

# In the United States Court of Federal Claims

(Filed Under Seal: June 16, 2021 | Reissued for Publication: July 1, 2021)\*

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VICTORIA LEMING and KEVIN LEMING,  
Parents and Natural Guardians of A.L.,  
A Minor,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN  
SERVICES,

Respondent.

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No. 18-232V

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*Julia M. Collison*, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, with whom were *Alexis B. Babcock*, Assistant Director, *Heather L. Pearlman*, Acting Deputy Director, *C. Salvatore D'Alessio*, Acting Director, and *Brian M. Boynton*, Acting Assistant Attorney General, for Respondent.

## **OPINION AND ORDER**

**KAPLAN, J.**

This case, which arises under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (“Vaccine Act” or “the Act”), is before the Court on a motion for review filed by the Secretary of Health and Human Services (“the Secretary”). The Secretary challenges Special Master Nora B. Dorsey’s ruling that a bone aspiration performed along with a biopsy to determine the proper treatment for petitioner A.L.’s vaccine-related injury was a “surgical intervention” for purposes of 42 U.S.C. § 300aa-11(c)(1)(D)(iii). The government contends that the Special Master’s interpretation of the statutory language was legally erroneous and that additionally—because A.L.’s injury did not last more than six months, *id.* § 300aa-11(c)(1)(D)(i), nor result in her death, *id.* § 300aa-11(c)(1)(D)(ii)—her injury was not severe enough to satisfy the Act’s minimum eligibility threshold.

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\* Pursuant to Vaccine Rule 18(b), this opinion was initially filed on June 16, 2021, and the parties were afforded fourteen days to propose redactions. The parties did not propose any redactions and, accordingly, this Opinion is reissued in its original form for publication.

For the reasons set forth below, the Court concludes that the Special Master’s decision was contrary to law. While the bone aspiration was a surgical procedure, it was not a surgical “intervention.” *Id.* § 300aa-11(c)(1)(D)(iii). The Secretary’s motion for review, ECF No. 75, is therefore **GRANTED**.

## **BACKGROUND**

### **I. A.L.’s Vaccine and Hospitalization**

On September 6, 2016, during a scheduled well-child visit, fifteen-month-old A.L. received the measles-mumps-rubella-varicella (MMRV) vaccine, the diphtheria-tetanus-acellular pertussis (DTaP) vaccine, and the Haemophilus influenzae type b (Hib) vaccine. Pet’r’s Ex. 1 at 37–39, ECF No. 5-1. Within the next week, A.L. developed a rash and fever. Pet’r’s Ex. 13 at 3, ECF No. 24-1. A.L.’s mother reported the rash to the pediatrician on September 16, 2016. *Id.* By this point, A.L. no longer had a fever, and she was sleeping and eating normally. *Id.* The pediatrician told A.L.’s mother that the rash was likely roseola and that no treatment was needed. Pet’r’s Ex. 8 at 214, ECF No. 5-8.

A few days later, however, on September 29, 2016, A.L. presented to the emergency room with a petechial<sup>1</sup> rash on her body and tongue, and bleeding gums. *Id.* at 215. A blood test revealed a low platelet count. *Id.*

A.L. was admitted to the hospital and administered one dose of intravenous (“IV”) immunoglobulin. *Id.*<sup>2</sup> After A.L. received the treatment, she exhibited increased bruising and the next day, on September 30, 2016, was transferred to Children’s Hospital in Omaha. *Id.* She received a second dose of IV immunoglobulin at Children’s Hospital and again showed no improvement. Pet’r’s Ex. 4 at 16, ECF No. 5-4.

On October 1, A.L.’s consulting physician, Dr. Stefanie Lowas, recorded that immune thrombocytopenia purpura (“ITP”) was the “most likely” explanation for A.L.’s symptoms, but that other diagnoses, albeit “very unlikely” ones, “could include congenital platelet disorders, acquired bone marrow failure, and leukemia.” *Id.* at 21.<sup>3</sup> Dr. Lowas commented that, while “IV

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<sup>1</sup> Petechiae are small pinpoint skin rashes that can arise due to insufficient platelets. *See Dorland’s Illustrated Medical Dictionary* 1401 (33d ed. 2020) (explaining that petechiae are “purplish red spot[s] caused by intradermal or submucous hemorrhage”).

<sup>2</sup> IV immunoglobulin is antibody-containing solution derived from plasma that is used to treat patients with antibody deficiencies and autoimmune diseases. S. Jolles, W.A.C. Sewell & S.A. Misbah, *Clinical Uses of Intravenous Immunoglobulin*, 142(1) *Clinical & Experimental Immunology* (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/>.

<sup>3</sup> ITP “is a disorder that can lead to easy or excessive bruising and bleeding [which] results from unusually low levels of platelets.” *Immune thrombocytopenia (ITP)*, Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/idiopathic-thrombocytopenicpurpura/symptoms-causes/syc-20352325>; *see also* 42 C.F.R. § 100.3(c)(7) (characterizing thrombocytopenic

[immunoglobulin] serves as a very good diagnostic and therapeutic measure for ITP, it may be ineffective in about 25% of patients with ITP.” Id. For these patients, she explained, “[t]here are numerous other treatment options,” but an ITP “diagnosis should be confirmed before any of these are given.” Id. Dr. Lowas recommended that, if A.L.’s platelet count did not increase within the next two or three days, A.L. receive a “bone marrow aspirate/biopsy to rule out bone marrow disorders” and that “[a]fter that, other ITP therapies may be considered.” Id.

In fact, A.L.’s platelet count did not improve over the next several days. As a result, and consistent with Dr. Lowas’ recommendation, her treating physician, Dr. James Harper, agreed that A.L. “should have a bone marrow aspirate and biopsy to [rule out other diagnoses] before starting steroids.” Id. at 53.

On October 4, 2016, Dr. Harper completed a preoperative checklist, id. at 74, and placed A.L. under general anesthesia, id. at 80. He conducted a bone marrow needle aspiration and biopsy. Id. at 79–81.<sup>4</sup> The procedure yielded no evidence of cancer or other blood cell disorders. Id. at 117. Dr. Harper therefore concluded that there was no contraindication to A.L. starting IV steroid treatment for her ITP. Id. at 52.

A.L. thereafter received steroid treatment which was effective and resulted in an improvement in her platelet count. Id. at 4. As a consequence, A.L. was discharged from the hospital on October 12, 2016. Id. at 3–5. A follow-up examination was conducted on December 30, 2016, almost four months after A.L. received the vaccinations. Pet’r’s Ex. 9 at 60–67, ECF No. 5-9. A.L.’s hematologist reported that her platelet counts were normal, and that she suffered from no other remaining symptoms. Id. at 60–61. In addition, a pediatric immunologist determined that A.L.’s ITP episode had resolved and that there was no need for further treatment. Pet’r’s Ex. 10 at 9, ECF No. 5-10.

## **II. The Vaccine Claim and the Special Master’s Ruling on Facts**

On February 14, 2018, A.L.’s parents, Victoria and Kevin Leming, filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-1 to -34. In their petition, the Lemings alleged that the vaccines that A.L. received on September 6, 2016 caused her to experience immune thrombocytopenic purpura, immune dysfunction, and immunodeficiency. Pet. for Comp. Under the Vaccine Act at 1, ECF No. 1.

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purpura as “the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm<sup>3</sup>”).

<sup>4</sup> The procedure to conduct a bone marrow aspiration and biopsy require that a child be sedated—occasionally with general anesthesia—and that specialized needles then be used to remove samples of bone and marrow from the child’s hip area. Oussama Abla, Jeremy Friedman & John Doyle, Performing bone marrow aspiration and biopsy in children: Recommended guidelines, 13(6) Paediatrics & child health 499–501 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2532899/>.

The case was assigned to then-Chief Special Master Nora Beth Dorsey on February 15, 2018. ECF No. 4. On December 21, 2018, the Secretary filed a Vaccine Rule 4(c) report. ECF No. 34. In it, he asserted petitioners were not eligible for compensation because they could not show that A.L. either suffered the residual effects or complications of a vaccine-related injury for more than six months after vaccination or that her injury resulted in inpatient hospitalization and surgical intervention, as required to satisfy the Act's so-called "severity" requirement. See Ruling on Facts ("Ruling") at 2, ECF No. 41 (characterizing 42 U.S.C. § 300aa-11(c)(1)(D) as the "severity requirement" of the Vaccine Act). On March 26, 2019, both parties filed motions for a ruling on the facts. ECF Nos. 38 & 39.

Special Master Dorsey issued her Ruling on Facts on July 12, 2019. She determined that A.L. was entitled to compensation under the Vaccine Act. Ruling at 9. As pertinent to the present motion for review, Special Master Dorsey acknowledged that A.L. had not suffered ITP-related sequelae for six months as required to be eligible for compensation pursuant to clause (i) of 42 U.S.C. § 300aa-11(c)(1)(D). Ruling at 5–7. However, she found her eligible for compensation under clause (iii), concluding that the bone aspiration and biopsy performed on A.L. while she was hospitalized constituted a "surgical intervention." Ruling at 8–9 (citing 42 U.S.C. § 300aa-11(c)(1)(D)(iii)).

In her decision, Special Master Dorsey purported to endorse the interpretation of clause (iii) set forth in Spooner v. Secretary of Health and Human Services, No. 13-159V, 2014 WL 504728 (Fed. Cl. Jan. 16, 2014) (Moran, Special Master). See Ruling at 7. In that case, Special Master Moran, relying primarily upon Dorland's Illustrated Medical Dictionary, defined a surgical intervention as "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." Spooner, 2014 WL 504728, at \*10 (citing Dorland's Illustrated Medical Dictionary 911, 1736–37, 1265 (29th ed. 2000) (defining "intervention," "surgery," and "operation")); Ruling at 7. Applying this definition, Special Master Moran concluded that a lumbar puncture conducted under general anesthesia was a "surgical procedure," but that it was not a "surgical intervention," because the lumbar puncture is a diagnostic procedure and not one whose purpose is to treat an injury. Spooner, 2014 WL 504728, at \*12.

Special Master Dorsey opined that A.L.'s bone aspiration and biopsy was both "surgical" and an "intervention." Ruling at 9. The procedure was a surgical one, she held, because: (1) A.L. was placed under general anesthesia; (2) "[a] preoperative checklist was completed"; (3) "A.L.'s mother signed a consent for a surgical procedure"; and (4) "A.L. was monitored by the [post-surgical anesthesia care unit] following the procedure." Id. at 8.

Special Master Dorsey further determined that the surgical procedure was an "intervention." Id. at 8–9. She acknowledged that "a bone marrow biopsy is, typically, not a treatment that alters the course of a disease or condition." Id. at 8. Rather, it is generally used for diagnostic purposes. However, Special Master Dorsey explained, "the facts of this case present an atypical situation" because "the bone marrow biopsy was required in order to institute treatment" and not to "diagnose A.L.'s condition." Id. at 8–9. In her view, the bone marrow biopsy was a surgical intervention because it was "a necessary and integral part of the overall treatment protocol that ultimately cured A.L.'s ITP." Id. at 9. Further, according to Special

Master Dorsey, her ruling was “narrowly tailored to the facts and circumstances presented by this case and is not a finding that [a] bone marrow biopsy constitutes a surgical intervention in all circumstances.” Id.

### **III. Subsequent Ruling on Entitlement**

On October 1, 2019, the case was reassigned to Special Master Brian H. Corcoran. The Secretary filed his Amended Vaccine Rule 4(c) report on November 2, 2020. ECF No. 65. In it, he preserved his right to appeal the Special Master’s July 12, 2019 Ruling on Facts but agreed that petitioners had otherwise satisfied the legal prerequisites for compensation under the Vaccine Act. Id. at 4–5. On November 4, 2020, Special Master Corcoran issued a Ruling on Entitlement, finding petitioners entitled to compensation in the amount of a lump sum payment of \$35,000 representing pain and suffering, and a lump sum payment of \$5,992.89 representing compensation for past un-reimbursable expenses. Decision Awarding Damages at 2, ECF No. 74.

### **IV. The Motion for Review**

On March 18, 2021, the Secretary moved for review of Special Master Dorsey’s Ruling on Facts pursuant to 42 U.S.C. § 300aa-12(e)(1). Resp’t’s Mem. in Supp. of Mot. for Review (“Resp’t’s Mot.”), ECF No. 75. The Secretary challenges the Special Master’s determination that A.L.’s injury met the so-called “severity” requirement set forth in 42 U.S.C. § 300aa-11(c)(1)(D). He argues that the Special Master “erred as a matter of law in failing to interpret ‘surgical intervention’ in the context of the Vaccine Act as a unified whole, including the legislative history,” Resp’t’s Mot. at 4, and that her finding that the bone aspiration and biopsy was a surgical intervention “diminishes the intent of the Vaccine Act’s severity requirement,” id. at 9.

Petitioners filed a response to the Secretary’s motion on April 19, 2021. Pet’r’s Mem. in Resp. to Resp’t’s Mot. for Review (“Pet’r’s Resp.”), ECF No. 78. The Court held oral argument on the motion via videoconference on May 26, 2021.

## **DISCUSSION**

### **I. Jurisdiction and Standard of Review**

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. Figueroa v. Sec’y of Health & Hum. Servs., 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). The Act is remedial legislation that should be construed to “effectuate[] its underlying spirit and purpose.” Id. at 1317 (citing Cloer v. Sec’y of Health & Hum. Servs., 675 F.3d 1358, 1362 (Fed. Cir. 2012)).

A petition seeking compensation under the Vaccine Act must be filed in the Court of Federal Claims, after which the Clerk of Court forwards it to the Office of Special Masters for assignment. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned “issue[s] a decision on such petition with respect to whether compensation is to be provided

under the [Vaccine Act] Program and the amount of such compensation.” Id. § 300aa-12(d)(3)(A).

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the decisions of special masters (subject to further review in the Federal Circuit). Mahaffey v. Sec’y of Health & Hum. Servs., 368 F.3d 1378, 1383 (Fed. Cir. 2004) (citing 42 U.S.C. § 300aa-12(d)(3)(A)). On review, the Court has several options. It may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2); see also Vaccine Rule 27.

When considering a motion for review of a special master’s decision, the Court applies the arbitrary and capricious standard to factual findings and the “not in accordance with law” standard to legal rulings. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). Its review of legal determinations is de novo. Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1278–79 (Fed. Cir. 2005); see also Carson v. Sec’y of Health & Hum. Servs., 727 F.3d 1365, 1368 (Fed. Cir. 2013) (instructing the reviewing court to “give no deference to the . . . Special Master’s determinations of law, but uphold the Special Master’s findings of fact unless they are arbitrary or capricious”).

## II. Merits

A petitioner may establish entitlement to compensation under the Vaccine Act by: (1) showing that he or she has “sustained” or “significantly aggravated” “any illness, disability, injury, or condition” set forth in the Vaccine Injury Table, in association with a vaccine set forth in the Table, and within the time period set forth in the Table, see Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1341–42 (Fed. Cir. 2010) (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i)); or (2) by proving by a preponderance of the evidence that his alleged injury was caused by a vaccine, 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)(A); see also Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). Either way, pursuant to what is sometimes characterized as the Vaccine Act’s “severity requirement,” see Ruling at 2, a petitioner must also prove that her alleged vaccine-related illness, disability, injury, or condition either lasted longer than six months, 42 U.S.C. § 300aa-11(c)(1)(D)(i), resulted in death, id. § 300aa-11(c)(1)(D)(ii); or “resulted in inpatient hospitalization and surgical intervention,” id. § 300aa-11(c)(1)(D)(iii). The issue in this case is the proper interpretation of the “surgical intervention” language contained in clause (iii) of 42 U.S.C. § 300aa-11(c)(1)(D), and its application to the bone marrow aspiration and biopsy procedure performed on A.L.

It is well-established that “[t]he best evidence of congressional intent [in passing legislation] is the plain meaning of the statutory language at the time Congress enacted the

statute.” Strategic Hous. Fin. Corp. of Travis Cty. v. United States, 608 F.3d 1317, 1323–24 (Fed. Cir. 2010); see also Park ‘N Fly, Inc. v. Dollar Park & Fly, Inc., 469 U.S. 189, 194 (1985) (“Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.”). The “court’s proper starting point,” therefore, “lies in a careful examination of the ordinary meaning and structure of the law itself.” Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019). Further, where “that examination yields a clear answer,” it is improper for the court to go further and look to extrinsic evidence of Congressional intent. Id.; see also Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 568 (2005) (instructing that “the authoritative statement is the statutory text, not the legislative history or any other extrinsic material[s]”); Myore v. Nicholson, 489 F.3d 1207, 1211 (Fed. Cir. 2007) (“If the statutory language is clear and unambiguous, the inquiry ends with the plain meaning.”); Capella Sales & Servs. Ltd. v. U.S., Aluminum Extrusions Fair Trade Comm., 878 F.3d 1329, 1334 (Fed. Cir. 2018) (rejecting the “use of legislative history and other extrinsic factors to create, rather than solve, an ambiguity in otherwise clear statutory text”).

The phrase “surgical intervention” is not defined in the Act. The Court therefore must endeavor to “afford the law’s terms their ordinary meaning at the time Congress adopted them.” Niz-Chavez v. Garland, 141 S. Ct. 1474, 1480 (2021); see also Williams v. Taylor, 529 U.S. 420, 431 (2000) (instructing that, when interpreting statutory language, “words of a statute [are given] their ‘ordinary, contemporary, common meaning,’ absent an indication Congress intended them to bear some different import”); Nichols v. Dep’t of Veterans Affairs, 11 F.3d 160, 163 (Fed. Cir. 1993) (words not defined in a statute are given their “ordinary and common meaning”). To that end, standard dictionaries are appropriate references to determine the meaning of statutory terms. Telecare Corp. v. Leavitt, 409 F.3d 1345, 1353 (Fed. Cir. 2005) (citing Lamar v. United States, 241 U.S. 103, 113 (1916)) (“[T]he plain meaning of a statute is to be ascertained using standard dictionaries in effect at the time of the statute’s enactment.”). In addition, “where Congress has used technical words or terms of art, ‘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)).

The provision in question here, which allows petitioners to establish their eligibility for compensation by showing that a vaccine-related illness or injury “resulted in inpatient hospitalization and surgical intervention,” was added to the Act in 2000. Children’s Health Act of 2000, Pub. L. 106-310, § 1701, 114 Stat. 1101 (“2000 amendment”), codified at 42 U.S.C. § 300aa-11(c)(1)(D)(iii). Before then, only injuries that resulted in death or lasted longer than six months were compensable.

The edition of Dorland’s Illustrated Medical Dictionary that was current in 2000, when the amendment was added, defined “surgery” as “the branch of medicine that treats diseases, injuries, and deformities by manual or operative methods,” Dorland’s Illustrated Medical Dictionary 1736–37 (29th ed. 2000), which include “any act performed with instruments or by the hands of a surgeon,” id. at 1265 (definition of “operation”). Similarly, “surgery” was defined in Stedman’s Medical Dictionary as “[t]he branch of medicine concerned with the treatment of disease, injury, and deformity by physical operation or manipulation.” Stedman’s Medical Dictionary 1736 (27th ed. 2000)).

The American Medical Association has endorsed a similar albeit more comprehensive definition of surgery, which was originally crafted by the American College of Surgeons. See Surgery, American Medical Association Policy Finder, <https://policysearch.ama-assn.org/policyfinder/detail/surgery?uri=%2FAMADoc%2FHOD.xml-0-4317.xml>.<sup>5</sup> It provides that “[s]urgery is performed [by licensed physicians] for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine.” Id. Further, the AMA statement instructs, surgery includes “the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles.” Id.

The bone marrow aspiration performed on A.L. qualifies as a surgical procedure under all of these references. It was performed by a surgeon, Dr. James Harper. Pet’r’s Ex. 4 at 22. It involved the insertion of an instrument in A.L.’s pelvis—specifically, a large specialized needle. See Bone Marrow Aspiration, National Cancer Institute, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bone-marrow-aspiration>. Further, the needle was used to extract a sample of human tissue (A.L.’s bone marrow) through a syringe. And its purpose was diagnostic—to nail down the etiology of A.L.’s low platelet count, by ruling out other potential causes such as leukemia or some other bone marrow disorder.

Further, the hospital staff treated the procedure as surgical in nature. To undergo it, A.L. was placed under general anesthesia. Pet’r’s Ex. 4 at 22. Dr. Harper explained the procedure to A.L.’s mother and answered her questions “about post[-operative] pain.” Id. at 53. The hospital required her to execute a form entitled “Authorization for and Consent to Surgery or Special Diagnostic or Therapeutic Procedures.” Id. at 658. A “preoperative checklist” was completed. Id. at 74. A “Surgery Report” was used to document the procedure, and it described A.L.’s “surgical wound” as an “incision.” Id. at 73. Finally, A.L. recovered from the procedure in the Post Anesthesia Care Unit. Id. at 78.

The Court agrees with the Special Master that A.L. underwent a surgical procedure. The more difficult question, however, is whether the bone marrow aspiration and biopsy can also be characterized as a surgical intervention. In the Court’s view, the Special Master’s conclusion that it could be so characterized was legally erroneous and therefore must be reversed.<sup>6</sup>

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<sup>5</sup> This definition was last revised in April of 2007. Charlotte Grill, State of the states: Defining surgery, American College of Surgeons (May 1, 2012), [https://bulletin.facs.org/2012/05/state-of-the-states-defining-surgery/#Definition\\_of\\_surgery](https://bulletin.facs.org/2012/05/state-of-the-states-defining-surgery/#Definition_of_surgery).

<sup>6</sup> Petitioner contends that the Special Master’s decision involved “application of [the term surgical intervention] to the facts . . . not the meaning of the term[] as a matter of law,” and that therefore “the standard of review should be deferential to the discretion and fact-finding of the special master, rather than de novo review.” Pet’r’s Resp. at 5. The Court disagrees. The Special Master’s ruling that the bone marrow biopsy was a “surgical intervention” involved the resolution of a mixed question of law and fact—the interpretation of the statutory language and its application to the facts of the case. “[T]he standard of review for a mixed question all depends—on whether answering it entails primarily legal or factual work.” U.S. Bank Nat. Ass’n ex rel. CWC Capital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC, 138 S. Ct. 960, 967 (2018).



The Court again considers both standard and medical dictionaries to discern the meaning of the word “intervention” as used in the statute. The Oxford English Dictionary defines the verb “intervene” as “[t]o come in or between so as to affect, modify, or prevent a result, action, etc.” Oxford English Dictionary vol. VIII, 2 (2d ed. 1989). Dorland’s similarly defines the word “intervention” as “the act or fact of interfering so as to modify” or, somewhat less precisely as “any measure whose purpose is to improve health or to alter the course of a disease.” Dorland’s Illustrated Medical Dictionary 911 (29th ed. 2000); see also Stedman’s Medical Dictionary 915 (27th ed. 2000) (defining an “intervention” as “[a]n action or ministrations that produces an effect or that is intended to alter the course of a pathological process”).

The needle aspiration and bone marrow biopsy that A.L. underwent was not intended to and in fact did not affect, modify, or prevent A.L.’s ITP. It therefore does not fit within the definition of intervention in the Oxford English Dictionary, Dorland’s, or Stedman’s. To be sure, the biopsy might be considered an “intervention” if that word encompassed any surgical procedure whose overarching purpose was to improve a patient’s health. The needle aspiration and biopsy, after all, were performed to rule out other possible causes for A.L.’s symptoms so that she could begin the steroid treatment for her ITP that ultimately proved effective. But given the statutory context, it is not reasonable to read the word “intervention” so broadly as to include all surgical procedures, including those whose purpose is to determine the causes of an individual’s symptoms. Instead, the term “surgical intervention” is best read to include only those surgical procedures that are administered to directly treat a condition once it has been diagnosed.

Thus, the phrase “surgical intervention” appears in a statutory provision whose purpose was “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” Cloer v. Sec’y of Health & Hum. Servs., 654 F.3d 1322, 1335 (Fed. Cir. 2011) (quoting H.R. Rep. No. 100–391(I), at 699 (1987)). As noted, before the 2000 amendment to the Act, only injuries that resulted in death or lasted at least six months were compensable. Given that context, the Court agrees with the special masters who have addressed the issue that it would be inconsistent with Congressional intent to treat purely diagnostic procedures (even surgical ones) as “interventions” for purposes of 42 U.S.C. § 300aa-11(c)(1)(D)(iii). See, e.g., Spooner, 2014 WL 504728, at \*12; Galvan v. Sec’y of Health & Hum. Servs., No. 20-313V, 2020 WL 4593163, at \*13 (Fed. Cl. July 6, 2020) (Horner, Special Master); Flores v. Sec’y of Health & Hum. Servs., No. 18-0759V, 2020 WL 6938375, at \*5 (Fed. Cl. Oct. 26, 2020) (Corcoran, Special Master).

The legislative history of the 2000 amendment is very limited, consisting only of a colloquy on the Senate floor between several of the amendment’s sponsors. During the colloquy, Senator Jeffords explained that the immediate impetus for the amendment was to address the recent discovery of cases of “intussusception” in individuals who had received the rotavirus

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Here, the critical questions the Secretary has placed before the Court are legal ones, concerning the meaning and scope of the phrase “surgical intervention” and what factors determine whether a particular procedure fits within the phrase. Where, as here, a mixed question requires the Court “to expound on the law, particularly by amplifying or elaborating on a broad legal standard” the Court should “typically review a decision de novo.” Id.

vaccine. Proceedings and Debates of the 106th Congress, First Session, 145 Cong. Rec. S15213-03 (November 19, 1999)).<sup>7</sup> Senator Jeffords observed that most cases of intussusception required only minimal treatment. *Id.* A small number, however, required hospitalization and abdominal surgery to remove the intestinal obstruction. *Id.* He opined that individuals who underwent hospitalization and surgery to treat a vaccine-related injury should receive compensation even if—and perhaps because of surgical intervention—their injuries did not last six months. Senator Jeffords also observed that, to his knowledge, 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.*

It is unclear why Senator Jeffords believed that the amendment he was sponsoring would only apply to intussusception cases involving abdominal surgery given that the language the amendment employed—“surgical intervention”—is generic in nature. Further, “[t]he Supreme Court has cautioned that ‘[t]he remarks of a single legislator, even the sponsor, are not controlling in analyzing legislative history.’” *Groff v. United States*, 493 F.3d 1343, 1354 (Fed. Cir. 2007) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 311 (1979)). Nonetheless, the Court finds Senator Jeffords’ statements useful to the extent that—consistent with the textual analysis set forth above—they suggest that the intent of the “surgical intervention” language was to cover surgical procedures that are performed to directly treat or alter the course of a vaccine-related injury, as opposed to those whose purpose is to determine what treatment to employ.<sup>8</sup>

In this case, the Special Master purported to accept the distinction between surgical procedures that are diagnostic and those that can be deemed interventions. *See* Ruling at 7. But her determination that the needle aspiration and bone marrow biopsy performed on A.L. was a surgical intervention does not honor that distinction. She acknowledged that “a bone marrow biopsy is typically not a treatment that alters the course of a disease or condition,” but opined that “the facts of this case present an atypical situation.” *Id.* at 8. Specifically, she observed, A.L. presented with symptoms of ITP but did not respond to the IV immunoglobulin. *Id.* at 8–9. The bone marrow biopsy was performed, she said, “to rule out bone marrow disorders for which steroid treatment would be contraindicated.” *Id.* at 9. It was a surgical intervention, she reasoned, because it was a “necessary and integral part of the overall treatment protocol that ultimately cured A.L.’s ITP.” *Id.*

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<sup>7</sup> The Vaccine Injury Table states that “intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow.” 42 C.F.R. § 100.3(c)(4).

<sup>8</sup> While the Court finds Senator Jeffords’ floor statement supportive of its textual analysis, it rejects the Secretary’s argument that to decide whether a particular procedure is a “surgical intervention” the Court should assess whether its effect is “of the magnitude contemplated by Congress and akin to that undertaken to treat severe cases of intussusception, and therefore could be an equivalent stand-in for six months of sequela or residual effects.” Resp’t’s Mot. at 8–9. Deciding whether a particular procedure falls within the statutory term “surgical intervention” does not depend upon the Court’s subjective assessment of its severity or how the procedure compares to the abdominal surgery used to treat intussusception.

The Special Master’s analysis and her conclusion that the bone marrow biopsy was a surgical intervention, and that it was performed “to institute treatment rather than diagnose A.L.’s condition,” does not withstand scrutiny. At the time the procedure was performed, A.L.’s medical providers had determined that her petechial rash and other symptoms, coupled with her low platelet count, suggested that she suffered from ITP. But after the initial IV immunoglobulin treatments administered to treat her presumed ITP were unsuccessful, they concluded that additional information was needed to determine whether, in fact, A.L. suffered from ITP or some other disorder. They ordered a bone marrow biopsy to confirm the ITP diagnosis by ruling out other disorders that can cause a low platelet count and for which the steroid treatments that her physicians wished to administer as a curative for her ITP would be contraindicated.

In short, the fact that the bone marrow biopsy procedure had to be performed before treatment could be instituted does not make it any less of a diagnostic procedure. Indeed, all treatments must be preceded by an accurate diagnosis of the condition to be treated. The Special Master’s approach would therefore eliminate the very distinction between diagnostic procedures and surgical interventions that she (and several other special masters) have purported to endorse.<sup>9</sup>

The Court concludes, therefore, that A.L. did not undergo a surgical “intervention” as a result of a vaccine-related injury within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(iii). The Special Master’s determination that the Act’s severity requirement was met is therefore inconsistent with law and must be set aside.

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<sup>9</sup> A blurring of the distinction between diagnostic procedures and surgical interventions is also on display in Flores v. Secretary of Health and Human Services, No. 18-0759V, 2020 WL 6938375 (Fed. Cl. Oct. 26, 2020) (Corcoran, Chief Special Master). Flores involved the same surgical procedure as the one performed here. In that case, the Chief Special Master opined that although a bone marrow aspiration and biopsy was “somewhat diagnostic” it was “not purely so” because “by the time a decision was made to perform [the procedure, petitioner’s] platelet counts had already been determined to suggest ITP, and she had also manifested clinical indicia of the condition (bruising and petechiae).” Flores, 2020 WL 6938375, at \*5. The Chief Special Master opined that the aspiration procedure (which he characterized as an “invasive” one) had a “dual character” because it also was “necessary to guide further treatment (which had already featured IVIG infusions) if platelet counts declined again.” Id. This “dual character,” he opined, “supports a finding that it is a ‘surgical intervention’ serious enough to satisfy the severity requirement.” Id. With respect, the Court is not persuaded by this reasoning for the same reason it was not persuaded by Special Master Dorsey’s. A surgical procedure that is employed to diagnose an illness or injury for purposes of determining or guiding appropriate treatment is not itself an “intervention.” To the contrary, the intervention is the treatment that is ordered on the basis of the diagnosis.

## CONCLUSION

For the foregoing reasons, respondent's motion for review, ECF No. 75, is **GRANTED**. The case is **REMANDED** to the Office of Special Masters for further proceedings consistent with the foregoing.

**IT IS SO ORDERED.**

s/ Elaine D. Kaplan  
ELAINE D. KAPLAN  
Chief Judge