# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

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TIARA SPOONER, parent of          *     No. 13-159V
G.S., a minor,                    *     Special Master Christian J. Moran
                                  *
              Petitioner,         *     Filed: January 16, 2014
                                  *
v.                                *     Vaccine Act; severity requirement;
                                  *     "surgical intervention;" legislative history;
SECRETARY OF HEALTH               *     lumbar puncture; intravenous
AND HUMAN SERVICES,               *     immunoglobulin; IVIG;
                                  *     medical dictionaries.
              Respondent.         *
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Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for petitioner.
Michael P. Milmoe, United States Department of Justice, Washington, DC, for respondent.

**PUBLISHED DECISION**[1]

On March 4, 2013, Tiara Spooner ("petitioner") filed a petition for Vaccine Compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10, et seq.[2] (2012) (the "Vaccine Act" or "Program"). Ms. Spooner alleged that the hepatitis A vaccine, which is contained in the Vaccine Injury Table (the "Table"), 42 C.F.R. § 100.3(a), and which her minor child, G.S., received on March 17, 2010, caused her child to suffer Guillain-Barré syndrome ("GBS").

On August 5, 2013, respondent moved to dismiss the petition. Respondent contends, in part, that Ms. Spooner failed to satisfy the Vaccine Act's severity requirement, a threshold issue. Resp't's Mot. to Dismiss at 13-14. Specifically, respondent asserts that G.S. "did not suffer the residual effects or complications of such illness, disability, injury or condition for more than six

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[1] The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa–12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

[2] Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa.

months after the administration of the vaccine," and did not suffer a vaccine-related injury resulting in surgical intervention. Id. (citing §11(c)(1)(D)).

Based on the record as a whole, and for the reasons explained below, Ms. Spooner has failed to produce preponderant evidence to satisfy the Act's severity requirement. Respondent's motion to dismiss is GRANTED.

## G.S.'s Relevant Medical History

On March 17, 2010, G.S. received a hepatitis A vaccine during his two-year well-child visit to his pediatrician, Dr. Leo Muido. Exhibit 1 at 1, 34-36. Five days later, on March 22, 2010, G.S. returned to Dr. Muido. Id. at 37. Ms. Spooner reported that G.S. was "'off balance' while trying to walk recently" and had been waking up multiple times a night for a week. Id. G.S.'s history of ear infections was noted, and an examination of his right ear revealed a distorted tympanic membrane and serous fluid. Id. Dr. Muido's impression was a right ear infection; however, he noted that it was unclear if the "ear is source of distress." Id. G.S. was prescribed an antibiotic. Id. at 38.

On March 24, 2010, G.S. returned to Dr. Muido, where it was reported that he was "still very weak, falls down alot [sic] and then can't get back up." Exhibit 5 at 16. Dr. Muido found G.S. to be "upset emotionally but physically not in distress." Id. On physical examination, G.S.'s right tympanic membrane was found to be "dull" with slight fluid. Id. Dr. Muido's impression was fatigue, possibly "related to illness and emotional trauma of recent illness." Id. at 17. He referred G.S. to Children's Hospital Boston. Id.

G.S. was admitted to the hospital's neurology department on March 24, 2010. Exhibit 6 at 79. His treatment for a "presumed ear infection" was noted. Id. A neurologic exam was "notable for mild LE [lower extremity] decrease tone and areflexia," and there was a concern for GBS. Id. The plan was to perform a lumbar puncture and to start IVIG treatment. Id. A lumbar puncture was scheduled for March 24, 2010. Id. at 121, 234. The hospital did not request Ms. Spooner's specific consent prior to preparing G.S. for the procedure. G.S. failed sedation, however, and the lumbar puncture was not performed on March 24. Id. at 121 ("failed sedation . . . for MRI/LP – wasn't adequately sedated, was still moving"), 234.

Lumbar Puncture with General Anesthetic

G.S. underwent a lumbar puncture on March 25, 2010.[3] Exhibit 6 at 69, 111, 120, 126, 142. A lumbar puncture, colloquially known as a "spinal tap" (see id. at 79.), is a procedure in

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[3] In the Children's Hospital medical records, G.S.'s March 25, 2010 lumbar puncture was described variously. Included in the hospital's "procedure information" was a completed field for "Date of Surgery." Exhibit 6 at 120; see also id. at 132 (listing "LUMBAR PUNCTURE" under "SURGICAL PROCEDURES"). Additionally, the order for the lumbar puncture lists the "Type of Order" as "Surgery." Id. at 207. On the hospital's Consent for Medical and Surgical

(continued . . . )

which cerebrospinal fluid ("CSF") is withdrawn from the spinal canal through a spinal needle. Court exhibit II (Robert M. Kliegman et al., Nelson Textbook of Pediatrics, *Chapter 584: Neurologic Evaluation, Special Diagnostic Procedures, Lumbar Puncture and Cerebrospinal Fluid Examination* (19th ed. 2011), http://www.expertconsult.com). Classified as a "diagnostic" procedure, a lumbar puncture is essential in confirming the diagnosis of conditions including meningitis and encephalitis, and helpful in diagnosing demyelinating diseases. See id.; see also Court exhibit I (International Classification of Diseases, Ninth Revision, Clinical Modification at 1370-71 (1997)) (classifying "Spinal tap" under "Diagnostic procedures on spinal cord and spinal canal structures"); exhibit B (Lee Goldman & Andrew I. Schafer, Goldman's Cecil Medicine 2231 (24th ed. 2012)) (classifying a lumbar puncture as a "neurologic diagnostic procedure"); exhibit A (James R. Roberts et al., Clinical Procedures in Emergency Medicine 1218 (6th ed. 2013)) ("Cerebrospinal fluid (CSF) examination is performed . . . to obtain information relevant to the diagnosis and treatment of specific disease entities.").

A lumbar puncture may be performed in a hospital's emergency department. Exhibit B at 1218. Prior to the insertion of the spinal needle, a patient lies down on his side or is situated in a seated position. After cleaning the injection site, a local anesthetic is applied or injected. The beveled spinal needle, one-and-a-half to three inches long and containing a stylet, is inserted in the center of the lower back and directed slightly upward, toward the head. Although a pop can occur as the needle penetrates the outermost membrane of the spinal cord, it is more common for the physician to feel a subtle change in resistance. Court exhibit II; see also exhibit A (Roberts) at 1221-28 (providing a more detailed description of the procedure).

Following complete insertion of the spinal needle, the stylet is removed and CSF begins to flow from the needle hub. The CSF is collected in vials as it drips from the hub. The amount of fluid collected depends on the studies desired. Finally, when the desired amount of CSF is collected, the stylet is replaced and the needle removed.[4] Exhibit B at 1222-25. "When performed with parenteral[5] sedation and proper local anesthesia, a spinal tap is neither overly distressing nor very painful to most patients." Exhibit B at 1222.

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Procedures form, Ms. Spooner acknowledged her understanding "that the procedure(s) proposed for treating or diagnosing [G.S.'s] condition is (are): lumbar puncture." Id. at 51.

[4] Later, the CSF is analyzed for aspects including protein concentration, which "is elevated in a variety of disorders, including . . . demyelinating neuropathies." Exhibit A at 2231; exhibit 6 at 111.

[5] "Parenteral" means "not through the alimentary canal, but rather by injection through some other route, such as subcutaneous, intramuscular, intraorbital, intracapsular, intraspinal, intrasternal, or intravenous." Dorland's Illustrated Medical Dictionary 1382 (32d ed. 2012) [hereinafter "Dorland's (32d)"].

G.S.'s lumbar puncture was performed in the hospital's operating room by neurology resident Dr. Jurriaan Peters.[6] Exhibit 6 at 69, 124, 288. Although lumbar punctures are usually performed with only a local anesthetic, G.S. was administered general anesthesia by mask because he had failed sedation the day before. Id. at 69, 121-22, 127, 137, 234. "General anesthesia" is "a reversible state of unconsciousness, produced by anesthetic agents, with absence of pain sensation over the entire body and a greater or lesser degree of muscular relaxation; the drugs producing this state can be administered by inhalation, intravenously, intramuscularly, or rectally." Dorland's (32d) at 81. These potent drugs "are used to blunt physiologic responses to what would otherwise be life-threatening trauma (surgery)." Robert M. Kliegman et al., Nelson Textbook of Pediatrics 359 (19th ed. 2011) [hereinafter "Nelson's (19th)"].

On March 25, prior to G.S.'s general anesthetization, Ms. Spooner signed two specific consent forms. She signed the hospital's "Consent for Medical and Surgical Procedures" form for the lumbar puncture, recognizing the risks associated with the procedure, including infection, spinal cord injury, and herniation. Exhibit 6 at 51-52. She also signed the hospital's "Consent for Anesthesia" form, which includes the statement, "I understand that anesthesia involves risks in addition to the risks of the procedure itself." Id. at 54. The form lists injury to teeth or dental work, damage to vocal cords, respiratory problems, minor pain and discomfort, damage to arteries or veins, headaches, or nausea and vomiting as risks associated with general anesthesia. Additionally, the form contains the statement, "Severe adverse drug reactions, brain damage or death may also occur but are rare." Id. "The increased risk of morbidity and mortality . . . demands the utmost vigilance." Nelson's (19th).

Anesthesiologist Felicity Billings administered general anesthesia to G.S. by mask. Exhibit 6 at 122. G.S. then was placed on his side in a lateral position. His skin was prepped with a topical antiseptic and a local anesthetic was injected. The spinal needle was introduced between G.S.'s "L3-4 intervertebral space" and "clear colorless CSF fluid [sic] was obtained." When the desired amount of fluid was collected, the needle was removed and a bandage was applied. Id. at 288. G.S. was then transported to the postanesthesia care unit. Id. at 126, 129. An analysis of G.S.'s CSF revealed a high protein concentration, a pattern consistent with GBS. Id. at 19, 63-66, 90, 111, 285.

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[6] Although the hospital's procedure information lists attending neurologist Dr. Michel Fayad as the lumbar puncture "Surgeon/Provider" (exhibit 6 at 120, 132; see also id. at 126, 207), Dr. Peters authored the procedure note, which Dr. Fayad authenticated (id. at 288). Other records also indicate that Dr. Peters performed the lumbar puncture with the assistance of Registered Nurse Duane Andrews. See id. at 133 (listing Dr. Peters as having performed the skin prep), 134 (noting Nurse Andrews's positioning of G.S.).

IVIG Treatment

In addition to undergoing a lumbar puncture, G.S. also received two days of IVIG treatment during his hospitalization.[7] Exhibit 6 at 64, 90, 248, 255, 264-65, 285, 293. IVIG treatment introduces immunity against a specific disease to immunodeficient persons through the intravenous ("IV") administration of immunoglobulin ("IG"), an antibody-containing solution derived from the plasma of adult humans. Exhibit C (Robert M. Kliegman et al., Nelson Textbook of Pediatrics 881-82 (19th ed. 2011)). IVIG "is used to treat a range of immune-mediated neurologic diseases," including GBS. Exhibit D (Patwa et al., Evidence-based guideline: Intravenous immunoglobulin in the treatment of neuromuscular disorders, 78 Neurology 1009 (2012)).

Administering intravenous fluids is "standard in nursing practice." After assisting the patient into a comfortable sitting or supine position, and following preparation of the IV bag and tubing, the administering nurse identifies an accessible vein and cleanses the injection site with an antiseptic swab. The nurse applies a tourniquet above the intended injection site and warns the patient of a "sharp, quick stick." With a well-dilated vein selected, the nurse pierces the skin with a metal stylet, part of the "commonly used over-the-needle catheter[]." The nurse then advances the catheter into the vein until the catheter hub is near the injection site. A "22- to 24-gauge catheter is used for children and or any patient with small fragile veins." After the catheter is stabilized and the tourniquet released, "there is the option of applying a local anesthetic to the site." Thereafter, the IV tubing is connected to the catheter. When a "nurse-driven IV team . . . implements the most current technologies, maintains IV therapy knowledge and aseptic technique, and incorporates the current standards and guidelines," patient outcomes improve and complications are reduced. Court exhibit III (Anne Griffin Perry, et al., Clinical Nursing Skills & Techniques 741-42, 746-52 (7th ed. 2010)); see also id. at 786, 792-95 (addressing the transfusion of blood and plasma-derived products).

G.S. was catheterized by Registered Nurse Nancy Shaffer on March 24, 2010. Exhibit 6 at 215; see also id. at 196 (order for "Peripheral IV Insertion"). Using a 22-gauge over-the-needle catheter, Nurse Shaffer inserted the catheter into G.S.'s right hand with no complications. Id. at 215. G.S. tolerated the catheterization well. Id. On both March 25 and 26, 2010, G.S. received 1 gm/kg of IG. Id. at 11, 19-20, 209-215, 246, 255, 293. Registered Nurses Jessica Bolduc, Katie Burba, and Erin Clover each administrated the IG throughout G.S.'s treatment. Id. at 246, 209-15. G.S. tolerated the treatments well and his condition improved following IVIG administration. Id. at 90, 97, 209-14, 285.

[7] Unlike G.S.'s lumbar puncture, IVIG treatment was not listed on the hospital's "Consent for Medical and Surgical Procedures" form. See exhibit 6 at 51. IVIG treatment was listed, however, on the hospital's "Extended Consent for Transfusion of Blood Components" form. Id. at 56.

Hospital Discharge and Post-Hospital Course of Treatment

G.S. was discharged from the hospital on March 27, 2010, three days after his admission. Exhibit 6 at 281. At that time, his condition had "improved." Id. On March 31, 2010, G.S. was seen by Dr. Peters and Dr. Fayad for a follow up. Id. at 19-21. According to a parental report, G.S.'s strength was returning. Id. at 20. He was able to climb and to run and walk stably without assistance. Id. On physical examination, he revealed "no weakness," although he tended to "minimally lock both knees indicating minor weakness at the hips." Id. His reflexes were still absent. Id. Dr. Peters assessed G.S. as "neurologically nearly back to baseline." Id.

G.S. returned to Dr. Peters on May 11, 2010. Id. at 11-13. At that time, G.S. was able to "walk stairs with an alternating gait." Id. at 12. Dr. Peters saw "no asymmetries during gaits, nor during running." Id. Although Ms. Spooner reported that G.S. seemed to be experiencing pain in his right knee, Dr. Peters did not observe right knee discomfort during his evaluation. Id. at 11-12. Dr. Peters noted the return of G.S.'s reflexes. Id. at 12.

On August 10, 2010, less than five months after the onset of G.S.'s GBS, Ms. Spooner reported to neurologists at Children's Hospital Boston that "[G.S.] is now completely normalized, . . . back to his prior behaviors and [exhibiting] no aftereffects of his hospitalization and treatment." Id. at 1. A physical and neurological examination confirmed Ms. Spooner's report.[8] Exhibit 6 at 1-2.

## Procedural History

Ms. Spooner filed a petition for vaccine compensation on March 4, 2013. On March 28, 2013, Ms. Spooner filed medical records from Children's Hospital Boston (the "hospital") (exhibit 6), which include records concerning G.S.'s March 25, 2010 lumbar puncture and two days of IVIG treatment. On May 3, 2013, Ms. Spooner filed an amended petition in which she alleged that G.S. "suffered a vaccine-related injury that resulted in inpatient hospitalization and surgical intervention." Second Am. Pet. at ¶ 16 (citing § 11(c)(1)(D)(iii)).

Respondent filed a motion to dismiss on August 5, 2013, contending that G.S.'s injury failed to satisfy the Vaccine Act's severity requirement. Specifically, respondent challenges Ms. Spooner's allegation that G.S. underwent a surgical procedure due to his alleged vaccine-related injury. Resp't's Mot. to Dismiss at 14. Anticipating Ms. Spooner's claim that a lumbar puncture is a "surgical intervention," respondent asserts that a lumbar puncture "is a medical and

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[8] During G.S.'s August 10, 2010 follow up appointment, Ms. Spooner raised the possibility that G.S.'s "hepatitis A vaccine may have brought about the [GBS], since it developed two days after receiving the shot." Exhibit 6 at 2. Neurologists Jeff Waugh and Eugene Roe "discussed this matter with Mrs. Spooner and reassured her that two days is too short a time period to have elicited [GBS]." Id. They added that the hepatitis A vaccine "was certainly not causative" of G.S.'s GBS. Id.

diagnostic procedure, *not* a surgical procedure." Id. Additionally, respondent contends that G.S. "was asymptomatic . . . five months post-vaccination," and thus did not suffer a vaccine-related injury persisting for more than six months. Id. at 13 (citing § 11(c)(1)(D)(i)).

Ms. Spooner filed a response to respondent's motion to dismiss on September 5, 2013. Ms. Spooner argues that both the lumbar puncture and the IVIG therapy G.S. received while hospitalized satisfy the "surgical intervention" requirement of subsection 11(c)(1)(D)(iii). Pet'r's Resp. at 14-15. Regarding the Act's six-month injury requirement (§ 11(c)(1)(D)(i)), Ms. Spooner adds that "it is inconceivable that G.S. did not suffer at least one (1) month of 'emotional distress' after his ordeal." Pet'r's Resp. at 15 (citing § 15(a)(4)).

On September 9, 2013, the parties were ordered to file briefs to support their positions with regard to the Act's severity requirement. The parties filed their briefs on September 25, 2013. Respondent's brief was filed with medical literature related to lumbar punctures and IVIG therapy (exhibits A-D). Ms. Spooner did not file any medical literature with her brief. Thereafter, on November 21, 2013, the undersigned filed additional medical literature (Court exhibits I-IV) and afforded the parties the opportunity to file supplemental briefs addressing the new material. On January 3, 2014, Ms. Spooner filed a status report in which she stated that she would not be filing a supplemental brief. On the same day, respondent filed a supplemental brief addressing the new material. The parties' briefs are discussed below, following a review of the legal standards applicable to a motion to dismiss and a summary of the pertinent legislative history of the Act.

## Standards for Adjudication

A special master may dismiss a petition for failure to state a claim upon which relief may be granted, pursuant to RCFC 12(b)(6). To properly state a claim, the petitioner must provide "a short and plain statement of the claim, which shows that the petitioner is entitled to relief." Totes–Isotoner Corp. v. United States, 594 F.3d 1346 (Fed. Cir. 2010) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). A complaint does not need detailed factual allegations, but "factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. at 555.

## The Pertinent Legislative History of the Vaccine Act

Congress established the Vaccine Program in 1988. See § 1 (Effective Date). Ms. Spooner correctly identifies the twin aims of the Program—to compensate vaccine-injured persons and to protect the nation's vaccine supply by limiting the exposure of vaccine manufacturers to resource-depleting lawsuits. Pet'r's Br. at 3 (citing H.R. Rep't No. 99-908, at 5 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6346). In establishing a no-fault compensation scheme, Congress envisioned that vaccine-injured persons would be compensated "quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3, 1986 U.S.C.C.A.N. at 6344.

Despite the generosity contemplated, Congress set limits as to who could receive compensation. For example, Congress imposed a statute of limitations of "36 months after the date of administration of the vaccine." § 16(a); see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322 (Fed. Cir. 2011) (en banc); Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1376 (Fed. Cir. 2012) ("The Vaccine Program is more generous to petitioners than civil tort actions in some ways . . . . Yet, there are limits under the Vaccine Act that do not apply in civil tort actions."). Additionally, the Act has always contained a severity requirement concerning the duration of a vaccine injury. Originally, a petitioner had to demonstrate the persistence of a vaccine injury "for more than 1 year." See § 11(c)(1)(D), amended by Pub. L. No. 100-203, § 4304(b)(2) (1987). In 1987, Congress shortened that duration to "more than 6 months." Id

The Vaccine Act's six-month injury requirement prevents some petitioners from receiving compensation. Prior to 2000, petitioners claiming that the rotavirus vaccine caused their child's intussusception likely were denied compensation. Revisions and Additions to the Vaccine Injury Table, 66 Fed. Reg. 36735, at 36737 (proposed July 13, 2001) ("Since most patients with intussusception recover after immediate treatment and do not suffer lasting complications for more than 6 months, some petitioners alleging intussusception might have been denied compensation under [the pre-2000 amendment standard]."). In 2000, however, the Act was amended in response to the discovery of a connection between the rotavirus vaccine and intussusception.

In March 1999, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), recommended the rotavirus vaccine for routine administration to infants in the United States. CDC, Rotavirus Vaccine for the Prevention of Rotavirus Gastroenteritis Among Children, Recommendations of the Advisory Committee on Immunization Practices, 48 Morbidity & Mortality Wkly. Rep't. No. RR-2 (Mar. 19, 1999), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00056669.htm. In July 1999, all vaccines against rotavirus were added to the Vaccine Injury Table (without specific associated Table injuries). National Vaccine Injury Compensation Program: Addition of Vaccines Against Rotavirus to the Program, 64 Fed. Reg. 40517-01 (July 27, 1999). Later, in November 1999, after reviewing scientific data, including "reports to the Vaccine Adverse Events Reporting System of intussusception (a type of bowel obstruction that occurs when the bowel folds in on itself) among 15 infants who received [the] rotavirus vaccine," the ACIP withdrew its recommendation. CDC, Withdrawal of Rotavirus Vaccine Recommendation, 48 Morbidity & Mortality Wkly. Rep't. No. 43 (Nov. 5, 1999), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm.

Following the ACIP's withdrawal of its recommendation, a bill to amend the Vaccine Act was proposed in the United States Senate. 145 Cong. Rec. S15213-03 (Nov. 19, 1999). Introducing the proposed amendment, one of the bill's sponsors noted that "[t]he statutory proxy for a serious [vaccine] injury is that the residual effect of the injury must be of six months' duration or longer." Id. The senator added, however, that "a new situation has developed that was not foreseeable at the time of enactment of this law." Id. Acknowledging the ACIP's

withdrawal of its recommendation of the rotavirus vaccine, he noted that some cases of intussusception require hospitalization and surgery,[9] and, under the law as it stood then, such cases would not be compensated. 145 Cong. Rec. S15213-03. Thus, the bill's sponsors proposed that subsection 11(c)(1)(D) be amended to include "or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention to correct such illness, disability, injury or condition, and . . . ." Id. The introducing senator added, however, that to the knowledge of the sponsors, "the amendment would only apply to circumstances under which a vaccine recipient suffered from intussusception as a result of administration of the rotavirus vaccine." Id.

In September 2000, the bill to amend subsection 11(c)(1)(D) was passed by the House of Representatives. 146 Cong. Rec. H8206-06 (Sept. 27, 2000). The Congressional Record does not reflect any debate concerning the proposed amendment. Id. Thus, there was no discussion of restricting the amendment to injuries due to only the rotavirus vaccine. Moreover, the language of the amendment, as passed, does not contain any such restriction. Id. The language, however, did change between the Senate and House. Specifically, the clause "to correct such illness, disability, injury or condition," was omitted from the final version of the amendment. Compare 145 Cong. Rec. S15213-03, with 146 Cong. Rec. H8206-06.

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[9] The senator noted that "[w]hile most cases of intussusception require only minimal treatment, a few cases require hospitalization and surgery." 145 Cong. Rec. S15213-03. This is consistent with the current pattern of treatment of intussusception.

Most cases of intussusception are treated with nonoperative methods such as hydrostatic or pneumatic reduction. Hydrostatic reduction involves inserting a lubricated catheter into the patient's rectum and expelling a contrast agent such as barium or a water-soluble isotonic solution into the intestinal tract. Hydrostatic pressure is continued as long as there is a reduction in the bowel obstruction and until the contrast agent flows freely past the obstruction. "Successful reduction in uncomplicated patients is seen in about 85% of cases and ranges from 42% to 95%." Pneumatic reduction is similarly administered, with air used instead of liquid. Such nonoperative reduction decreases morbidity, cost, and the length of hospitalization. Court exhibit IV (George Whitfield Holcomb III, et al., Ashcraft's Pediatric Surgery 511-13 (5th ed. 2010)).

When nonoperative reduction is unsuccessful, surgery is undertaken. Prior to surgery, broad-spectrum antibiotics and intravenous fluids are administered, and a tube is inserted through the nose and into the stomach for decompression. A general anesthetic is also administered, bringing with it risks not associated with nonoperative reduction. An incision is made in the right lower quadrant of the abdomen. With the intestines revealed, "the leading edge of the intussusception is identified [and] gently manipulated back toward its normal position. . . . Excessive force or pulling is avoided to prevent injury." When manual manipulation fails to reduce the intussusception or part of the intestine is damaged, the affected portion of the intestine is removed and the intestine is reconnected. "After complete reduction of the intussusception, an incidental appendectomy is usually performed because the location of the abdominal scar is similar to an open appendectomy incision." Court exhibit IV at 513-14.

Currently, to be eligible for an award of vaccine compensation a petitioner must prove by a preponderance of the evidence[10] that a vaccinee suffered a vaccine-related injury meeting one of three severity requirements. Pursuant to subsection 11(c)(1)(D), a vaccinee must have:

> (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*.

§ 11(c)(1)(D)(i-iii) (emphasis added).[11] A finding that a vaccinee satisfies one of these requirements may not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1).

The term "surgical intervention" is not defined in the Act. See § 33 (Definitions). Although a special master has addressed the meaning of "surgical intervention" once before, (Stavridis v. Sec'y of Health & Human Servs., No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009)), the Federal Circuit has yet to address the issue.[12] Consequently, the parties filed briefs regarding the meaning and scope of the term "surgical intervention" on September 25, 2013.

## The Parties' Arguments

### Petitioner's Contentions

Ms. Spooner contends that either the lumbar puncture G.S. underwent, which "required the administration of general anesthesia," or the IVIG therapy he received during his hospitalization satisfies the "surgical intervention" requirement of subsection 11(c)(1)(D)(iii). Pet'r's Br., filed Sept. 25, 2013, at 2, 6. She argues that the term "surgical intervention" must be construed broadly. Id. at 9. In support of her position, Ms. Spooner provides definitions of

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[10] Subsection 13(a)(1)(A) provides that a petitioner must demonstrate "by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)."

[11] In addition to satisfying one prong of the Act's severity requirement, petitioners must establish four additional facts required by subsection 11(c)(1). § 13(a)(1)(A). Although most disputes concern subsection 11(c)(1)(C), concerning causation, this case implicates only subsection 11(c)(1)(D) at this juncture.

[12] The decisions of special masters and judges of the Court of Federal Claims constitute persuasive, but not binding authority. Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998). The decisions of the Federal Circuit, however, are binding on special masters and judges of the Court of Federal Claims. Guillory v. Sec'y of Health & Human Servs., 59 Fed. Cl. 121, 124 (2003), aff'd, 104 Fed. Appx. 712 (Fed. Cir. 2004).

"surgery" and "intervention." Additionally, she cites the Act's legislative history, and in particular, the 2000 amendment of subsection 11(c)(1)(D).

Ms. Spooner argues that the definition of "surgical intervention" must be construed broadly to include "surgical procedures that require general anesthesia, such as a lumbar puncture." Pet'r's Br. at 9. She adds that the definition should also include "invasive IVIG treatments." Id. According to the definitions Ms. Spooner submits, "surgery" is "[a] procedure to remove or repair part of the body or to find out whether disease is present," and "intervention" is "a treatment or action taken to prevent or treat disease, or improve health in other ways." Id. (citing National Cancer Institute at the National Institutes of Health, Online Medical Dictionary, http://www.cancer.gov/dictionary (last visited Sept. 2013)).

Echoing the Supreme Court's description of the Vaccine Program as a "generous compensation scheme" (Pet'r's Br. at 4 (citing Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1079 (2011)), Ms. Spooner notes the impetus for the creation of the Program—to ensure the widespread availability of vaccines to prevent childhood diseases—and the congressional means of achieving that end—a compensation system that protects the vaccine supply by alleviating vaccine manufacturers of otherwise crushing liability. Pet'r's Br. at 3-4 (citing H.R. Rep't No. 99-908, 99th Cong., 2d Sess., at 3-5 (1986)). Although not stated explicitly, Ms. Spooner seems to argue that a broad definition of "surgical intervention" better achieves Congress's original intent.

Additionally, Ms. Spooner contends that, in amending the Act's severity requirement to include serious injuries not persisting for more than six months, Congress expressed a clear intent "to expand, not restrict[,] the class of persons who could receive compensation." Pet'r's Br. at 4-6.[13] Concerning G.S., specifically, Ms. Spooner argues that his injury was serious, necessitating inpatient hospitalization and surgical procedures, including a lumbar puncture and IVIG therapy.[14] Pet'r's Br. at 6, 8.

Based on the definitions Ms. Spooner submits, in conjunction with the Act's legislative history, which Ms. Spooner contends evinces Congress's intent that "surgical intervention"

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[13] In addition to citing Congress's insertion of subsection 11(c)(1)(D)(iii) in 2000 (Pet'r's Br. at 4-5), Ms. Spooner also cites a 1998 amendment to subsection 11(c)(1)(D)(1) requiring that petitioner must have "incurred unreimbursable expenses . . . in an amount greater than $1,000" (id. at 7 (quoting § 11(c)(1)(D)(iii), amended by Pub. L. No. 105-277).

[14] Ms. Spooner acknowledges that the Federal Circuit has not yet commented on the 2000 amendment to the Act, but notes that, in a 2005 case, the Court of Federal Claims "found [that] respondent had conceded that hospitalization and a 'lumbar puncture' satisfied the requirements of section 11(c)(1)(D)(iii)." Pet'r's Br. at 8 (citing Hocraffer v. Sec'y of Health & Human Servs., 63 Fed. Cl. 765, 768 n.4 (2005)).

should be defined broadly, Ms. Spooner argues that a lumbar puncture and/or IVIG therapy satisfies the Act's severity requirement.[15] Pet'r's Br. at 9-10.

Respondent's Contentions

Respondent contends that a lumbar puncture and IVIG therapy are not "surgical inventions."[16] Resp't's Br. at 5-6. She asserts that a lumbar puncture is a "diagnostic procedure" and IVIG therapy is a "treatment." Id. at 5 (citing exhibit A), 6 (citing exhibit C); see also Resp't's Supp'l Br. at 2 (noting that Court exhibit I "clearly differentiates [a lumbar puncture] as being a diagnostic procedure as opposed to a surgical operation").[17] Like Ms. Spooner, respondent addresses the 2000 amendment to subsection 11(c)(1)(D) and provides a dictionary definition of "surgery." Resp't's Br. at 3-5. Unlike Ms. Spooner, respondent filed medical literature to support her position.

According to respondent, the legislative history surrounding the inclusion of "surgical intervention" in the Act's severity provision is "quite instructive" in determining the meaning and scope of the term. Id. at 3. Citing the lone Program decision addressing the term, respondent notes that "[t]he surgical intervention requirement was clearly included to permit recovery for those individuals who suffered from intussusception and required surgery." Id. at 3-4 (citing Stavridis, 2009 WL 3837479, at *5 (citing 145 Cong. Rec. S15213-03 (1999))).[18]

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[15] The majority of Ms. Spooner's brief is devoted to an argument in favor of a broad interpretation of "surgical intervention." Immediately preceding her conclusion, however, Ms. Spooner notes that "the special master may also find that [G.S.]'s vaccine-related injury *did* persist for more than six months" because "it is inconceivable that [G.S.] did not suffer at least one (1) month of 'emotional distress' after his ordeal." Pet'r's Br. at 10 (citing §§ 11(c)(1)(D)(i), 15(a)(4)); see also Pet'r's Resp. at 15.

[16] Respondent concedes that G.S. "was hospitalized for evaluation and treatment of GBS" (Resp't's Mot. to Dismiss at 13), thus satisfying the first requirement of subsection 11(c)(1)(D)(iii)—that the alleged vaccine-related injury "resulted in inpatient hospitalization."

[17] Respondent acknowledges that, in the ICD-9, "Spinal tap" falls under the broad category, "Operations on spinal cord and spinal canal structures," and appears under the subcategory, "Diagnostic procedures on spinal cord and spinal structures." Additionally, respondent recognizes that ICD-9 codes "are used primarily for billing and insurances purposes and not for defining conditions or procedures." To this point, however, she notes that lumbar puncture is "coded separately from more invasive [spinal] procedures such as excision, destruction, repair or plastic operations." Resp't's Supp'l Br. at 2 (citing Court exhibit I).

[18] In addition to citing Stavridis, respondent addressed Ms. Spooner's reliance on Hocraffer. Resp't's Br. at 6; see supra note 14. Respondent contends that the holding in Hocraffer "that respondent had conceded that petitioner's lumbar puncture was a surgical procedure by not objecting to petitioner's characterization of petitioner's spinal tap as a surgical procedure" was erroneous. Resp't's Br. at 6. Respondent adds that "[t]he scope of what

(continued . . . )

Respondent adds that "[t]he specific surgical procedure in contemplation by Congress required a large abdominal incision and potential removal of intestine." Resp't's Br. at 4. Commenting on Court exhibit IV, respondent notes that the surgery for intussusception requires "exploration and manipulation of the abdomen and intestines," which is "graphically deomonstrate[d]" by the pictures within the textbook chapter. Resp't's Supp'l Br. at 4. In contrast, she notes that a lumbar puncture can be performed outside the operating room by a non-surgeon and does not require general anesthesia. Id. at 3 (commenting on Court exhibit II).

Although arguing for a narrower definition of "surgical intervention," respondent acknowledges that Congress did not limit the term to surgeries involving intussusception. Resp't's Br. at 4-5 (citing Stavridis, 2009 WL 3837479, at *5 n.10 (quoting 145 Cong. Rec. S15213-03; 146 Cong. Rec. H8206-06)). Respondent, however, relies on the reasoning applied in Stavridis to support her position that a lumbar puncture and IVIG therapy are not surgeries. Respondent contends that the term "surgical intervention," "when examined in its ordinary and everyday usage," does not apply to diagnostic procedures like lumbar punctures or intravenous treatments like IVIG therapy. Resp't's Br. at 5-6 (citing Stavridis, 2009 WL 3837479, at *6). Additionally, respondent notes that lumbar punctures "are typically performed by non-surgeons" and that "IVIG administration is a nursing function." Resp't's Supp'l Br. at 3-4 (commenting on Court exhibits II and III). Ultimately, respondent defines "surgery" as "'the branch of medicine concerned with the treatment of disease, injury, and deformity by operation or manipulation.'"[19] Resp't's Br. at 3 (quoting Stedman's Medical Dictionary (26th ed. 1995)). Although she does not state expressly that a surgeon's participation is dispositive, respondent considers the type of health care professional who performs a given procedure as relevant in determining whether that procedures is a "surgery."

## Discussion

The principle issue is whether the lumbar puncture and/or IVIG treatment G.S. received during his inpatient hospitalization satisfies the Vaccine Act's severity requirement.[20] See Resp't's Mot. to Dismiss at 13-14; Pet'r's Resp. at 14-15. Ms. Spooner and respondent submit

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constitutes a surgical intervention was otherwise not discussed by the Court of Federal Claims" and thus "petitioner's argument is not aided by the Court's ruling in Hocraffer." Id.

[19] Like Ms. Spooner, respondent devoted the majority of her brief to arguments about "surgical intervention." Respondent does, however, respond to Ms. Spooner's argument regarding the Act's six-month injury requirement. Resp't's Br. at 6. Respondent states that "petitioner's assertion that [G.S.] suffered from emotional distress for one month after his injury subsided lacks any factual or legal basis." Id. She adds that the special master can make no finding "based upon the unsupported claims of petitioner alone." Id. (citing § 13(a)(1)).

[20] Respondent also addressed the issue of causation in her motion to dismiss. Resp't's Mot. to Dismiss at 8-13. Because the undersigned finds that Ms. Spooner has failed to produce preponderant evidence to satisfy the Act's severity requirement, a discussion of causation would be premature at this point in the proceedings.

diametrically opposing arguments regarding the scope of "surgical intervention." In sum, Ms. Spooner argues that the term should be construed broadly to comport with Congress's vision of a generous compensation scheme and its intent to expand the class of eligible petitioners, as evidenced by amendments to subsection 11(c)(1)(D). Pet'r's Br. at 2-9. Conversely, respondent argues that the term should be construed narrowly in accordance with the vaccine-linked condition and associated surgery that spurred Congress to amend the Act in 2000. Resp't's Br. at 3-4. Determining whether a lumbar puncture and/or IVIG treatment satisfies the Act's severity requirement necessitates consideration of the plain language of the Act and the Act's legislative history.

The Plain Language

The analysis of whether a lumbar puncture and/or IVIG therapy satisfies the Vaccine Act's severity requirement begins with the plain language of the statute. See Cloer, 654 F.3d at 1330. As the parties acknowledge, the term "surgical intervention" is not defined in the Act. See § 33 (Definitions). Generally, words not defined in a statute are given their ordinary and common meaning. Nichols v. Dep't of Veterans Affairs, 11 F.3d 160, 163 (Fed. Cir. 1993) (citing Perrin v. United States, 444 U.S. 37, 42 (1979)). Where Congress has used technical terms, "'it [is] proper to explain them by reference to the art or science to which they [are] appropriate.'" Corning Glass Works v. Brennan, 417 U.S. 188, 201 (1974) (quoting Greenleaf v. Goodrich, 101 U.S. 278, 284 (1880)). In such cases, the Federal Circuit has expressed approval of defining medical terms through the use of medical dictionaries, albeit in a non-precedential opinion. Abbott v. Sec'y of Health & Human Servs., No. 93-5129, 19 F.3d 39, slip op. at *6 (Fed. Cir. 1994) (discerning "no error" in the Court of Federal Claims's definition of a medical term not defined in the Vaccine Act, borrowed from "well known medical dictionaries" (Stedman's Medical Dictionary and Dorland's Illustrated Medical Dictionary)); see also Hervey v. Sec'y of Health & Human Servs., 88 F.3d 1001, 1002 (Fed. Cir. 1996) (using a dictionary to define a term in the Vaccine Act). Additionally, when words are joined in a phrase, the phrase "must, if possible, be construed in such fashion that every word has some operative effect." United States v. Nordic Village, Inc., 503 U.S. 30, 36 (1992); see also Mitchell v. Merit Sys. Prot. Bd., No. 2013-3056, slip op. at 5 (Fed. Cir. Jan. 15, 2014) ("Our answer starts with the text, where our task is to 'give effect, if possible, to every clause and word of [the] statute, avoiding, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language it employed.'") (quoting Inhabitants of Montclair Twp. v. Ramsdell, 107 U.S. 147, 152 (1883)); Saunders v. Sec'y of Health & Human Servs., 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.").

To determine the intended meaning of "surgical intervention," it is appropriate to look at the definitions of "surgical" and "intervention" in the reputable medical dictionaries that were available to Congress in 2000, when subsection 11(c)(1)(D) was amended. Additionally, and pursuant to the principle of statutory interpretation that a court should "construe a statute in a way which is consistent with the intent of Congress," it is also appropriate to consider the Act's legislative history. Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1570-71 (Fed. Cir. 1993). To that end, it is important to understand the problem Congress sought to remedy with the amendment. Liberation News Service v. Eastland, 426 F.2d 1379, 1383 (2d Cir.

1970) (quoting Interstate Commerce Comm'n v. J-T Transport Co., 368 U.S. 81, 107 (1961)) (Frankfurter, J., dissenting).

At the time the term "surgical intervention" was added to subsection 11(c)(1)(D) of the Act, "surgery," the nominative form of the adjective "surgical," was defined as "the branch of medicine that treats diseases, injuries, and deformities by manual or operative methods." Dorland's Illustrated Medical Dictionary at 1736-37 (29th ed. 2000) [hereinafter "Dorland's (29th); see also Stedman's Medical Dictionary at 1736 (27th ed. 2000) [hereinafter "Stedman's"] (defining "surgery" in nearly identical terms). In the medical context, "operative methods" includes "any act performed with instruments or by the hands of a surgeon." Dorland's (29th) at 1265 (defining "operation").

"Intervention" was also defined by reputable medical dictionaries in 2000. Dorland's defined "intervention" as "1. the act or fact of interfering so as to modify. 2. specifically, any measure whose purpose is to improve health or to alter the course of a disease." Dorland's (29th) at 91; see also Stedman's at 915 ("An action or ministration that produces an effect or that is intended to alter the course of a pathological process.").[21] In sum, "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.

Legislative History

As respondent recognizes, the amendment of the Act's severity requirement to include vaccine injuries resulting in "inpatient hospitalization and surgical intervention" was spurred by the recognition of the rotavirus-intussusception connection. Respondent also acknowledges, however, that the language of subsection 11(c)(1)(D)(iii), by itself, does not evidence congressional intent to restrict the term "surgical intervention" to surgeries for certain conditions. Resp't's Br. at 4. Moreover, Ms. Spooner correctly illustrates Congress's pattern of expansion regarding the class of persons eligible to receive compensation. Pet'r's Br. at 4, 7.

Although Congress did not limit the language of subsection11(c)(1)(D)(iii) to "surgical intervention" to treat intussusception, the amendment's legislative history supports an interpretation of "surgical intervention" that is consistent with the definitions of "surgery" and "intervention" at the time of the amendment, and thus is consistent with surgeries like that undertaken to treat intussusception. Recognizing the link between the rotavirus vaccine and intussusception, Congress acknowledged a "new situation" that "was not foreseeable" when the Vaccine Act was passed—that is, vaccine-linked injuries correctable with surgery and thus not persisting for longer than six months. Like severe cases of intussusception, these injuries likely would persist but for surgical intervention. Thus the definition of "intervention" as a measure to alter the course of a disease is consistent with congressional intent.

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[21] The omission of the words "to correct such illness, disability, injury or condition" from the final version of the 2000 amendment may have been due to redundancy. Compare 145 Cong. Rec. S15213-03, with 146 Cong. Rec. H8206-06.

Just as the definition of "intervention" is consistent with the problem Congress sought to remedy with subsection 11(c)(1)(D)(iii), so too is the definition of "surgery." The six-month injury requirement of subsection 11(c)(1)(D)(i) represents Congress's acknowledgment that a petitioner who has endured six months of pain and suffering (and who has established all other elements of subsection 11(c)(1)) deserves to be compensated for that pain and suffering. Implicit in 11(c)(1)(D)(i) is the potentially harsh reality that a petitioner who has endured only five months of pain and suffering (and who also has established all other elements of subsection 11(c)(1)) should not be compensated for his or her pain and suffering. Thus, 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 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.

Conclusions of Law

Although 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. As such, and for the reasons explained below, neither a lumbar puncture nor IVIG therapy qualifies as a "surgical intervention."

1. Lumbar Puncture

Although a lumbar puncture may be performed in a hospital's emergency department by a non-surgeon without the use of general anesthesia (Resp't's Supp'l Br. at 3; exhibit B at 1218), Ms. Spooner astutely points out that G.S.'s lumbar puncture was performed with general anesthesia. Pet'r's Br. at 6, 9. Additionally, and probably consequently, the procedure was performed in an operating room. Exhibit 6 at 69, 124, 288. To Ms. Spooner, the use of general anesthesia should impact the classification of a lumbar puncture. The hospital records support this position.

There is no indication in G.S.'s medical records that Ms. Spooner's signed consent for a specific procedure was a prerequisite to the first scheduled lumbar puncture, when sedation failed. However, prior to the rescheduled lumbar puncture, for which general anesthesia was planned, Ms. Spooner was required to sign a "Surgical Procedures" consent form for the lumbar puncture, and a separate consent form for the general anesthesia. Exhibit 6 at 51-54. The hospital records indicate that the use of general anesthesia changed the classification of the procedure to a "Surgical Procedure."[22] This reclassification is understandable given the

[22] Other hospital records referencing the March 25, 2010 lumbar puncture (but not the March 24, 2010 scheduled lumbar puncture) also use the terms "surgery" and "surgical procedure." See, e.g., exhibit 6 at 120, 132; see supra note 3.

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additional risks associated with general anesthesia, evidenced as well by heightened vigilance in the postoperative period. See exhibit 6 at 54 (listing the risks associated with general anesthesia), 126, 129 (referencing G.S.'s transfer to the postanesthesia care unit). Because the term "surgery" is not defined in the Act, it is proper to define it by referring to the scientific community in which it is used. Corning Glass Works, 417 U.S. at 201. As such, a lumbar puncture, when performed in an operating room with the use of general anesthesia, constitutes a "surgery" under the Act.

Despite this classification, however, the question remains whether such a procedure constitutes an "intervention" under the Act. The 2000 amendment did not authorize compensation to otherwise qualified vaccinees who underwent a "surgery." The surgery must be an "intervention." Interpreting a statute requires giving meaning and effect to each word in the relevant phrase. See Nordic Village, Inc., 503 U.S. at 36; Mitchell, No. 2013-3056, slip op. at 5; Saunders, 25 F.3d at 1035. Thus, the next question is whether a lumbar puncture is an intervention. Based on the medical definition of "intervention," a lumbar puncture ultimately is not an "intervention" under the Act.

A lumbar puncture is classified as a diagnostic procedure. See Court exhibit I; Court exhibit II; exhibit B (Goldman & Schafer) at 2231. The purpose of extracting CSF is "to obtain information relevant to the diagnosis and treatment of specific disease entities." Exhibit A (Roberts) at 1218. A lumbar puncture is not a "surgical intervention" because, based on the medical definition of "intervention," neither its purpose nor its effect is "to improve health or to alter the course of a disease."[23] Dorland's (29th) at 91. The cessation of a condition like GBS following a lumbar puncture is not due to the lumbar puncture, but rather subsequent medical treatment and/or natural biological processes. In other words, although confirming a diagnosis with a lumbar puncture may lead to the proper treatment, the procedure itself is not directly responsible for altering the course of a disease—it is not an "intervention."

Ms. Spooner argues that "surgical intervention" must be construed broadly to include procedures requiring general anesthesia. Pet'r's Br. at 9. Although the use of general anesthesia resulted in the hospital's reclassification of G.S.'s lumbar puncture as a "surgical procedure," that reclassification did not change the diagnostic nature of the procedure. For this reason, a lumbar puncture does not qualify as a "surgical intervention," under subsection 11(c)(1)(D)(iii) of the Vaccine Act.

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[23] In the event of hydrocephalus, colloquially known as "water on the brain," a lumbar puncture may have the purpose and effect of improving a patient's health. In such as case, a lumbar puncture may relieve the pressure caused by the accumulation of CSF. See Doe/34 v. Sec'y of Health & Human Servs., 2009 WL 1955140, at *9 (quoting a doctor who testified that "if you're suspicious of elevated pressure, we frequently defer to spinal tap"); see also Dorland's (32d) at 877 (defining "hydrocephalus").

2. IVIG Therapy

As explained above, a lumbar puncture may lead to the treatment responsible in whole or in part for resolving a condition. In the case of GBS, a diagnosis confirmed through CSF analysis frequently results in the administration of IVIG treatments. Thus, unlike a lumbar puncture, IVIG therapy, having a curative purpose and effect, is an "intervention." Also unlike a lumbar puncture under general anesthetic, and contrary to Ms. Spooner's contention, IVIG therapy is not a surgery. This conclusion is based on the medical definition of "surgery" and the legislative history of the 2000 amendment.

At the time "surgical intervention" was added to subsection 11(c)(1)(D) of the Act, "surgery" was defined as "the branch of medicine that treats diseases, injuries, and deformities by manual or operative methods." Dorland's (29th) at 1736-37. This definition incorporated, by reference, action "with instruments or by the hands of a surgeon." Id. at 1265 (defining "operation"). IVIG administration is not performed by a surgeon, or even a physician,[24] rather it is a nursing function. See Court exhibit III. This reality weighs against classifying IVIG treatment as a surgery. The legislative history of the 2000 amendment also weighs against such a classification.

In amending subsection 11(c)(1)(D)(iii), Congress drew a distinction between nonoperative reduction treatment and the surgery performed to resolve intussusception. One of the senators who sponsored the amendment noted the difference between "most cases of intussusception," which "require only *minimal treatment*," and the "few cases" requiring "hospitalization and *surgery*." 145 Cong. Rec. S15213-03; see supra note 9. The surgery performed to correct those "few cases" of intussusception requires general anesthesia and involves preoperative intubation, an incision in the abdomen, and manipulation and possible partial removal of the intestine. Court exhibit IV at 513-14; see supra note 9.

Less severe than intussusception surgery, IVIG treatment is analogous to the hydrostatic or pneumatic reduction treatment used to resolve most cases of intussusception. Neither reduction treatment nor IVIG therapy is performed with a general anesthetic. See Court exhibit IV at 513 (noting that the risks of radiation associated with several reduction attempts "must be weighed against the risks of emergency surgery and anesthesia"), Court exhibit III at 749 (indicating the optional use of a local anesthetic in IV administration). The analogy, however, is not perfectly symmetrical as a doctor (specifically a radiologist) performs reduction treatment (Court exhibit IV at 511) where IVIG administration is a nursing function (see Court exhibit III).

IVIG treatment is an "intravenous therapy," which treats diseases through the "introduction of . . . liquid agents directly into the venous circulation." Dorland's (32d) at 1911

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[24] There is a distinction between the terms "physician" and "surgeon" in the medical community. "Physician" is defined, in part, as "one who practices medicine as distinct from surgery." Dorland's (32d) at 1443. A "surgeon" is "a physician who specializes in surgery." Id. at 1808. Thus, while all surgeons are physicians, not all physicians are surgeons.

(defining "therapy"), 1913 (defining "intravenous therapy"). The intravenous administration of IG is markedly less severe than the surgery to resolve intussusception. Although IV catheterization, like the nonoperative reduction treatment to resolve intussusception, involves minimal invasion, it is not the type of problem that spurred Congress to amend the Vaccine Act's severity requirement. It is clear from the Congressional Record that subsection 11(c)(1)(D)(iii) was not added to the Act to address "minimal treatments" like the IVIG therapy G.S. received to treat his GBS.

For these reasons, IVIG therapy does not qualify as a "surgical intervention," under subsection 11(c)(1)(D)(iii) of the Vaccine Act.[25]

## Conclusion

For the reasons stated above, Ms. Spooner has failed to present factual allegations that G.S. suffered an injury that satisfies the Vaccine Act's severity requirement. Even assuming that all of Ms. Spooner's allegations are true, she has failed to state a claim upon which relief may be granted. Thus, respondent's motion to dismiss is **GRANTED**. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

**IT IS SO ORDERED.**

s/Christian J. Moran
Christian J. Moran
Special Master

[25] In addition to arguing that either a lumbar puncture or IVIG therapy satisfies the Act's severity requirement, Ms. Spooner also argues that G.S.'s injury could be found to have persisted for more than six months because "it is inconceivable that G.S. did not suffer at least one (1) month of 'emotional distress' after his ordeal." Pet'r's Resp. at 15 (citing § 15(a)(4)); see supra note 15. G.S. received the hepatitis A vaccine on March 17, 2010. Exhibit 1 at 1. On August 10, 2010, less than five months after G.S.'s vaccination, Ms. Spooner reported to doctors that G.S. was exhibiting "no after effects of his hospitalization." Exhibit 6 at 1. Ms. Spooner has filed no records to support her contention that G.S. suffered emotional distress following the resolution of his GBS. Moreover, Ms. Spooner herself acknowledges that G.S. was back to normal less than five months after his vaccination. A finding that a vaccinee satisfies one of the requirements of subsection 11(c)(1) may not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1). Ms. Spooner has failed to establish by preponderant evidence that G.S. suffered the residual effects of a vaccine injury for more than six months, pursuant to subsection 11(c)(1)(D)(i).