In the United States Court of Federal Claims

No. 18-759V
Filed: November 30, 2021[†]

SARAH FLORES and RYAN C. FLORES, on behalf of M.F., a minor child,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Jennifer Anne G. Maglio, Maglio Christopher & Toale, Sarasota, Florida, for Petitioner.

Kyle E. Pozza, Trial Attorney, *Traci R. Patton,* Assistant Director, *Heather L. Pearlman,* Acting Deputy Director, *C. Salvatore D'Alessio,* Acting Director, and *Brian M. Boynton,* Acting Assistant Attorney General, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent.

MEMORANDUM OPINION AND ORDER

TAPP, Judge.

Stripped of legalese and dense medical terminology, this case involves the effects of the measles, mumps, and rubella ("MMR") vaccine on a 14-month-old infant ("M.F."). Shortly following vaccination, M.F. developed an illness that Sarah Flores and Ryan C. Flores, parents and natural guardians of M.F., believed could be attributed to the administration of the vaccine. They filed a petition seeking compensation pursuant to the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, title III, Nov. 14, 1986, 100 Stat. 3755 (codified as amended at 42 U.S.C. §300aa-10, *et seq*.) (the "Vaccine Act" or "Vaccine Law").

The compensation program established by the Vaccine Act qualifies petitioners for compensation if they can establish that a vaccine injury led to "inpatient hospitalization and surgical intervention," ("surgical intervention provision") or caused "residual effects or

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[†] This opinion was originally filed under seal on November 5, 2021. Pursuant to Vaccine Rule 18(b), the Court provided the parties with the opportunity to review this opinion for any proprietary, confidential, or other protected information and submit proposed redactions no later than November 26, 2021. The parties did not propose any redactions, and, accordingly, this opinion is reissued for public access without redactions.

complications" that lasted "for more than 6 months after the administration of the vaccine" ("residual effect provision"). 42 U.S.C. §300aa-11(c)(1)(D)(i),(iii). Here, the Chief Special Master found that the child qualified for compensation under both conditions. The Respondent, Secretary of Health and Human Services ("the Secretary") objects. The Court affirms the Chief Special Master's finding that the Petitioner qualifies for compensation because of the residual effects of her injury but sets aside the Chief Special Master's finding that the child underwent "inpatient hospitalization and surgical intervention."

I. BACKGROUND

On June 23, 2016, M.F. received an MMR vaccine. This vaccine protects against three diseases: measles, mumps, and rubella.[1] (Petitioner's Exhibit "Ex." 1 at 1, ECF No. 7). Following vaccination, and after two accidental falls, M.F.'s parents noticed bruising and small red spots (later assessed to be petechiae) on her body. (Ex. 2 at 53). M.F.'s parents transported her to the Emergency Room on July 20, 2016, where she was assessed with a scalp contusion from her fall and diagnosed with severe idiopathic thrombocytopenic purpura ("ITP"), a condition in which a significant decrease in the number of blood platelets contributes to excessive bleeding and significant bruising. (Ex 9. at 33–34). Laboratory tests showed that M.F.'s blood platelet count was at two thousand.[2] (Ex. 10 at 9).

Doctors admitted M.F. to the hospital on July 20, for a hematology consultation. (*Id*.). She began receiving intravenous immune globulin ("IVIG"), with the goal of elevating her platelet counts.[3] (*Id*.) doctors recommended discharging M.F. after platelet levels went beyond 20 thousand. (Ex. 10 at 9–13). The medical assessment also noted that, should her platelet counts remain low, a "bone marrow/biopsy" needed to be considered "as next step in order to consider steroid trial as long as bone marrow findings are consistent with ITP." (*Id*.).

After M.F.'s platelet count reached 23 thousand, doctors discharged M.F. from the hospital on July 23, 2016, with follow-up labs scheduled with her pediatrician. (*Id*. at 9, 13, 216). During her follow up visit, lab tests again showed a short-lived response to IVIG treatment, with blood platelet levels back at 2 thousand. (*Id*. at 216, 219). M.F.'s pediatrician and the hospital determined that she should be re-admitted to the hospital to begin steroid treatment and "likely

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[1] *Measles, Mumps, and Rubella (MMR) Vaccination: What Everyone Should Know*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/vpd/mmr/public/index.html#what-is-mmr (last visited Oct. 22, 21).

[2] The normal range for children is between 150-400, and for infants between 200-475. K. Pagana & T. Pagana, MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th. Ed. 2010) at 416.

[3] 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. Robert M. Kliegman et al., NELSON TEXTBOOK OF PEDIATRICS 881-82 (19th ed. 2011).

undergo bone marrow testing" to "confirm diagnosis." (*Id*. at 216; Ex.15 at 164). On July 26th, M.F. underwent bone marrow aspiration and biopsy. (Ex. 10 at 494). The results of the operation indicated that "[t]he morphology in bone marrow and peripheral blood" were most consistent with ITP and that "[n]o evidence of Leukemia" was seen. (*Id*. at 448).

Medical professionals use bone marrow biopsy to assist in determining whether the marrow is producing a normal level of blood cells.[4] Dependent on the circumstances, such biopsies may be done on an in-patient or out-patient basis and may use general or local anesthetics. *See Bone Marrow Biopsy and Aspiration,* Mayo Clinic; *see also, e.g., Faup v. Sec'y of Health & Hum. Servs.*, No. 12-87V, 2017 WL 2257429, at *2 (Fed. Cl. Apr. 21, 2017). Here, the biopsy's pre-operation steps included filling out a "pre-surgery" checklist and completing surgical and anesthesia consent forms. (Ex. 10 at 294–303, 312). During the procedure, which was conducted under general anesthesia, a radiologist made a 3-millimeter incision in M.F.'s pelvis, inserted a boring needle through the bone into the marrow, and then aspirated marrow needed for testing. (Ex. 10 at 222, 317, 483, 494). After the procedure was completed, M.F. spent an hour and a half in the hospital's post-anesthesia care unit ("PACU") (*Id*. at 456). After the bone marrow operation, M.F. remained in the hospital to begin the steroid course that same night, consisting of Prednisone and Zantac for gastrointestinal protection. (*Id*. at 220). Doctors released M.F. from the hospital on July 28, 2016, with a blood platelet count of 6 thousand; the treatment plan included Prednisone and Zantac and checking platelet counts weekly to wean off the prescription as platelet counts normalized. (*Id*.)

Gradually, M.F.'s blood platelet counts returned to normal levels, and M.F.'s treating physician ordered a reduction in her medications in early September 2016. (Ex. 2 at 41, 53–54). Despite fluctuating, M.F.s platelet counts remained within the normal range long enough for the doctors to again decrease her steroid dosage later that month. (Ex. 2 at 33–35). Thereafter, M.F.'s blood platelets remained "within normal limits" over the upcoming months. (Ex. 2 at 19). On November 4, 2016, she was reported to be "fully off medication . . . for a couple of days," to "take a break," from lab testing. (Ex. 2 at 12). M.F. continued to be tested throughout the rest of 2016, and as late as February 10, 2017 (six months and 21 days after M.F. was first assessed with ITP); the lab tests showed that she maintained normal platelet count. (Ex. 2 at 6–7, 11).

On May 30, 2018, M.F.'s parents filed a petition for compensation under the Vaccine Act and submitted medical records establishing the facts described above. (*See generally* Pet., ECF No. 1). The Petition claimed that M.F. was entitled to compensation because the "related injuries [had] lasted more than six months," and "the minor child underwent hospitalization and surgical intervention as the result of her vaccine injury." (*Id*. at 3). The Chief Special Master issued the Ruling on Entitlement on February 1, 2021, finding that the Petitioner was entitled to compensation. (*See* ECF No. 59). Subsequently, the Chief Special Master issued a decision awarding damages according to the parties' agreement. (ECF No. 67). The Secretary reserved the right to seek review of the Chief Special Master's Findings of Fact and Conclusion of Law and

[4] *Bone Marrow Biopsy and Aspiration*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/bone-marrow-biopsy/about/pac-20393117 (last visited Oct. 25, 2021).

filed the motion to review on June 6, 2021. (Mot. for Review ("Resp't's Mot."), ECF No. 68; *see also* Findings of Fact and Conclusions of Law ("Facts and Law Ruling"), ECF No. 50).

II. ANALYSIS

Under the Vaccine Act, the judges of the Court of Federal Claims review a decision from the Office of Special Masters to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B). Upon review, the Court may either uphold findings of fact and conclusions of law, remand the petition to the special master for further action, or set aside the findings of fact or conclusions of law and issue its own. *Id*. In considering the Motion for Review and the record below, the Court applies the arbitrary and capricious standard to factual findings and reviews all legal conclusions de novo. *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

A. Inpatient Hospitalization and Surgical Intervention

The parties disagree on whether the legislative language that seeks to compensate those with vaccine-related injuries who undergo "inpatient hospitalization and surgical intervention" extends to patients who receive bone marrow aspiration and biopsy. (*See* Resp't's Mot. at 7). The Vaccine Act does not define "inpatient hospitalization and surgical intervention." Neither has the Federal Circuit addressed the definition before. A few decisions by the special masters have sought to define its contours. First, in *Stavridis v. Sec'y of Health & Hum. Servs.*, No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009), the question revolved around whether intravenous steroid treatments and blood transfusion qualified as surgical intervention. There, the Special Master refused to adopt a broad medical dictionary definition of "surgical intervention," holding that neither "the proposed medical definition of surgery" nor "lay persons" understanding of that term's ordinary meaning would encompass procedures such as "injections of medication or blood transfusions." *Id*. at *6.

Subsequently, in *Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014), the Special Master reviewed the question of whether a lumbar puncture and IVIG treatment qualified patients. The petitioner in *Spooner* preferred a broad definition. *Id*. at *7. They argued that any "invasive" procedure that aims "to remove or repair part of the body or to find out whether disease is present" qualifies as a surgical intervention. *Id*. at *8. The respondent in *Spooner* focused instead on the underlying purpose of the intervention, intending to draw a clearer line between "diagnostic procedures" and "treatment[s]." *Id*. The respondent in *Spooner* also urged the Special Master to consider the type of healthcare professional who performs a given procedure, as well as other trappings of the procedure, such as the use of general anesthesia, as relevant factors in determining whether a medical procedure counts as surgical intervention. *Id*. at *8–9. Reviewing the medical dictionary definitions of the terms "surgical" and "intervention," *Spooner* arrived at the following definition for "surgical intervention": "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*. at *10.

Under this definition, in *Spooner*, neither the lumbar puncture nor the IVIG treatment qualified as surgical interventions for different reasons. IVIG treatment *did* improve health or alter the course of the disease (therefore, was an intervention) but was not a surgery, because it

was administered by a nurse, carried low risk, and did not require anesthesia. *Id*. at *12–13. A lumbar puncture, on the other hand, *did* qualify as a surgery, as it was performed in an operating room with the use of general anesthesia yet was *not* an "intervention" because it was mainly conducted for diagnostic purposes (therefore, not intended to improve health or alter the course of the disease). *Id*. at *11–13.

Ivanchuk v. Sec'y of Health & Hum. Servs., No. 15-357V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. Sept. 18, 2015), followed and was the first attempt at resolving whether a bone marrow biopsy constituted "surgical intervention." *Ivanchuk* adopted *Spooner*'s definition of surgical intervention. *Id*. at *2. First, *Ivanchuk* held that a bone marrow operation is a surgical operation due to the use of anesthesia, existence of a preoperative checklist and consent forms, and the potential risks of such a procedure. *Id*. But in determining whether the operations qualified as an "intervention," *Ivanchuk* recognized that *Spooner*'s exclusion of diagnostic procedures from the definition presented "an incomplete characterization." *Id*. at *3. That is because, even though the bone marrow aspiration and biopsy did not directly improve health or alter the course of the disease, they might have done so indirectly. *Id*. Concerned with the full application of *Spooner*, the special master in *Ivanchuk* narrowly tailored its finding to the facts of the case, holding that because the bone marrow operation played "an integral part" in determining the course of the treatment going forward, it did constitute an intervention. *Id*.

Uncertainty persisted as to whether procedures that are not mainly aimed at treating the underlying condition can be considered intervention merely because they can have an impact on the course of treatment. After *Ivanchuk*, *Leming v. Sec'y of Health & Hum. Servs.*, No. 18-232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019), wrestled with the same issue, and the Special Master once again departed from the bright-line rule in *Spooner*. *Id*. at *6 (describing that the case presented an "atypical situation" outside of *Spooner*'s definition of "intervention"). In that instance, the Special Master found that because the bone marrow operation had an impact on the course of steroid treatments prescribed after the operation, it was not merely diagnostic and qualified as an "intervention." *Id*. Following a motion for review from that case, the Court of Federal Claims reversed that decision. *Leming v. Sec'y of Health & Hum. Serv*s., 154 Fed. Cl. 325, 2021 WL 2708938 (2021).[5] Chief Judge Kaplan agreed with the Special Master that the use of general anesthesia, existence of surgical consent forms, and characterization of an incision wound qualified the bone marrow operation as a surgery. *Id*. at *6. Chief Judge Kaplan, however, reversed the Special Master's determination that the operation involved an "intervention," holding that the qualification should be exclusively reserved for surgical procedures that are administered "to directly treat" the underlying illness after it has been diagnosed. *Id*. at *7.

Against the background of this Vaccine Act case law, in this case, the Chief Special Master's Findings of Fact and Conclusions of Law regarding M.F.'s bone marrow biopsy determined that her biopsy was "somewhat diagnostic," and therefore qualified as a surgical

[5] Neither previous decisions of special masters nor other decisions of the Court on this matter set binding precedent for a separate and distinct case pending in the Court such as this. *W. Coast Gen. Corp. v. Dalton*, 39 F.3d 312, 315 (Fed. Cir. 1994).

intervention. (Facts and Law Ruling at 7, ECF No. 50). The Secretary urges the Court to reverse the Chief Special Master's decision and reject the reasoning that bone marrow operations can qualify as a "surgical intervention" even if they can be conceived as having a "dual character" (having seemingly assisted in both diagnosis and treatment). (Resp't's Mot. at 16, ECF No. 68). Further, the Secretary contends that categorizing bone marrow operations as "somewhat diagnostic"—as the Chief Special Master did—creates a slippery slope whereby any diagnostic procedure with some "bearing on subsequent treatment" will be considered an "intervention." (*Id*. at 11). Such an approach, the Secretary argues, betrays the congressional intent behind the Vaccine Act's severity requirement by allowing minimally invasive cases to qualify for compensation. (*Id*. at 18–19). Conversely, the Petitioner argued that adherence to a bright-line rule separating diagnostic procedures from curative procedures fails to capture the complexity of many medical procedures that blur that line. (Petitioner's Response to Motion to Review ("Pet.'s Resp.") at 15, ECF No. 72).[6]

As the post-*Spooner* Vaccine Act case law indicates, this case presents the rare case in which the dictionary definition adds to the ambiguity in the phrase "surgical intervention," as opposed to curing it. Although *Spooner*'s dictionary-guided definition attempts to extrapolate the meaning of "intervention" as the act of "improving health or altering the course of a disease," that phrase does not announce its relationship to the term diagnosis any better than the term "intervention" does. The dictionary definitions of the term intervention, though informative, simply do not resolve the ambiguity as to what surgical procedures were intended to be covered by the law. The Court must therefore resort to a deeper analysis of the context in which the phrase surgical intervention appears in order to resolve the ambiguity.

In interpreting statutes, the Court must adhere to plausible interpretations of the statutory text that would "give effect to the intent of Congress." *In re Swanson*, 540 F.3d 1368, 1375 (Fed. Cir. 2008). The Court therefore looks not only to the particular text but "to the design of the statute as a whole and to its object and policy." *Id*. (citing *Crandon v. United States*, 494 U.S. 152, 158 (1990)).

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

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[6] The Petitioner incorrectly frames the Chief Special Master's decision with regards to the surgical intervention provision as one of applying an already "accepted interpretation of the statute" to the facts of this case. (Pet.'s Resp., at 5). Based on this framing, the Petitioner believes that the decision should be reviewed under the more deferential arbitrary and capricious standard of review. (*Id*.). The Chief Special Master's decision involved reviewing a "divergence" in case law on how to interpret the surgical intervention provision's language and ultimately adopting one approach in favor of the other. (Facts and Law Ruling, at 4,7). Statutory interpretation is a question of law, and, therefore, the Court reviews that ruling *de novo*. *Hanlon v. Sec'y of Health & Hum. Servs.*, 191 F.3d 1344, 1348 (Fed. Cir. 1999); *see also Leming*, 154 Fed. Cl. 325, 333 n.6 (2021).

which claimants could petition for compensation due to alleged vaccine-related injuries or death. 42 U.S.C. § 300aa-10(a). Most importantly, although Congress realized that experiencing adverse events after vaccination was a common occurrence, the goal of the Vaccine Act was not to compensate individuals for every unavoidable side-effect of vaccination.

The intent of the law, from its inception and through its amendments, has been to compensate those who suffer grave and serious injuries. *See* H.R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 (describing the proposed Vaccine Act as protection for "a small but significant number" of recipients who "have been gravely injured"); *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011) (en banc) (quoting H.R. Rep. No. 100-391 (1), at 699 (1987)) (noting that the Vaccine Act's "6 month requirement" should also be read to limit the availability of compensation to only those "who are seriously injured"); *see also* 145 Cong. Rec. S15213-03 (Nov. 19, 1999) (statement from Sen. Jim Jefford) (stating that the 2000 amendment was intended to protect those suffering from "cases of intussusception" who needed more than "only minimal treatment").

Congress amended the Vaccine Act in 2000 to expand compensation coverage in cases where the vaccine-related injury resulted in inpatient hospitalization and surgical intervention. *See* Children's Health Act of 2000, Pub. L. 106-310, § 1701, 114 Stat. 1151 ("2000 Amendment"). The Vaccine Act's 2000 Amendment evinces the same objective and policy as the original act. The main impetus behind passage of the 2000 Amendment was to address an ongoing issue with the administration of the Rotavirus vaccine. 145 Cong. Rec. S15213-14 (Nov. 19, 1999). In 1999, the CDC's Advisory Committee on Immunization Practices ("ACIP") informed Congress of an increased rate of intussusception among infants who had received the Rotavirus immunization. *See* Vaccines—Finding the Balance Between Public Safety and Personal Choice, 106th Cong. 40 (Aug. 3, 1999). ACIP described the condition to Congress as one in which segments of the intestine "telescop[es]" inside of another, causing an intestinal obstruction. *See* FACA: Conflicts of Interest and Vaccine Development—Preserving the Integrity of the Process, 106th Cong. 112 (June 15, 2000). Although most cases of intussusception were, and continue to be, treated by barium enema procedures, some patients require surgical operation. *Id; see also Spooner*, 2014 WL 504728, at *6. Because those patients who would undergo surgical operation would likely recover under six months, they were not qualified for compensation under the Vaccine Law as it existed. *See* Revisions and Additions to the Vaccine Injury Table, 66 Fed. Reg. 36735, at 36737 (proposed July 13, 2001) ("[M]ost patients with intussusception recover after immediate treatment and do not suffer lasting complications for more than 6 months."); *see also Spooner*, at *11. Congress found the surgical operation involved in treating intussusception severe enough that the law was amended accordingly to add an exception for those patients who undergo "inpatient hospitalization and surgical intervention." *Id*. In other words, in the surgical treatment protocol for intussusception, Congress saw a medical procedure that *by itself* could be severe enough to entitle patients for compensation even when their injuries did not last beyond the recovery from the medical procedure or up to six months. *Id*. Therefore, the legislative history of the 2000 amendment indicates that Congress must have fashioned the phrase "inpatient hospitalization and surgical intervention" to serve as a statutory proxy for measuring the degree of severity of individual invasive medical procedures. *Id*. This was done to ensure that medical operations that are similar in their degree of severity to the intussusception surgery would qualify under the Vaccine Act in the future. *Id*.

With this legislative background in mind, the Court finds that neither the Secretary nor the Petitioner's textual interpretation of the phrase "inpatient hospitalization and surgical intervention" is correct. The Petitioner overreads the statutory text while the Secretary underreads it. *See Nat'l Veterans Legal Servs. Program v. United States*, 968 F.3d 1340, 1350 (Fed. Cir. 2020). The Secretary's interpretation would improperly exclude a class of medical procedures that, despite their underlying diagnostic nature, are severe enough in magnitude to match intussusception surgery; the Petitioner's interpretation will improperly expand the scope of the law to cover minimally invasive diagnostic procedures. *See Young v. United Parcel Serv.*, 575 U.S. 206 (2015) (rejecting statutory interpretations that would "fail to carry out a key congressional objective in passing the Act.").

First, under the Secretary's interpretation, many of the other medical procedures that equally blur the line between diagnostic and curative—but are far more invasive and riskier than a bone marrow biopsy—would fail the test merely because they are diagnostic. *See, e.g.*, *Harmon v. Sec'y of Health & Hum. Servs*., No. 12-298V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. June 6, 2017) (brain biopsy to assess diagnosis of chronic autoimmune demyelinating illness as a result of receiving the Gardasil vaccination for the human papillomavirus ("HPV") vaccine); *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1277 (Fed. Cir. 2005) (conducting a brain biopsy to find causes of optic neuritis that could have been caused by tetanus toxoid ("TT") vaccination); *Portee v. Sec'y of Health & Hum. Servs.*, No. 16-1552V, 2018 WL 5284599 (Fed. Cl. Sept. 14, 2018) (conducting diagnostic arthroscopic surgery in case of shoulder injury after influenza vaccination); *Fields v. Sec'y of Health & Hum. Servs.*, No. 02-311V, 2008 WL 2222141, at *13 (Fed. Cl. May 14, 2008) (receiving a kidney biopsy to diagnose the cause of renal failure that could have been caused by hepatitis B vaccine).[7]

Second, the Secretary's bright-line rule for excluding all diagnostic procedures from the definition of "inpatient hospitalization and surgical intervention" cannot be easily squared with the legislative history of the 2000 Amendment. As noted, the legislative history behind the 2000 Amendment clearly indicates that Congress included the language "inpatient hospitalization and surgical intervention" to cover those who had required surgery to recover from intussusception. *Stavridis*, 2009 WL 3837479, at *3. Yet, the surgical operation associated with intussusception itself does not fit comfortably in either the diagnostic or curative categories. As our Vaccine Act case law indicates, intussusception is commonly treated by conducting a surgical operation which entails making a comparatively large incision in the abdomen to gain access to the abdominal cavity. *Spooner*, 2014 WL 504728, at *4. In many cases of intussusception, the procedure is followed by the curative step of bowel resection to remove parts of the intestine. *See, e.g., Carda v. Sec'y of Health & Hum. Servs.*, No. 14-191V, 2017 WL 6887368, at *6 (Fed. Cl. Nov. 16, 2017). However, in other instances, the same surgical procedure can be conducted

[7] It is irrelevant whether patients in the preceding cases were found to be entitled to compensation or even if the petitions sought compensation under the surgical intervention provision. The underlying fact patterns of such cases are merely illustrative of the universe of relatively similar medical procedures that the Court is likely to be presented with again in the future that under the Secretary's definition would be categorically excluded despite being more invasive than the bone marrow biopsy and aspiration in the present case.

in a more diagnostic nature and is aptly referred to as an "exploratory" laparotomy or celiotomy. *See, e.g.*, *Brooks v. Sec'y of Health & Hum. Servs.*, No. 14-563V, 2016 WL 2656110, at *2 (Fed. Cl. Feb. 26, 2016) ("An exploratory laparotomy and small bowel resection were performed . . . revealing a postoperative diagnosis" of intussusception). Therefore, because the exact procedure that motivated Congress to enact the 2000 Amendment could potentially be administered for either curative or diagnostic reasons, it is difficult to imagine that Congress intended to exclude a surgical procedure solely due to the underlying purpose behind its administration. Stated plainly, this reading would have excluded many vaccine-injury victims that Congress intended to protect.

Third, the Secretary's position fails to account for cases in which a patient's experience with a diagnostic procedure can be described as severe due to rare complications that can occur as a result of such diagnostic procedures. *See, e.g.*, *Puroll v. Sec'y of Health & Hum. Servs.*, No. 14-1112V, 2017 WL 3598108, at *4 (Fed. Cl. July 28, 2017) (developing an infection following an exploratory laparoscopy, extending hospital stay); (*see also* Ex. 10 at 295–303) (listing pain, bleeding and damage to surrounding areas as potential side effects of bone marrow biopsy).

As the Secretary contends, the rationale in allowing all cases of ITP in which the injured person undergoes bone marrow aspiration and biopsy, regardless of the outcome of the operation, belies the congressional intent to limit compensation to cases where injury is clearly severe. *See Cloer*, 654 F.3d at 1335 (Fed. Cir. 2011) (finding that petition requirements in the Vaccine Act are "intended to restrict eligibility to the compensation program"). Yet the Secretary's position, by tethering the definition of surgical intervention to the underlying purpose of the procedure equally risks betraying congressional intent.

Because the Court finds the dictionary definitions of "surgical intervention" inadequate in defining the full scope of that phrase, it must look to other tools of statutory construction to clarify its full meaning. *See United States v. Trek Leather, Inc.*, 767 F.3d 1288, 1300 (Fed. Cir. 2014) (finding that in analyzing statutory language, the court "is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and apply the proper construction of governing law.") (citing *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99 (1991)). When the dictionary definition does not resolve an ambiguity, the next best clues are neighboring terms and phrases. *See Life Technologies Corp. et al. v Promega Corp*, 137 S. Ct. 734 (2017); *see also United States v. Williams*, 553 U.S. 285, 294 (2008) ("[A] word is given more precise content by the neighboring words with which it is associated."). The maxim *noscitur a sociis*—that a word is known by the company it keeps—is used to define phrases that are capable of many meanings and to ground the definition of ambiguous phrases in a way that would avoid giving the Acts of Congress "unintended breadth." *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961).

The Court begins its analysis of the text with the cardinal proposition that a statute is to be read as a whole. *Massachusetts v. Morash*, 490 U.S. 107, 115 (1989). The meaning of the statutory language depends on the context, as words "have only a communal existence." *Florsheim Shoe Co., Div. of Interco v. United States*, 744 F.2d 787, 795 (Fed. Cir. 1984) (citing *National Labor Relations Board v. Federbush Co.*, 121 F.2d 954, 957 (2d Cir. 1941) (Hand, J.)). Each word takes its meaning from the setting it is used in, and each meaning, in turn, interpenetrates the other. *Shell Oil Co. v. Iowa Dept. of Revenue*, 488 U.S. 19, 26 (1988).

The first operative term in the phrase "inpatient hospitalization and surgical intervention" is "inpatient." Given the fact that most patients seeking treatment for intussusception were likely to be admitted to the hospital, the Court must analyze why Congress qualified the term hospitalization with the term "inpatient." *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (statutes must be construed so as to avoid rendering any word insignificant or superfluous). The best way to understand this is that Congress believed that, just like the term intervention, the phrase "inpatient hospitalization" also qualified the scope of the term surgical. Under this reading, whether a procedure is carried out on an inpatient or outpatient basis will have some bearing on the severity of the operation. By including the term inpatient, Congress was communicating that outpatient procedures should not normally meet the severity qualifications. *Max v. Gen. Revenue Corp*., 568 U.S. 371 (2013) (the courts should resort to the canon of *expressio unius*, the inclusion of a term means exclusion of the other, when the context indicates that Congress indeed considered "the unnamed possibility and meant to say no to it."). Following this reasoning, the phrase "inpatient hospitalization" can be read to qualify the reach of the phrase "surgical intervention," limiting its application to operations that are accompanied by inpatient care (an overnight stay in the hospital) to guide and monitor the recovery from the operation. *See* Dorland's Illustrated Medical Dictionary at 903 (29th ed. 2000) (defining inpatient as "a patient who comes to a hospital or other healthcare facility for diagnosis or treatment that requires an overnight stay."). Under this reading, the scope of the term surgical is modified by *both* the word "intervention" *and* the phrase "inpatient hospitalization." In particular, Congress coupled the phrase surgical intervention with the phrase inpatient hospitalization to provide at least one clear benchmark for severity of surgeries: surgical operations that are severe enough to require at least one overnight stay in the hospital.

As *Spooner* noted, unlike the statute's six-month limitation which focuses on the whole picture of the patient's vaccine-related illness and its long-term and temporal consequences, the surgical intervention provision narrows the lens to *one* potentially severe medical procedure. The Congressional intent behind the surgical intervention provision was to focus on "medical procedures" that 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." *Spooner*, 2014 WL 504728, at *11.

While it is conceivable that Congress intended a more tenuous relationship between inpatient hospitalization and the surgical operation, unmooring the two phrases from each other will clearly open the door for compensation in cases that seem to betray Congress's focus on severity and lead to absurd results. For example, program case law has clearly established that many common vaccine-related treatments that have resulted in inpatient hospitalization *by themselves* do not qualify for compensation under the surgical intervention provision. *See, e.g.*, *Stavridis*, 2009 WL 3837479, at *3–4 (denying compensation to a patient who received four days of inpatient hospitalization because blood transfusion did not constitute a surgery). Decoupling inpatient hospitalization and surgical intervention would lead to an absurd result. *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1570–71 (Fed. Cir. 1993) ("court[s] should seek to avoid construing a statute in a way which yields an absurd result and should try to construe a statute in a way which is consistent with the intent of Congress."). Patients who receive inpatient hospitalization solely to receive minimally invasive and non-surgical treatments, such as IVIG treatment or blood transfusion, can subsequently elect for a diagnostic bone marrow biopsy operation, which today can be routinely carried out on an outpatient basis. *See e.g.*, *Faup*, 2017 WL 2257429, at *2 (involving a patient who received bone marrow biopsy on an outpatient

basis).[8] The patient can then claim that the two isolated episodes of inpatient hospitalization and outpatient operation qualify them for compensation, even though no indicia of severity would be present in such a case. Therefore, both the term "inpatient hospitalization" and the term "surgical intervention" must be understood to apply to a medical procedure and not the underlying illness in general.

In this case, the record indicates that M.F.'s bone marrow operation and biopsy were not severe enough to have a connection with her inpatient hospitalization. Although M.F. was admitted to the hospital on July 25, 2016, a day before her bone marrow operation, the record indicates she was admitted on July 25th due to another episode of critically low blood platelet count as a short-lived response to IVIG treatment. (Ex. 10 at 226, 228 (indicating that the medical team approved of discharging M.F. only after her platelet levels reached 6 thousand)). The inpatient hospitalization was therefore not caused by the surgical intervention itself. After M.F. received her bone marrow operation on July 26th, the post-operation notes clearly indicated that the operation itself was not severe enough to require further inpatient care. The Physician's Post Procedure Orders indicated that M.F. only needed to stay in PACU for an hour and a half. (Ex. 10 at 313 (admitted at 1:01 PM and discharged at 2:50 PM)). Critically, the records of M.F.'s bone marrow biopsy procedure also indicate that further inpatient hospitalization after the bone marrow operation was due to management of M.F.'s still-low blood platelets levels, and not associated with the bone marrow operation itself. (Ex. 10 at 219–220 (physician notes indicating: "Goal >20 platelets for discharge"; "If platelet counts >20, ok for discharge home.")). *See Uetz v. Sec'y of Health & Hum. Servs.*, No. 14-29V, 2014 WL 7139803, at *4 (Fed. Cl. Spec. Mstr. Nov. 21, 2014) (finding the petitioner who received a lumbar puncture procedure to be ineligible for compensation because the procedure was not coupled with inpatient hospitalization).

Accordingly, M.F.'s case fails to meet the statutory definition of "inpatient hospitalization," and therefore fails to qualify under the surgical intervention provision of the Vaccine Law. Because the Court finds that M.F.'s bone marrow operation fails to meet the first clause of "inpatient hospitalization and surgical intervention," it need not consider the question of whether the bone marrow operation constituted surgical intervention. Answering whether a bone marrow operation—or a biopsy procedure in general—can constitute a surgical intervention is more suitably left for a case in which the patient's overnight stay at the hospital had a closer connection to the bone marrow operation, meeting the requirements of inpatient hospitalization. The Chief Special Master's finding of law that M.F. qualified for compensation because she received "inpatient hospitalization and surgical intervention" is reversed.[9]

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[8] Bone marrow operations are "usually performed as an outpatient procedure with the use of local anesthesia." *Standard Process for Bone Marrow Transplant*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/kimmel_cancer_center/cancers_we_treat/bone_marrow_transplant/standard_bone_marrow_transplant.html (last visited Nov. 5, 2021).

[9] The Secretary also argued that the Chief Special Master's finding that a bone marrow biopsy is a "surgical intervention" improperly expanded the Vaccine Act's limited waiver of sovereign

B. Residual Effects of Injury

The Secretary also argues that the Chief Special Master erred as a matter of law in finding that M.F. qualified for compensation under an alternative theory—namely, that she "suffered the residual effects or complications" of her injury for more than six months." 42 U.S.C. § 300aa-11(c)(1)(D)(i)). The Secretary's argument is twofold. (Resp't's Mot. 14–16). First, the Petitioner did not properly allege that M.F. was qualified for compensation under the residual effects provision, and, therefore, the Chief Special Master could not use that reasoning as a basis for granting compensation. (*Id*.). Second, the Secretary argues that the Chief Special Master erred in finding that evidence of continual testing and check-up for potential reoccurrence of a vaccine-injury was enough to constitute "residual effects or complications" of injury, even though the underlying vaccine-injury had, by all signs, subsided. (*Id*.)

Neither argument is availing. The Secretary's claim that the Petitioner "did not allege that M.F. had suffered the residual effects of her ITP beyond six months to satisfy the Act's residual effects requirement" is incorrect. The Petition, after claiming vaccine causation, expresses a claim based on residual effects, reading in relevant part: "M.F.'s related injuries have lasted more than six months; the minor child underwent hospitalization and surgical intervention as the result of her vaccine injury." (Pet. at 4); *see also* RCFC, App. B, Vaccine Rule 2(c)(1) ("Vaccine Rules") ("The petition must set forth "a short and plain statement" of the grounds for an award"). Likewise, the Secretary's argument that the Petitioner failed to rebut its statement that "[p]etitioners do not allege that M.F. suffered the residual effects of her ITP beyond six months" is also inaccurate. (Resp't's Mot. at 15). Vaccine Rules 8(f) only requires that facts or arguments be raised "in the record before the Special Master" to be preserved. Accordingly, the issue was not waived.

Secondly, the main interest protected by the waiver doctrine is ordinarily presumed to be preserving the opposing party's right to be notified and the fair opportunity to respond. *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005) (citing *Smith v. Sushka*, 117 F.3d 965, 969 (6th Cir. 1997)). Given the record below, it can hardly be credibly argued that the parties were deprived of adequate notice and the opportunity to respond to the Chief Special Master's reasoning. During the hearing conducted on October 2, 2020, the Chief Special Master clearly laid out his reasoning prior to issuing a ruling on entitlement and notified both parties that the upcoming ruling will rely on both his definition of "surgical intervention" as it applied to the facts of the case and his finding that the Petitioner had satisfied the six-months requirement for residual effects. (*See* Transcript, ECF No. 52 at 17–19). After notifying both parties of the basis of his forthcoming ruling on entitlement, the Chief Special Master also gave the Secretary the opportunity to express any objections "to other aspects of the claim" in a status report in advance of the ruling being issued. (*Id.*) The record does not suggest that the Secretary used this opportunity to object. *See also* Vaccine Rule 20(a)(3) (motions can also be made at any time "orally during a hearing").

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immunity. (Resp't's Mot. at 12). Because the Court sets aside that finding, it finds the Secretary's sovereign immunity argument to be moot at this juncture.

Speedy resolution of Vaccine Law cases is exceedingly important. As the Supreme Court has noted, the Act established a no-fault compensation program that is particularly designed to "work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). To that end, the Federal Circuit has confirmed that the Vaccine Act eschews many procedural elements of tort litigation with a goal of establishing what instead could be labeled as a "compensation program." *Knudsen v. Sec'y of Health & Hum. Servs*, 35 F.3d 543, 549 (Fed. Cir. 1994). Under this system, petitioners' claims are to be reviewed and handled "quickly, easily, and with certainty and generosity." *Id*. Congress has routinely stressed the need for preserving the "informal, flexible, and expeditious," nature of the vaccine injury compensation system. H.R. Rep. No. 101-247, at 510 (1989). The Vaccine Rules of the Federal Court of Claims also clearly embody this spirit. For example, Vaccine Rule 1(b) provides that in all matters not specified by the vaccine rules, the special master and the court may regulate the practice "with the purpose of the vaccine act" in mind: "to decide the case promptly and efficiently." Vaccine Rule 3(b)(2) emphasizes the role of the special master in "endeavoring to make the proceedings expeditious, flexible, and less adversarial," but with an eye towards "creating a record sufficient to allow review of the special master's decision." With this goal established, an adequate record has been created before the Chief Special Master in this case to consider the Petitioner's claim for qualifying under the residual effects provision.

As to the merits of the Chief Special Master's finding that M.F. qualifies for compensation under the residual effects provision, the Court finds no error. Under that provision, patients are qualified for compensation if they can establish that they "suffered the residual effects or complications" of their "illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. §300aa-11(c)(1)(D)(i).

The parties agree on the following timeline: M.F. received her vaccine on June 23, 2016. The first symptoms of M.F.'s injury appeared only a few days after. M.F. was hospitalized intermittingly in July 2016 and began a course of steroid treatment on July 26, 2016. M.F.'s blood platelet count entered the normal range on or around September 1, 2016. When the decision was made to cut the steroid dose in half in response to those numbers, M.F.'s platelet count dropped once again, and the dosage was increased again. Throughout the rest of September 2016, M.F.'s platelet level returned to normal again, with fluctuations. On October 5, 2016, M.F.'s mother was directed to decrease the dosage again, and labs from the end of October showed platelet count that was within normal limits. At the end of October, M.F.'s mother was instructed to reduce the dosage to "every other day for a week, then stop." (Ex. 12 at 18). By November 4, 2016, M.F.'s mother reported that she had been "off medication now for a couple of days," and that the plan was to "take a break" from lab testing. (Ex. 2 at 12). The final medical test on the record for M.F. is from February 10, 2017, showing a normal platelet count. Importantly, undisputed medical records establish that M.F.'s treatment and monitoring continued until finally discharged by the hematology clinic in August 2017. (Ex. 12 at 5). The Secretary did not suggest, much allege or establish, that M.F.'s continual monitoring by the hematology clinic was medically unnecessary or outside the appropriate standard of care.

Reviewing these facts, the Chief Special Master found that although M.F.'s blood platelet levels (the most pronounced symptom of her vaccine-injury) stabilized in under six months, she continued to be subject to "ongoing monitoring," and a "need for medication," beyond six-months to ensure that her condition did not return. (Facts and Law Ruling at 7). This, the Chief

Special Master found, was enough to constitute "residual effect," and qualify M.F. for compensation. (*Id*.).

The Secretary finds that conclusion to be incompatible with *Crabbe v. Sec'y of Health and Hum. Servs.*, No. 10-762V, 2011 WL 4436724, at *5 (Fed. Cl. Spec. Mstr. Aug. 26, 2011). In *Crabbe*, the vaccine-related injury was also ITP, and like this case, the patient's medication course had ended in under six months with all symptoms of ITP (low blood platelet count, rash, or petechiae) successfully disappearing. Although the Special Master in *Crabbe* refused to consider other medical visits made in the six-month period as "residual effects" of the injury, the nature of those visits differed from the medical visit in this case. Importantly, in *Crabbe*, the patient's ongoing medical visits were brought about by bouts of illnesses unrelated to ITP; the petitioner in *Crabbe* argued that each of these episodes of unrelated illness nonetheless triggered in the patient's parents a worry that their child's ITP condition might have returned (concerns that were negated through diagnosis). *Id*. at *4-5. The *Crabbe* special master therefore viewed the argument presented as whether "a mere increased risk of recurrence of an injury" can constitute "residual effect." *Id*. Unlike *Crabbe*, the facts of this case indicate that M.F. received "ongoing monitoring" of her condition and repeated check-ups on her platelet levels not because of an unfounded fear that her ITP might have reoccurred but as an actual part of her ongoing "treatment protocol" with the same medical team that had overseen her recovery from ITP. (Ex. 2 at 6, 19; Ex. 12 at 5–6) (detailing ongoing visits with the same hematology team that oversaw M.F.'s ITP recovery). Reviewing the specific records in this case, the Chief Special Master gave weight to the fact that unlike in *Crabbe*, M.F.'s continual monitoring was prescribed by her medical team and therefore constituted part and parcel of a longer but uninterrupted treatment plan (Facts and Law Ruling at 7); *see also, Faup*, 2015 WL 443802, at *2 (Fed. Cl. Spec. Mstr. Jan. 13, 2015) (finding ongoing monitoring of the vaccine-related injury to be a residual effect when routine check-ups were ordered by the medical team); *H.S. v. Sec'y of Health and Hum. Servs.*, No. 14-1057V, 2015 WL 1588366, at *3 (Fed. Cl. Spec. Mstr. March 13, 2015) (same).

At least one other judge on the Court of Federal Claims has determined that ongoing monitoring or testing could constitute residual effects lasting more than six months from administration of the vaccine so long as "testing is causally connected to the underlying vaccine injury and triggered by subsequent symptoms of the conditions," and even when monitoring and testing do not reveal the reoccurrence of any ongoing symptoms. *Wright v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 608 (2019). Like this case, *Wright* also involved continual platelet testing in response to ITP. Unlike this case, however, *Wright* involved the patient "repeatedly undergoe[ing] unscheduled medical tests," after the hematology team overseeing the onset of symptoms had already viewed the ITP condition as "resolved." *Id*. at 610, 614. *Wright* raises more difficult questions over whether subsequent testing and check-ups conducted at the patient's behest can demonstrate residual effects after the original treatment course has ended. *Wright* answers that in the affirmative. Yet *Wright's* holding is inapplicable here because no part of M.F.'s treatment was either elective or occurred after the original treatment course concluded. Although M.F. ceased taking steroids in early November, the hematology team overseeing the treatment saw this as "tak[ing] a break," indicating that the medical team viewed M.F.'s treatment as contingent and continuing. (Ex. 2 at 12). Doctors ordered both subsequent lab drawings in late November and in February 2017. (Ex. 12 at 13, 15, 20). Both the decision to "space[] out" the lab draws and to eventually stop them was made by the medical team. (Ex. 12 at 7,13). M.F.'s last visit to the hematology clinic in August of 2017 was also prescribed by the

medical team and viewed as a precondition for discharge from the hematology clinic, thereby ending the course of treatment. (Ex. 12 at 5, 10 (clinical note reading: "Parents to notify us when labwork obtained so we can follow up results. If normal, will discharge her from Hematology.").[10] The Chief Special Master's assessment that M.F.'s ongoing monitoring of her condition satisfied the residual effect standard was not a legal error, and, therefore, the Chief Special Master's decision as to that issue should be affirmed.

III. Conclusion

Based on the foregoing, the Court hereby **GRANTS** the Secretary's Motion for Review, (ECF No. 68), and **AFFIRMS IN PART** and **REVERSES IN PART** the Chief Special Master's October 26, 2020 Findings of Fact and Conclusions of Law (ECF No. 50). Based on the Court's Findings of Fact and Conclusions of Law, the Court finds that the Petitioner is entitled to compensation only under 42 U.S.C. §300aa-11(c)(1)(D)(i). The Chief Special Master's ruling on entitlement granting compensation to Petitioner is **SUSTAINED**. The Clerk is directed to enter final judgment accordingly.

IT IS SO ORDERED.

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

[10] It is conceivable that certain ITP treatment plans involve prescribed monitoring and checkups for such an unreasonably extended period of time so as to fall outside any reasonable standard of care. Because neither party has called the reasonableness of standard of care in this case into question, the Court has no occasion to review or decide whether the ordered duration of checkups and monitoring in this case falls short of that standard.