concluded that they "need only assess whether the petitioner could meet the Act's requirements and prevail, drawing all inferences from the available evidence in petitioner's favor. *Herren*, 2014 WL 38889070, at *2; *Warfle*, 2007 WL 760508, at *2.

[11] Moreover, it has been observed that the standards for pleading in the Vaccine Program are similar to the standards for pleading in traditional civil litigation such that application of Rule 12(b)(6) is appropriate. *E.g.*, *Herren*, 2014 WL 3889070, at *1.

VI. Discussion

My review of the complete record compiled to date reveals that petitioner did not (and will not be able to) state a claim for which relief can be granted because she has not met the severity requirement contained within the Vaccine Act. As described above, the parties agree that petitioner did not experience at least six months of residual effects from her alleged injury. They further agree that she did experience inpatient hospitalization. Accordingly, the issue to be resolved is whether she underwent any "surgical intervention" pursuant to §300aa-11(c)(1)(D) during her hospitalization.

I conclude that the dispositive factor in this case is that petitioner's arthrocentesis is not a surgical procedure. First, I examine this question in light of petitioner's proffered evidence regarding the correct understanding of "surgery." I then turn to whether arthrocentesis should be considered surgical in light of prior Program cases interpreting the relevant statutory language.

For the sake of clarity regarding the scope of this decision, I will also briefly address those aspects of the case that do not favor dismissal of this case at this time. Specifically, drawing all inferences in favor of petitioner, there is sufficient evidence on this record that petitioner's arthrocentesis likely did constitute an intervention for purposes of the Vaccine Act's severity requirement. The remaining question is whether that intervention was in treatment of petitioner's alleged vaccine injury. This decision will not resolve that question as it would require further development of the record.

a. Petitioner's Proffered Definition of Surgery Does Not Support Her Claim

Because this decision addresses a motion to dismiss, all inferences must be drawn in petitioner's favor. Accordingly, I will start by accepting as accurate petitioner's proffered evidence regarding the definition of surgery and description of knee arthrocentesis. (Exs. 7-8.) This includes a January 2020 online article titled "Knee Arthrocentesis" by Akbarnia and Zahn from the National Center for Biotechnology Information ("NCBI") "Bookshelf" service (Ex. 7) and the above referenced definition of "surgery" as adopted by the AMA based on a statement from the American College of Surgeons (Ex. 8). Comparing these pieces of evidence, the specific AMA definition of surgery preferred by petitioner does not support petitioner's claim that arthrocentesis constitutes a surgery. The AMA definition of surgery provides three separate descriptions of what constitutes a surgery. Arthrocentesis does not fit into any of the three descriptions.

Arthrocentesis is a procedure performed to aspirate synovial fluid from a joint cavity. (Ex. 7, p. 1.) It can be performed by a clinician or by other medical care professionals or healthcare workers and typically does not require any assistance. (*Id.* at 2-3.) For arthrocentesis of the knee, a patient is placed in a comfortable position with the knee fully extended at 15-20 degrees. (*Id.*) A local, lidocaine anesthetic is used. (*Id.*) The procedure itself involves insertion of an 18g needle with a 30-60cc syringe into

the joint to aspirate fluid. (*Id.*) Potential complications are generally limited to local trauma and the procedure is typically completed on an outpatient basis. (*Id.* at 3.) In this case, it was performed bedside while petitioner was otherwise hospitalized. (ECF No. 15, p. 13; Ex. 4, p. 220; Ex. 5.)

Turning to the AMA definition of surgery, the AMA first indicates, most basically and most severely, that 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." (Ex. 8, p. 1.) Arthrocentesis does not fit this definition because it does not structurally alter the body. Arthrocentesis of the knee removes synovial fluid from the joint by needle. (Ex. 7.) It is not a structural alteration of the knee joint. Nor, for that matter, does it reach the joint by incision or result in destruction of tissue.[12]

Expanding on that statement, the AMA provides a second description of seemingly more minor surgery that does not require structurally altering the body, indicating that "[s]urgery 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." (*Id.*)

This description does allow that procedures involving needles may constitute surgery; however, it should be stressed that inclusion of the specific term "needle" is not illuminating on its own. For example, needlescopic surgeries are performed by passing surgical instruments through a hollow needle.[13] This more detailed description is still limited to the context of "localized alteration or transposition of live human tissue," which is not consistent with arthrocentesis. (Ex. 8.) Again, arthrocentesis only removes synovial fluid from within the joint via needle puncture, it does not alter or transpose tissue. (Ex. 7.) Here, respondent's suggestion that petitioner's proposed interpretation fails to meaningfully distinguish between a surgical procedure and a routine blood draw illustrates the point. (ECF No. 18, p. 11.)

[12] Though it likely goes without saying, a quick review of medical terminology confirms that removal of synovial fluid by needle puncture cannot be equated to an incision or destruction of tissue. "Incision" refers to either "the act of cutting" or "a cut, or a wound produced by cutting with a sharp instrument." *Dorland's*, p. 914. "Puncture" refers to "the act of piercing or penetrating with a pointed object or instrument." *Id.* at 1532. A "fluid" is "a liquid or gas" that is "composed of elements or particles that freely change their relative positions without separating. *Id.* at 712. "Tissue" is loosely defined in medicine as "an aggregation of similarly specialized cells united in the performance of a specialized function;" "cells" being "the smallest living unit capable of independent function." *Id.* at 307, 1901. Synovial fluid, or synovia, in particular is "a transparent alkaline viscid fluid, resembling the white of an egg, secreted by the synovial membrane, and contained in joint cavities, bursae, and tendon sheaths." *Id.* at 1826.

[13] Specifically, "needlescopic" is defined as a procedure "done with a minilaparoscopic technique in which tiny instruments are passed through the lumen of a hollow needle such as a Veress needle. *Dorland's*, p. 1219. A Veress needle is "a hollow needle consisting of a sharp trocar with a slanted end surrounding an inner cylinder with a blunt end." *Id.*

Finally, the AMA definition of surgery also indicates that "[i]njection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery." (Ex. 8) Arthrocentesis, however, removes fluid. It does not inject any substance into the body. (Ex. 7.) The fact that this description explicitly singles out needle injection of diagnostic and therapeutic substances as surgical further suggests that the invasiveness of the substance itself (and its effects), and not merely the needle puncture, helps give rise in this context to the characterization of an injection as a surgical procedure.

Petitioner argues that penetration of the skin by a needle does constitute "manipulation of live tissue with an instrument." (ECF No. 15, p. 13.) Notably, however, the AMA definition does not discuss manipulation of tissue broadly. Rather, it discusses the specific procedure of "manipulation by closed reduction for major dislocations or fractures."[14] (Ex. 8.) The AMA implicates needles only in two specific contexts, localized alteration or transposition of live tissue or injection of therapeutic and diagnostic substances. (*Id.*) As described above, arthrocentesis fits neither category. Moreover, despite extensively listing specific means of altering tissue (including cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction), the definition does not otherwise suggest that mere puncturing by needle gives rise to a surgery.[15] Thus, I do not find that arthrocentesis constitutes a surgery under the specific descriptions included in this definition.

Moreover, even if I accepted petitioner's implicit argument that a needle puncture of the cutaneous or subcutaneous tissue in itself was sufficient to constitute a destruction or alteration of tissue under these descriptions, the definition as a whole still makes clear that arthrocentesis of the knee lacks the requisite gravity to constitute a surgery. Specifically, the AMA cautions that:

> All of these surgical procedures are invasive, including those that are 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

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[14] In medical terminology, a "reduction" refers to "the correction of a fracture, dislocation, or hernia." A "closed reduction" refers to "the manipulative reduction of a fracture or dislocation without incision." *Dorland's*., p. 1584.

[15] As discussed further below, in addition to advancing this definition of surgery, petitioner also argues that her arthrocentesis should be considered surgical because of its similarity to the lumbar puncture and bone marrow aspirations discussed in *Spooner*, *Ivanchuk*, and *Leming*; however, like arthrocentesis, it does not appear that a lumbar puncture would satisfy this definition of surgery. This is at least partly consistent with the conclusion reached in *Spooner* in that the special master concluded that not all lumbar punctures may be deemed surgical. In contrast, the bone marrow aspirations in *Ivanchuk* and *Leming* arguably meet this definition because they remove bone marrow from the body, which is a form of tissue, but this distinguishes these precedents from the instant case. This underscores that the use of the word "needle" in this definition does not bring all needle-based procedures within the definition of surgery.

> licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

(Ex. 8, p. 1.)

According to petitioner's submission, however, although arthrocentesis is characterized as a "minor surgical procedure," it may be "performed by *healthcare workers* who do have knowledge of the anatomy of joints." (Ex. 7, p. 1 (emphasis added).) This marks a contrast to the AMA definition above, wherein all of the procedures included in the definition by any description are procedures that should be reserved for execution by a licensed physician due to their inherent risks. (Ex. 8, p. 1.) Moreover, even though petitioner's arthrocentesis was performed by a physician in this instance, the photographs petitioner submitted of her procedure being performed further illustrate how minimally invasive and nontraumatic the bedside procedure at issue actually was. (Ex. 5.)

b. Petitioner's Allegation is Not Consistent with This Program's Long-Standing Understanding of "Surgical" Intervention

Petitioner also argues that her arthrocentesis constitutes a surgical intervention when viewed in the context of this Program's prior caselaw. Although special masters are not bound by the prior decisions of other special masters,[16] in this case I find the prior decisions rendered in *Stavridis*, *Spooner*, *Ivanchuk* and *Leming* to be both instructive and persuasive. Moreover, both parties framed their arguments within the context of these prior decisions. Contrary to petitioner's assertions, however, these decisions do not support petitioner's position in this case. Thus, even setting aside her proffered definition of surgery, petitioner still does not prevail.

Like this case, *Stavridis*, *Spooner*, *Ivanchuk*, and *Leming*, each examined needle-based procedures that occurred during the course of a hospitalization, including blood transfusion and intravenous steroids (*Stavridis*), lumbar puncture and IVIG treatment (*Spooner*), and bone marrow aspiration and biopsy (*Ivanchuk* and *Leming*). In that regard, petitioner argues that "[p]etitioner's right knee arthrocentesis is very similar to both lumbar puncture and bone marrow aspiration and biopsy in that all three procedures involve puncturing or penetrating the cutaneous and subcutaneous tissue with a needle by a physician; removal, drainage or aspiration of bodily fluid; and typically some type of microbiologic analysis of the fluid extracted." (ECF No. 15, p. 13.) Significantly, however, the key characteristic of lumbar punctures and bone marrow aspirations is not that they merely penetrate the cutaneous and subcutaneous tissue, but that they further penetrate the spinal canal and bone respectively. Moreover, respondent correctly notes that in those prior cases where a surgical procedure was found to have occurred, the hospital "took notable steps to classify the questioned procedure as a surgery" whereas the procedure in this case did not involve general anesthesia, was conducted bedside rather than in an operating room, and had no written consent. (ECF No. 13, p. 8; ECF No. 18, p. 8.)

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[16] *See, e.g.*, *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998).

Importantly, the above-referenced body of case law does not support the idea that all needle-based procedures involving puncture wounds are inherently surgical. Rather, it is the distinctions highlighted by respondent that have previously been found instructive in determining whether a surgical procedure has occurred. *Stavridis* rejected entirely the idea that either blood transfusion or intravenous steroid treatments were surgical in nature. 2009 WL 3837479, at *5-6. *Spooner* subsequently distinguished between lumbar punctures performed by non-surgeons without the use of general anesthesia and those having the character of a surgery. 2014 WL 504728, at *11. In contrast, the *Spooner* special master rejected the idea that IVIG was surgical. *Id.* at *13. This is consistent with the explanation in both *Stavridis* and *Spooner* 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. 2009 WL 3837479, at *5-6; 2014 WL 504728, at *11.

Additionally, *Ivanchuk* and *Leming* likewise stand for the proposition that needle-based procedures such as bone marrow aspiration, though not inherently surgical, may be considered surgical when they rise to a level of concern such that a hospital facility treats them with the same gravity as other, more invasive surgical procedures. Both *Ivanchuk* and *Leming* stressed that they were limited to their facts and that bone marrow aspiration should not be considered surgical in all instances. 2015 WL 6157016, at *3; 2019 WL 5290838, at *6. These decisions explained that the procedures at issue were treated in all regards by the treating hospital as surgical in nature. The *Ivanchuk* decision also considered the fact that the procedure was performed – likely with an appropriate degree of hesitation – on an "incredibly young" child and, again, with the added risk of general anesthesia.[17] 2015 WL 6157016, at *3

Petitioner contends, however, that requiring indicia of surgery such as the use of consent forms and general anesthesia would read additional requirements into the statutory language. (ECF No. 15, p. 15.) Petitioner focuses on the fact that not all surgical procedures bear all of these hallmarks. Petitioner argues, for example, that intussusception surgeries, cesarean sections, and breast augmentation surgeries may all be performed with either general or local anesthesia; a fasciotomy may be performed bedside in an emergency department; and a failure to obtain written consent for open heart surgery would not alter the nature of that procedure. (*Id.* at 14-15.) However, petitioner's argument rests on a much different starting premise, namely that incisional procedures can be recognized as surgical regardless of these specific distinctions. In that context, petitioner may be correct that hypothetically the type of consent, type of anesthesia, or location of the procedure, would not necessarily cause a procedure

[17] In both *Ivanchuk* and *Leming*, the special master stressed that the child had undergone post-operative recovery and monitoring protocols for potential complications from general anesthesia. 2015 WL 6157016, at *2; 2019 WL 5290838, at *6. This underscores the fact that general anesthesia is not viewed as merely a measure of the gravity of the procedure, but also as a factor contributing additional risk.

otherwise commonly understood to be surgical to be excluded from any definition of surgery.

This case, however, represents a different context. Both the above-discussed case law and petitioner's proffered AMA definition make clear that needle punctures are not in all (or even most) instances surgical. With that as a starting premise, the question posed by prior cases has been whether any militating factors suggest that a type of procedure that is not necessarily viewed as surgical in all instances can rise to the level and character of a surgery in a specific instance based on how it is viewed and handled by the treating hospital. *Spooner*, *Ivanchuk* and *Leming* all answered yes based on specific fact patterns that do not match the facts of this case. It is immaterial that consent forms, operating rooms, and general anesthesia are not fundamental aspects of the definition of surgery. These factors need not be definitional to have provided additional indicia that a surgical procedure occurred. However, the presence of these factors in some cases does not confer the same significance to all needle punctures in all cases. Accordingly, the absence of these added factors in this case does prevent petitioner from meaningfully or persuasively relying on these prior cases as precedent favoring petitioner's claim. On the whole, precedent weighs against petitioner's claim.

Finally, petitioner also stresses that these prior decisions confirm that lumbar puncture and bone marrow aspiration require only a physician and not a surgeon. (ECF No. 15, p. 12.) Significantly, however, as described above, the material submitted by petitioner in this case confirms that arthrocentesis does not require *any physician at all*. (Ex. 7, p. 1.) 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. In that regard, *Spooner* similarly rejected the suggestion that IVIG is surgical in nature because it was considered a nursing function.

c. Petitioner's Arthrocentesis Likely was an Intervention

Both parties rely on the definition of "intervention" discussed in *Spooner*, i.e. a procedure that would "alter the course of a disease. (ECF No. 13, p. 7 (quoting 2014 WL 504728, at *12; ECF No. 15, p. 16.) This phrasing has generally been understood to mean that to be an intervention, a procedure must be a part of a treatment protocol rather than merely diagnostic. *E.g., Ivanchuk*, 2015 WL 6157016, at *2-3. In this case, both parties acknowledge that arthrocentesis can be used both diagnostically and therapeutically. (ECF No. 13, p. 7; ECF No. 15, p. 5; Ex. 7, p. 1.) Specifically, arthrocentesis may be used diagnostically to differentiate between septic arthritis and inflammatory causes of arthritis. (Ex. 7, p. 1.) Respondent stresses that in petitioner's case this was explicitly indicated as the reason for the procedure and that it was billed as a diagnostic procedure. (ECF No. 13, p. 8; ECF No. 18, p. 3; Ex. 4, pp. 53, 219, 250.) And while this is correct, arthrocentesis is also used for pain relief for "large and painful joint effusions." (Ex. 7, p. 1.) Petitioner stresses this aspect of the procedure. (ECF No. 15, p. 16.)

Respondent is correct that the procedure served a diagnostic function; however, the records also include notations that may suggest the procedure was also pursued at least in part as a response to petitioner's painful swelling. Moreover, petitioner is also correct that a joint effusion had been identified in petitioner's right knee, that reduction of effusions is a recognized use of arthrocentesis, that 30ml of fluid was removed from the knee, and that the effusion resolved during petitioner's hospitalization. Drawing all inferences in petitioner's favor, the records support petitioner's contention that, regardless of the initial purpose, petitioner's right knee arthrocentesis likely had the effect of reducing her effusion. Thus, for purposes of this motion, I find that petitioner's right knee arthrocentesis constitutes an intervention within the meaning of the Vaccine Act.

d. Additional Evidence is Necessary to Determine Whether Petitioner's Right Knee Arthrocentesis was in Treatment of her Alleged Vaccine Reaction

In his motion to dismiss, respondent argues that petitioner's medical records show that her joint swelling was related to osteoarthritis and unrelated to her alleged vaccine reaction. (ECF No. 13, pp. 8-9.) He stressed that petitioner's initial symptoms dissipated and that upon discharge her diagnosis was only "post vaccination fever." (*Id.* at 4, 9 (citing Ex. 4, p. 39-52, 222).) He also stressed that serum sickness was considered during petitioner's hospitalization, but believed to be unlikely. (*Id.*)

Petitioner counters, however, that her joint effusion and arthrocentesis occurred in the context of a hospitalization for which petitioner's primary intake diagnosis was "other complications following immunization, not elsewhere classified," and that she had secondary diagnoses including "other serum reaction due to vaccination, initial encounter," and "adverse effect of other viral vaccines, initial encounter." (ECF No. 15, p. 7 (quoting Ex. 4, p. 219).) Moreover, petitioner was discharged with instructions to follow up with her primary care physician. (Ex. 4, p. 221.) That primary care physician in turn recorded a history of "serum sickness-like reaction" and recorded an impression of "adverse reaction to mixed bacteria vaccine." (Ex. 1, pp. 33, 35.)

Respondent challenges the weight that should be afforded the specific notations highlighted by petitioner; however, the conflicting medical record notations being debated by the parties speak to the question of petitioner's correct diagnosis and whether that diagnosis accounts for all or only some of petitioner's symptoms. These issues go to the core allegations of petitioner's claim and are not appropriately resolved at this time and on this motion.

In determining eligibility to compensation, a special master must consider the diagnoses, conclusions and medical judgments reflected in the medical records; however, "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Instead, petitioner may support her claim by either medical records or medical opinion.

Id. Moreover, special masters "must determine that the record is comprehensive and fully developed before ruling on the record." *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

Here, further development of the record could ultimately validate respondent's argument. However, at this early juncture, petitioner has highlighted medical records in which her treating physicians at least contemplated the possibility that serum sickness-like reaction could explain her symptoms. Moreover, petitioner has provided a further offer of proof in the form of an internet publication suggesting that serum sickness can present with rheumatic features, including arthralgia of the knees as well as "tenderness to palpation and movement" in a minority of patients. (Ex. 6, p. 8.) This is enough to suggest that petitioner could potentially develop the record of this case in meaningful ways if provided the opportunity.

Whether petitioner's right knee arthrocentesis was performed in treatment of her alleged vaccine reaction depends on petitioner's correct diagnosis which is debated by the parties and subject of conflicting notations in the medical records. For the reasons discussed above, that question cannot be answered on the existing record. Accordingly, it does not serve as a basis for granting respondent's motion to dismiss.

VII. Conclusion

For all the reasons discussed above, I find that petitioner's right knee arthrocentesis is not a surgical intervention. Specifically, I conclude that it is not a surgical procedure. Therefore, even with the benefit of all inferences, petitioner has failed to state a claim upon which relief can be granted because she cannot meet the statutory severity requirements pursuant to the Vaccine Act at §300aa-11(c)(1)(D). According, respondent's motion is **GRANTED** and this petition is dismissed.[18]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[18] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.