United States Court of Appeals for the Federal Circuit

HEATHER WRIGHT, AS MOTHER AND NATURAL GUARDIAN OF MINOR CHILD, B.W.,
Petitioner-Appellee

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant

2021-1524

Appeal from the United States Court of Federal Claims in No. 1:16-vv-00498-EGB, Senior Judge Eric G. Bruggink.

Decided: January 5, 2022

MICHAEL P. MILMOE, Law Offices of Leah V. Durant, PLLC, Washington, DC, argued for petitioner-appellee.

TRACI PATTON, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellant. Also represented by BRIAN M. BOYNTON, C. SALVATORE D'ALESSIO, HEATHER LYNN PEARLMAN.

Before PROST, TARANTO, and HUGHES, *Circuit Judges*.

HUGHES, *Circuit Judge*.

The son, B.W., of Petitioner-Appellee Heather Wright experienced immune thrombocytopenic purpura after receiving his measles, mumps, and rubella vaccine. Later blood tests showed his condition had resolved. More than six months after he was first diagnosed, B.W. presented with bruising, a possible symptom of immune thrombocytopenic purpura, but blood tests showed the condition had not recurred. The Court of Federal Claims held that those blood tests, occurring more than six months after his initial diagnosis, were "residual effects" of B.W.'s vaccine injury that satisfied the severity requirement of 42 U.S.C. § 300aa-11(c)(1)(D). We disagree. A residual effect must be a change within the patient that is caused by the vaccine injury. Because B.W.'s later bruising was not caused by his vaccine injury, and his tests did not reveal, constitute, or cause any somatic change, we reverse the Court of Federal Claims's decision.

BACKGROUND

A

In 1986, Congress established the National Vaccine Program within the Department of Health and Human Services "to achieve optimal prevention of human infectious diseases through immunization and to achieve

optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. With the same statute (the "Vaccine Act"), Congress also established the National Vaccine Injury Compensation Program, "under which compensation may be paid for a vaccine-related injury or death." *Id.* § 300aa-10(a). A petitioner seeking compensation must establish by a preponderance of the evidence that the injury or death was caused by a vaccine. *See id.* §§ 300aa-11(c)(1)(C), -13(a)(1). The petitioner may establish causation in two ways. First, the petitioner may prove that the injury is one listed in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a) (2020), and occurred within the time provided within the Table, establishing a presumption of causation. *See Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Alternatively, for injuries not listed in the Vaccine Injury Table, the petitioner may prove causation in fact. *Id.* at 1320 (citing 42 U.S.C. § 300aa-13(a)(1), -11(c)(1)(C)(ii)(I)). The causation-in-fact inquiry is governed by traditional principles of tort law described in the Second Restatement of Torts. *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351–52 (Fed. Cir. 1999).

Compensation is not available for minor injuries, whether on or off the Table. Instead, a showing of severity is required. As originally enacted, 42 U.S.C. § 300aa-11(c)(1)(D) required that a petition for compensation contain

> (1) . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died . . .
>
> > (D)(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

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

National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99–660, § 2111, 100 Stat. 3743, 3760–61. (1986). A 1987 amendment shortened "1 year" to "6 months" and combined subsections (i) and (ii), allowing compensation with a showing of six months of residual effects *and* $1,000 in unreimbursable expenses. Vaccine Compensation Amendments of 1987, Pub. L. No. 100–203 § 4304(b)(2), 101 Stat. 1330, 1330-223 to -224 (1987). The legislative history explains that the 1987 amendment

> *limits compensation program to cases in which a person dies from the result of vaccine or in which a person incurs unreimbursable medical expenses of more than $1,000 and suffers ongoing disabilities for at least six months. This subsection eliminates the Act's provision of eligibility for persons who incur expenses in excess of $1,000 but do not suffer ongoing disabilities. The effect of this provision is to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.*

H.R. Rep. No. 100-391, pt. 1, at 699 (1987). A 1998 amendment eliminated the $1,000 requirement altogether. Vaccine Injury Compensation Program Modification Act, Pub. L. No. 105-277 § 1502, 112 Stat. 2681, 2681-741 (1998). Today, the petitioner must show that the injured person

> (D)(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).

B

Thrombocytopenic purpura is included in the Vaccine Injury Table for the measles, mumps, and rubella (MMR) vaccine. 42 C.F.R. § 100.3(a) (2015). At the time this petition was filed, thrombocytopenic purpura was defined as "a serum platelet count[1] less than 50,000/mm^3."[2] *Id.* at § 100.3(b)(8). A normal platelet count is between 150,000

---

[1] Platelet counts reveal "the number of platelets (thrombocytes) per cubic milli[meter] of blood." *Crabbe v. Sec'y of Health & Hum. Servs.*, No. 10-762V, 2011 WL 4436724, at *2 n.9 (Fed. Cl. Spec. Mstr. Aug. 26, 2011) (quoting Kathleen D. Pagana & Timothy J. Pagana, *Mosby's Manual of Diagnostic and Laboratory Tests* 416 (4th ed. 2010)).

[2] "Thrombocytopenia" is defined as a platelet count less than 150,000/mm^3. National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 60 Fed. Reg. 56,289, 56,295 (Nov. 8, 1995). "Purpura" refers to a pattern of bleeding under the skin which is "generally only seen when the platelet counts are less than 50,000/mm^3," *id.*, although such patterns were not part of the definition of thrombocytopenic purpura in the Vaccine Injury Table at the time this claim was filed, 42 C.F.R. § 100.3(b)(8) (2015).

Today, thrombocytopenic purpura is defined in the Table "by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3 with normal red and white blood cell indices." 42 C.F.R. § 100.3(c)(7) (2020). The International Working Group on ITP uses a platelet count of less than or equal to 100,000/mm^3 for diagnosis. Appx33 n.3.

and 400,000/mm^3. *Crabbe v. Sec'y of Health & Hum. Servs.*, No. 10-762V, 2011 WL 4436724, at *2 n.20 (Fed. Cl. Spec. Mstr. Aug. 26, 2011) (citing Kathleen D. Pagana & Timothy J. Pagana, *Mosby's Manual of Diagnostic and Laboratory Tests* 416 (4th ed. 2010)). Thrombocytopenic purpura produces bruising as well as more unusual patterns of bleeding under the skin called petechiae and purpura. *See* National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table—II, 60 Fed. Reg. 56,289, 56,295 (Nov. 8, 1995). As the Secretary recognized when adding it to the Table, thrombocytopenic purpura is rarely chronic, i.e., lasting more than 6 months, and chronic cases are thought to be the result of an autoimmune disorder rather than viral vaccination or viral infection. *Id.*

C

B.W. was a two-year-old in good health. At his well-child visit on March 28, 2014, B.W. received the MMR vaccine. About two weeks later, B.W. presented to an emergency room with bruises on his forehead, abdomen, and all four extremities. B.W.'s platelet count was only 43,000/mm^3. He was diagnosed with thrombocytopenia and discharged. The following day, B.W. arrived at Children's Healthcare of Atlanta, where his platelet count was found to be 68,000/mm^3. His treating physicians diagnosed B.W. with "thrombocytopenia likely secondary to acute ITP."[3] Appx4.

---

[3] ITP stands for immune thrombocytopenic purpura or immune thrombocytopenia. "Immune" refers to the cause of the thrombocytopenia and distinguishes thrombocytopenia associated with anti-platelet antibodies, which may be caused by viral infections and vaccinations, from other forms of thrombocytopenia, such as heparin-induced thrombocytopenia or congenital thrombocytopenia. *See*

Over the following weeks, B.W. saw various pediatricians for frequent blood tests. His platelet count fluctuated between 68,000 and 180,000/mm^3. B.W.'s hematologists concluded that he had thrombocytopenic purpura resulting from his MMR vaccination, but noted that his thrombocytopenia was "not severe at this time" and recommended follow-up visits "every 1–2 months until resolution." Appx4.

On July 8, 2014—less than three months after onset of his thrombocytopenic purpura—B.W.'s pediatrician ordered a platelet count, which came back normal. The pediatrician concluded that B.W.'s thrombocytopenic purpura had "resolved." Appx4.

On several occasions in the following two years, B.W. returned to his pediatrician with bruising and had his platelet count tested. Each time he was seen, his platelet count was well above 50,000/mm^3 and within the normal range. B.W. was seen for bruising and headaches; his platelet count was 312,000/mm^3. He was seen for bruising on his shins and abdomen; his platelet count was 381,000/mm^3. He was seen for bruising on his back and extremities, as well as petechiae on his mid and lower back; his platelet count was 289,000/mm^3. He was seen again for bruising; his platelet count was 318,000/mm^3.

D

Ms. Wright filed a petition for compensation alleging that B.W.'s MMR vaccine caused thrombocytopenic purpura. The Secretary filed a Motion to Dismiss, arguing that Ms. Wright could not meet the "severity requirement" of 42

---

generally 42 C.F.R. § 100.3(b)(7); National Vaccine Injury Compensation Program, 60 Fed. Reg. at 56,295; *Thrombocytopenia*, *Dorland's Illustrated Medical Dictionary* 1892 (33d ed. 2020); Douglas B. Cines et al., *Congenital and Acquired Thrombocytopenia*, 2004 Hematology 390.

U.S.C. § 300aa-11(c)(1)(D), given that B.W.'s thrombocytopenic purpura had resolved less than six months after he got the vaccine. The special master dismissed the petition for failure to meet the severity requirement. The special master held that "testing for a possible recurrence is not a 'residual effect' within the meaning of the statute." *Wright v. Sec'y of Health & Hum. Servs.*, No. 16-498V, 2019 WL 1061472, at *11 (Fed. Cl. Spec. Mstr. Jan. 18, 2019) (*Special Master Decision*) (quoting *Crabbe*, 2011 WL 4436724, at *5).

Ms. Wright filed a motion for review of the *Special Master Decision* by the Court of Federal Claims. The court ruled that the special master erred as a matter of law in holding that there was no residual effect of B.W.'s thrombocytopenic purpura. *Wright v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 608, 615 (2019) (*Court of Federal Claims Decision*). The court reasoned that "ordering platelet counts when a patient with a history of ITP is presented with bruising" was "within the doctor's reasonable standard of care" and that B.W.'s testing was "causally connected to the vaccine injury" because "it [wa]s unlikely B.W. would have undergone continued platelet testing if it were not for his history with ITP." *Id.* at 614 & n.8. The court held that

> testing for a condition that could return ought to be compensated under the Vaccine Act when that testing is causally connected to the underlying vaccine injury and triggered by subsequent symptoms of the conditions. The fact that those tests did not reveal the presence of ITP is not controlling. The tests became necessary when later symptoms triggered concern because of the earlier injury; they were not mere monitoring.

Id. The court remanded to the special master, who awarded damages. *Wright v. Sec'y of Health & Hum. Servs.*, No. 16-498V, 2020 WL 6281782, at *1, *3 (Fed. Cl. Spec. Mstr.

Sept. 25, 2020). The Secretary timely appealed. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

The facts of this case are not disputed. The construction of "residual effects" in the Vaccine Act is a question of law, which we review de novo. *Flowers v. Sec'y of Health & Hum. Servs.*, 49 F.3d 1558, 1559 (Fed. Cir. 1995).

A

The "starting point" in statutory construction "is the language of the statute"—not a single sentence or word of the statute, but rather the "provisions of the whole law," its object, and its policy. *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990). The term "residual effects," read with the entirety of 42 U.S.C. § 300aa-11(c)(1)(D)(i), requires a change within the patient that is caused by the vaccine injury.

The language "effect . . . of such illness, disability, injury, or condition" dictates that a residual effect must be caused by the vaccine injury. The Vaccine Compensation Program was intended as an alternative to the tort system. *See Shalala v. Whitecotton*, 514 U.S. 268, 269–70 (1995) (citing H.R. Rep. No. 99-908, at 3–7 (1986)) (explaining that the Act "establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system"). Absent legislative history to the contrary, we have applied traditional principles of causation in tort law to the Vaccine Act. *See Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351–52 (Fed. Cir. 1999) (adopting the causation standard from the Second Restatement of Torts for purposes of proving causation for off-Table injuries under 42 U.S.C. § 300aa-11(c)(1)(C)(ii)). Here, Congress has not spoken on the standard of causation, *see* H.R. Rep No. 99-908, at 15 (1986) (not addressing causation for purposes of the provision at the time of enactment); H.R. Rep. No. 100-391, pt. 1, at 699 (1987) (not addressing causation at the time of

amendment, when discussing the severity requirement). Thus, we follow the Second Restatement and the causation standards articulated for purposes of 42 U.S.C. § 300aa-11(c)(1)(C)(ii).[4] Under this approach, it is sufficient that the vaccine injury be both a but-for cause of the residual effect and a substantial factor in bringing about the residual effect, even if it is not the predominant factor. *Shyface*, 165 F.3d at 1352 (citing Restatement (Second) of Torts).

Petitioner has not shown or argued in this case that B.W.'s bruising after six months was caused by thrombocytopenic purpura. In fact, the later tests "did not reveal the presence of ITP." *Court of Federal Claims Decision* at 614. So the bruising cannot itself be a "residual effect" under the severity requirement.

The Court of Federal Claims concluded that B.W.'s testing was "triggered by" his prior history of thrombocytopenic purpura and therefore "causally linked" to the condition. *Court of Federal Claims Decision* at 613. It cited evidence of but-for causation. *Id.* at 614 n.8. But the court identified a separate cause, bruising and petechiae, and linked B.W.'s testing to his "presentation of symptoms of ITP." *Id.* at 614. Neither the Court of Federal Claims nor the special master expressly applied a causation standard or considered both the thrombocytopenic purpura and the

---

[4] "Residual effects or complications" in the severity requirement bears similarity to "complication or sequela" in the Vaccine Injury Table, 42 C.F.R. § 100.3(b)(1), and the Secretary has defined a but-for causation standard for that language. 42 C.F.R. § 100.3(d)(3) (2020) ("Sequela means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table."). However, the Secretary specifically defined the word "sequela," not "complication," and "sequela" does not appear in the severity requirement.

presentation of bruising after six months to determine whether the thrombocytopenic purpura was a "substantial factor" in bringing about the testing. But even if legally caused by his thrombocytopenic purpura, B.W.'s testing was not a "residual effect" for reasons discussed next.

"Residual" suggests something remaining or left behind from a vaccine injury. *See Parsley v. Sec'y of Health & Hum. Servs.*, No. 08-781V, 2011 WL 2463539, at *16 (Fed. Cl. Spec. Mstr. May 27, 2011) ("'Residual' is defined as 'remaining or left behind.'" (quoting *Dorland's Illustrated Medical Dictionary* 1650 (31st ed. 2007))). An effect that is "residual" or "left behind" is one that never goes away or that recurs after the original illness. Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, *see* 42 C.F.R. § 100.3(c), their residues are similarly defined.

The words "suffered" and "complication," used in association with "residual effects" in § 300aa-11(c)(1)(D)(i), also suggest that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms.

"Suffered" suggests something detrimental, especially something painful. *See Suffer*, *Webster's Third New International Dictionary* 2284 (1986) ("to be subjected to physical or mental pain because of : endure with distress"). One does not naturally "suffer" from ongoing, minimally invasive monitoring or diagnostic testing, particularly when the underlying injury was found to have resolved.

In the context of the Vaccine Injury Table, "complication" is understood to have its medical meaning, "[a] morbid process or event occurring during a disease which is not an essential part of the disease, although it may result from it." *Abbott v. Sec'y of Dep't of Health & Hum. Servs.*, 27 Fed. Cl. 792, 794 (1993) (citing *Stedman's Medical Dictionary* 336 (25th ed. 1990), *aff'd in pertinent part, remanded in part*, 19 F.3d 39 (Table) (Fed. Cir. 1994)); *see*

also Parsley v. Sec'y of Health & Hum. Servs., No. 08-781V, 2011 WL 2463539, at *16 (Fed. Cl. Spec. Mstr. May 27, 2011) (defining "complication" for purposes of the severity requirement as "'disease or diseases concurrent with another disease' or as 'the concurrence of two or more diseases in the same patient'" (quoting *Dorland's Illustrated Medical Dictionary* 404 (31st ed. 2007))). These medical definitions characterize complications as "diseases" and "morbid processes." Read together, "residual effects" and "complications" appear to both refer to conditions within the patient, with "residual effects" focused on lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury, and "complications" encompassing conditions that may not be "essential part[s] of the disease" or may be outside the ordinary progression of the vaccine injury.

Read in context, "residual effects" is focused on effects within the patient, particularly lingering signs and symptoms of the original vaccine injury. B.W.'s testing did not fall into this category. The tests revealed B.W. had no lingering symptoms or recurrence of thrombocytopenic purpura. And although Petitioner contends that the testing itself was a "residual effect," there has been no showing or argument that it was detrimental to B.W.'s health such that it might qualify under § 300aa-11(c)(1)(D)(i) as a "residual effect" or a "complication" of thrombocytopenic purpura.

B

The legislative history accords with this interpretation. *See Flowers v. Sec'y of Dep't of Health & Hum. Servs.*, 49 F.3d 1558, 1560 (Fed. Cir. 1995) ("Our statutory interpretation begins with the language of the statute itself, which must ordinarily be regarded as conclusive absent a clearly expressed legislative intent to the contrary." (citing *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980))). The elimination of the $1,000

requirement as a standalone option under § 300aa-11(c)(1)(D) and the accompanying legislative history illustrate Congress's intent to require changes within the patient.

The 1987 amendment "*eliminate[d] . . . eligibility for persons who incur expenses in excess of $1,000 but do not suffer ongoing disabilities" and are not "seriously injured." H.R. Rep. No. 100-391, pt. 1, at 699 (1987) (emphases added). Injuries and disabilities are detrimental changes within the patient. Further, Congress contrasted "ongoing disabilities" with expenses in excess of $1,000. Unlike ongoing disabilities, expenses are decidedly external effects more clearly meant to encompass the detriments of ongoing monitoring. With its 1998 amendment, Congress wrote expenses out of the severity requirement altogether, indicating our analysis should focus on the vaccine injury and its medical consequences.*

By pairing "suffer" with "ongoing disability" and equating that with being "seriously injured," Congress further demonstrated that it intends the word "suffered" to require painful or otherwise detrimental effects. And *like its use in the text of the statute, the repeated use of the word "suffer" in the 1987 report and the stated intent to* limit compensation to only those individuals who are "*seriously injured* from taking a vaccine," H.R. Rep. No. 100-391, pt. 1, at 699 (1987), show that the types of residual effects contemplated by the statute do not encompass relatively non-invasive testing.

B.W.'s relatively non-invasive ongoing monitoring is neither an "ongoing disability" nor indicative that he "suffered" or was "seriously injured" within Congress's intended meaning of the severity requirement. B.W. did not suffer ongoing disabilities from his vaccine and in fact was not shown to have suffered any lingering somatic effects at all after six months.

C

We do not disturb existing case law holding that a course of treatment lasting longer than six months can be a "residual effect." *See H.S. v. Sec'y of Health & Hum. Servs.*, No. 14-1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015) (holding that restriction on physical activity after a concussion, which was medically necessary to prevent further consequences, was a residual effect); *Faup v. Sec'y of Health & Hum. Servs.*, No. 12-87V, 2015 WL 443802 (Fed. Cl. Spec. Mstr. Jan. 13, 2015) (holding that an individual's chronic arthritis was a residual effect even though it was well-controlled by medication). During a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary.

We do not decide today whether a course of testing or monitoring that is part of the management or treatment of a condition, necessary even in the absence of possible symptoms, could be a "residual effect." In such a case, the monitoring may be considered part of treatment of a condition that has not resolved, if the patient's somatic condition increases the risk of recurrence. For example, if a patient were shown to have a chronic condition that does not ordinarily resolve on its own within six months, and where some somatic change (e.g., a dormant infection or autoimmune condition) underlies the chronic condition, then testing might be medically appropriate as part of the course of treatment even in the absence of recurring symptoms.

We also do not decide whether diagnostic procedures that are more invasive, high-risk, or painful than the routine blood draws of this case may be "residual effects" or "complications" even for a condition that has resolved. Such testing may be more in line with Congress's intent to compensate those who "suffered" for more than six months. In addition, such procedures could cause somatic changes that

are "complications" within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(i).

Finally, although we focus here on medical effects, we do not intend to exclude psychological effects from the definition of "residual effects." *See Special Master Decision* at *11 (citing *Tauer v. Sec'y of Health & Hum. Servs.*, No. 08-703V, 2009 WL 2045676, at *1 (Fed. Cl. Spec. Mstr. June 22, 2009) (decision on stipulation)).

CONCLUSION

Because the Court of Federal Claims erred in holding that B.W.'s platelet count tests were residual effects within the meaning of the statute, we reverse the *Court of Federal Claims Decision*.

REVERSED

COSTS

No Costs.