

**United States Court of Appeals
for the Federal Circuit**

**VICTORIA LEMING, KEVIN LEMING, PARENTS
AND NATURAL GUARDIANS OF A.L., A MINOR,**
Petitioners-Appellants

v.

**SECRETARY OF HEALTH AND HUMAN SER-
VICES,**
Respondent-Appellee

2023-1032

Appeal from the United States Court of Federal Claims
in No. 1:18-vv-00232-EDK, Chief Judge Elaine Kaplan.

Decided: April 15, 2024

ROBERT JOEL KRAKOW, I, Law Office of Robert J. Krakow, New York, NY, argued for petitioners-appellants.

JULIA COLLISON, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by ALEXIS B. BABCOCK, BRIAN M. BOYNTON, C. SALVATORE D'ALESSIO, HEATHER LYNN PEARLMAN.

Before MOORE, *Chief Judge*, STOLL, *Circuit Judge*, and
BENCIVENGO, *District Judge*.¹

BENCIVENGO, *District Judge*

A.L., the daughter of Petitioners-Appellants Victoria and Kevin Leming, experienced immune thrombocytopenic purpura after receiving the DTaP, Hib, and MMR vaccines. As a result of her vaccine injury, she was hospitalized for two weeks and underwent a bone marrow aspiration and biopsy. The Court of Federal Claims held that the Lemings could not establish by a preponderance of the evidence that A.L. satisfied the “surgical intervention” severity requirement of 42 U.S.C. § 300aa-11(c)(1)(D)(iii). Because the court below relied upon a legally erroneous construction of “surgical intervention,” we reverse and remand.

BACKGROUND

A

In 1986, the National Childhood Vaccine Injury Act (the “Vaccine Act”) was enacted to provide compensation to vaccine recipients who suffered from injury or death caused by a vaccine. *See* Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755-84 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34).

The Vaccine Act initially restricted recovery to only those recipients who:

- (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 1 year after the administration of the vaccine,
- (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or

¹ Honorable Cathy Ann Bencivengo, District Judge, United States District Court for the Southern District of California, sitting by designation.

condition in an amount greater than \$1,000, or (iii) died from the administration of the vaccine[.]

Id. § 311, 100 Stat. at 3761.

In 2000, however, this “severity requirement” was amended by the Children’s Health Act, Pub. L. No. 106-310, 114 Stat. 1101, to require Vaccine Act petitioners prove that the recipient:

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

42 U.S.C. § 300aa-11(c)(1)(D) (emphasis added).

The burden is on a petitioner to prove that one of these requirements is met by a preponderance of the evidence.

B

On September 6, 2016, Appellants’ daughter, A.L., received the DTaP, Hib, and MMR vaccines at her fifteen-month well-child visit. Appx3. On September 29, 2016, A.L. was taken to the emergency room with a rash, bleeding gums, and black spots on her tongue. *Id.* A.L. was admitted to the hospital where doctors discovered a low platelet count and presumed A.L. was suffering from immune thrombocytopenic purpura (“ITP”).² Appx1102. A.L.

² ITP is defined in the Vaccine Injury Table as the “presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum

received one dose of intravenous immunoglobulin (“IVIG”) as a treatment for the ITP. A.L. failed to respond to the initial IVIG treatment. She was transferred to Children’s Hospital in Omaha, where she received a second dose of IVIG. She again showed no improvement.

After A.L. failed to respond to two doses of IVIG, the doctors conducted a bone marrow aspiration and biopsy to ensure that A.L. was not suffering from cancer or other blood cell disorders. Appx3. The aspiration and biopsy showed no evidence of cancer or blood cell disorders. *Id.* The doctors then gave A.L. intravenous steroids, which improved her platelet count. *Id.* On October 12, 2016, A.L. was discharged from the hospital. *Id.*

Between October 12 and November 21, 2016, A.L. had multiple follow-up visits with the treating hematologist, who consistently noted improving platelet counts and lessening symptoms. Appx43-44.

On December 30, 2016, A.L.’s hematologist noted that A.L. was asymptomatic and had a normal platelet count. At this visit, it was also noted that A.L.’s ITP “had likely resolved at this time.” Appx2209. On April 13, 2017, the hematologist stated that A.L. was “completely free of bleeding symptomology.” Appx2238. At another visit on June 29, 2017, while some bruising was reported on A.L.’s face and ear, and her blood smear indicated evidence of “giant platelets,” A.L. had a normal platelet count and the doctor wrote that A.L.’s mild B cell elevation was “likely due to the immature immune system at her age and new B cell differentiation following the ITP episode now resolved.” Appx2256.

platelet count less than 50,000/mm³.” 42 C.F.R. § 100.3(c)(7).

C

In February 2018, Victoria Leming and Kevin Leming (“the Lemings”) filed a petition for compensation as guardians of A.L. under the Vaccine Act, alleging that the vaccines A.L. received at her fifteen-month well-child visit caused A.L. to suffer from ITP, immune dysfunction, and immune deficiency. The Secretary challenged the petition. The first special master issued a Ruling on the Facts, finding that the Lemings did not establish by a preponderance of the evidence that A.L. suffered the residual effects of the vaccine injury for more than six months. However, the special master found that the Lemings did establish that A.L. underwent an inpatient hospitalization and surgical intervention to meet the Vaccine Act’s severity requirement.

On review, the Court of Federal Claims found that the special master’s decision on “surgical intervention” was contrary to law. *See Leming v. Sec’y of Health & Hum. Servs.*, 154 Fed. Cl. 325, 334 (2021). The court below found that dictionary definitions and the legislative history of § 300aa-11(c)(1)(D)(iii) “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.” *Id.* Finding that the bone marrow aspiration and biopsy performed on A.L. was purely diagnostic, the court below reversed the decision of the original special master and remanded for further proceedings.

On remand, the case was reassigned to another special master who requested the Lemings offer more evidence to address the “residual effects” prong of the severity requirement. The Lemings provided new arguments and a supplemental affidavit from Ms. Leming. The special master found that the Lemings still could not prove that A.L. suffered from the “residual effects” of the vaccine injury for more than six months in light of this Court’s decision in

Wright v. Secretary of Health and Human Services, 22 F.4th 999, 1001-02 (Fed. Cir. 2022), issued after the Court of Federal Claims’ reversal of the original special master decision on the Lemings’ petition. The Lemings filed a motion for reconsideration, which was denied. The Lemings again appealed to the Court of Federal Claims, which affirmed the decision of the second special master on residual effects.

The Lemings timely appeal both the Court of Federal Claims’ decision on “surgical intervention,” *Leming*, 154 Fed. Cl. at 325, and the second special master’s finding on “residual effects.” We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

The statutory construction of “surgical intervention” in § 300aa-11(c)(1)(D) is a question of law, subject to de novo review. *See Wright*, 22 F.4th at 1004.

A

We are first tasked with defining “surgical intervention” as the phrase is used in the Vaccine Act. 42 U.S.C. § 300aa-11(c)(1)(D)(iii). As explained below, we hold the term “surgical intervention,” read with the entirety of 42 U.S.C. § 300aa-11(c)(1)(D)(iii), requires a surgical act or measure, either diagnostic or therapeutic, taken to prevent harm to a patient or to improve the health of a patient.

Statutory construction “begins with the language of the statute.” *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) (internal citations and quotations omitted). We consider not just a “single sentence or word of the statute, but rather the ‘provisions of the whole law,’ its object, and its policy.” *Wright*, 22 F.4th at 1004 (quoting *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990)). If the statute provides a clear answer, the inquiry ends there. *Hughes Aircraft Co.*, 525 U.S. at 438. “Beyond the statute’s text, [the traditional tools of statutory construction] include the

statute's structure, canons of statutory construction, and legislative history." *Timex V.I., Inc. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998).

Starting with the phrase "surgical intervention," like the Court of Federal Claims, we recognize that the Vaccine Act does not define this phrase. As such, it is helpful to look at the phrase's "ordinary meaning . . . at the time Congress enacted the statute." *Wisconsin Cent. Ltd. v. United States*, 585 U.S. 274, 277 (2018) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)). Because neither we nor the parties were able to find a definition of the phrase "surgical intervention," we look to the definitions of its individual components, "surgery" and "intervention," for guidance.

In 2000, one medical definition of "surgery" was "the branch of medicine that treats diseases, injuries, and deformities by manual and operative methods." *Dorland's Illustrated Medical Dictionary* at 1736-37 (29th ed. 2000). This definition does not limit "surgery" to the purpose of the procedure, e.g., whether it is primarily therapeutic versus diagnostic. The same dictionary defines "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." *Id.* at 911. Relying on these *Dorland's* dictionary definitions taken together, we understand "surgical intervention" to require an act or measure taken to prevent harming of a patient or to improve the health of a patient, and is of the surgical variety, for either diagnostic or therapeutic purposes.

It is also helpful to look to neighboring terms and phrases. See *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."). Here, "surgical intervention" exists in the larger phrase "inpatient hospitalization and surgical intervention." 42 U.S.C. § 300aa-11(c)(1)(D)(iii). "Inpatient hospitalization" works together with "surgical intervention" to provide a

benchmark for the class of petitioners that Congress intended to meet the severity requirement of the Vaccine Act—that is, those individuals who “suffered such illness, disability, or condition from the vaccine,” that are severe enough to result in “inpatient hospitalization and surgical intervention.” *Id.* By requiring “inpatient hospitalization” in addition to surgical intervention, Congress limited the type of injury required to qualify for relief. Notably, Congress did not limit the type of injury required for relief by limiting the purpose of the surgical intervention received. *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 381 (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.”).

The legislative history accords with our understanding of the term “surgical intervention.” Although the legislative record leading to the 2000 Amendment of the severity requirement is sparse, the Amendment’s sponsors referred to the need to expand compensation for those who suffered from intussusception, a negative effect of the rotavirus vaccine that required surgery to remedy but did not typically produce residual effects lasting longer than six months. The 2000 Amendment’s language is not limited to cases of intussusception, or any other specific vaccine-related injury. One of the cosponsors, in supporting the 2000 Amendment, stated “[t]he modified program makes compensation available if the injury requires a hospital stay or surgery.” 146 Cong. Rec. H8206 (daily ed. Sep. 27, 2000) (statement of Rep. Gilman).

Additionally, the original language proposed in 1999 included “(iii) suffered such illness, disability, injury or condition from which resulted in inpatient hospitalization and surgical intervention *to correct such illness, disability, injury or condition.*” 145 Cong. Rec. S15213 (daily ed. Nov. 19, 1999) (emphasis added). The language in italics was omitted from the final version of the Amendment. This

limited legislative history leads us to believe that Congress intended for the “surgical intervention” language to expand access to recovery for those injured by the vaccines, not limit it.

B

Here, the court below distinguished between surgical procedures that are diagnostic and surgical procedures that are required to treat the vaccine injury, holding that purely diagnostic procedures do not qualify as “surgical interventions” under the Vaccine Act. *See Leming*, 154 Fed. Cl. at 333. We find no support for this distinction between diagnostic and therapeutic surgical procedures in the Vaccine Act.

The 2000 Amendment requires only that the petitioners establish the vaccine recipient “suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.” 42 U.S.C. § 300aa-11(c)(1)(D)(iii). In light of the conjunctive quality of the clause “inpatient hospitalization and surgical intervention,” we hold that any surgical procedure—i.e., a surgical act or measure for diagnostic or therapeutic purposes taken to prevent harm of a patient or to improve the health of a patient—required to be conducted as a result of the vaccine injury qualifies, so long as the vaccine recipient is also hospitalized as an inpatient. Further, the hospitalization and the surgery must both be causally related to the recipient’s negative reaction to the vaccine.

Here, under the proper interpretation of “surgical intervention,” there is no dispute that the bone marrow aspiration and biopsy performed on A.L. was a surgical intervention. It was a surgical act taken to improve the health of and prevent harm to A.L. The record demonstrates that A.L. was hospitalized for two weeks as a result of her negative reaction to the vaccine, and also had to undergo a bone marrow aspiration and biopsy because she did

not react to the initial ITP treatment. Appx1102. These undisputed facts on their face satisfy 42 U.S.C. § 300aa-11(c)(1)(D)(iii).

CONCLUSION

Accordingly, we reverse the Court of Federal Claims' determination that A.L. does not satisfy 42 U.S.C. § 300aa-11(c)(1)(D)(iii) and remand for further proceedings consistent with this opinion.³

REVERSED AND REMANDED

COSTS

Costs awarded to petitioners.

³ In finding that the Lemings have satisfied the severity requirement via the “surgical intervention” language, we find it unnecessary to address the “residual effects” argument.