Knudsen by Knudsen v. Secretary of Dept. of Health and Human Services

35 F.3d 543 (1994) | Cited 26 times | Federal Circuit | September 9, 1994

ARCHER, Chief Judge.

Doris P. Knudsen and Dale Knudsen, on behalf of their daughter Debra Arm Knudsen, appeal from a judgment of the United States Court of Federal Claims, No. 90-2067V (filed Feb. 2, 1993). The Court of Federal Claims upheld the decision of a special master dismissing the Knudsens' petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to -34 (1988 & Supp. III 1991), for an encephalopathy and sequelae injuries allegedly caused by a diptheria-tetanus-pertussis (DTP) vaccine. We vacate and remand.

I.

Debra Arm Knudsen was born a normal and healthy baby. She was apparently healthy and in good medical and physical condition when, on the morning of April 21, 1956, at the age of seven-months one-week, she received her third DTP vaccine.

The afternoon following her vaccination Debra was "fussy" and had a slight fever, and that evening she ate well and went to bed without problem. At two o'clock in the morning, April 22, Debra's parents were awakened by the sounds of Debra suffering a seizure. Mrs. Knudsen found Debra stiff, with her eyes rolled back in her head, having a high fever and darker than usual stools. Debra was making high-pitched sounds, her skin color was abnormal, and she was having trouble breathing. She may have vomited while in her crib. Soon after finding her, Debra's parents took her to the hospital. On the way, Debra vomited after consuming a few swallows of milk from her bottle, and had a convulsion lasting about one minute.

At the hospital, the family's physician, Dr. Frederick Lohr, examined Debra, noting that she was listless and pale with a temperature of 104 degrees. Although Debra vomited during Dr. Lohr's examination, she did not cry and did not offer any resistance. Dr. Lohr's notes show that Debra had a slight bulging anterior fontanel, sluggishly reactive pupils, an injected right ear drum, a slightly runny nose, and clotted mucus in her throat. A spinal fluid exam was performed; the spinal fluid was clear, and later tested negative. Dr. Lohr deferred making a diagnosis. He prescribed an antibiotic (penicillin) and an anticonvulsant. That afternoon, Debra's temperature was down and she seemed to be improving.

By 11:15 that night, however, and despite administration of a second antibiotic, Debra suffered three more convulsions and her temperature rose to 105.4 degrees. She was sponged off and her

temperature dropped to 102.8 degrees.

The following morning, April 23, Debra was seen by Dr. James Boysen, a pediatrician. Debra's white blood cell count was elevated, her fontanel was still bulging slightly, and her fever had varied through the night from 102 to 105.4 degrees. Dr. Boysen prescribed gamma globulin, a drug used to fight viral and bacterial infections. Dr. Boysen also noted his impression at that time: "Convulsive seizure as result of DPT immunization." (Emphasis added.)

The following morning, April 24, Debra was still febrile with a moderately bulging fontanel, and was semi-conscious having been heavily sedated. Dr. Boysen's diagnosis entered in Debra's medical records was: "Encephalopathy most likely due to D.P.T. immunization (pertussis) received today [sic, April 21]." (Emphasis added.)

On April 25, Debra seemed more alert and fussy, and had a temperature of 101 degrees. On April 26, she developed a rash over her entire body. She was taking formula well and seemed improved to Dr. Lohr, despite a distended abdomen and frequent flatus. On April 27, Debra's temperature was down to 99.2 degrees, the rash was gone, and her color was good. The antibiotics and anticonvulsants were discontinued. On April 28, it was noted that Debra had not had a seizure for 24 hours and her white blood cell count was down. On April 29, however, her temperature increased to 100.2 degrees, she had clay-colored stools and was again expelling flatus.

On April 30, Debra was discharged from the hospital. Her temperature was 100 degrees and her fontanel was still bulging slightly. The discharge diagnosis was: "Encephalitis - etiology unknown; possibly due to D.P.T. immunization." (Emphasis added.)

Two months later, in June of 1956, Debra was again hospitalized with a convulsive seizure and high fever. She was diagnosed with bronchitis, bilateral otitis media, and atypical pneumonia. Debra did not have any more seizures until 1963, when Dr. Boysen diagnosed her with a convulsive disorder. Dr. Boysen's final diagnosis was that the convulsive disorder was idiopathic, meaning of unknown cause, but "possibly" due to an encephalopathy and DTP vaccination in infancy. Debra presently suffers from seizures on a continuing basis and has permanent mental deficiencies.

II.

On September 28, 1990, Mr. and Mrs. Knudsen filed, on behalf of their daughter, a petition pursuant to the Vaccine Act seeking compensation for Debra's injuries. The Knudsens alleged that the DTP vaccine administered April 21, 1956, caused Debra to suffer an encephalopathy on April 22, and a residual seizure disorder, which are injuries listed on the vaccine table for which vaccine causation is presumed. See 42 U.S.C. § 300aa-14(a)(I).

In addition to Debra's medical records, the Knudsens' evidence in support of their petition included

testimony by Dr. Lohr and Drs. Stephen A. Smith and James Curtis Beeler. Dr. Boysen did not testify. Dr. Lohr testified that, although the medical records reflect that he was not certain at the time, his opinion now is that the DTP vaccine caused Debra to suffer an encephalopathy on April 22 and caused the resultant seizure disorder. Dr. Lohr acknowledged that Debra's other symptoms at the time of her admission to the hospital were consistent with the presence of a viral infection. Dr. Beeler testified that nuclear magnetic resonance imaging (MRI) films taken of Debra's brain are consistent with her having suffered an encephalopathy caused either by a DTP vaccine or a viral infection.

Dr. Smith testified that Debra's seizures were caused by the DTP vaccine. He acknowledged that certain of Debra's other symptoms could be consistent with a viral infection, but felt that in Debra's case those symptoms either were in fact caused by the DTP vaccine or were not significant at all. Dr. Smith testified that in his opinion the DTP vaccine caused the encephalopathy and a viral infection did not cause the encephalopathy based on the temporal relationship between the vaccination and the onset of symptoms, the lack of white cells in Debra's spinal fluid, the clinical picture of Debra's neurological illness from onset to the present, and the MRI films.

Opposing this evidence, the government offered the testimony of Dr. Michael Nigro. Dr. Nigro agreed that Debra suffered an encephalopathy following vaccination. However, he testified that Debra's non-encephalopathic symptoms following vaccination could not be explained by the DTP vaccine but are consistent with a systemic viral infection. He further testified that in his opinion the encephalopathy was caused by the viral infection and not the DTP vaccine based on the MRI films and the clinical picture of Debra's neurological illness. Dr. Nigro also testified that the lack of white cells in the spinal fluid was not inconsistent with a viral encephalopathy. In addition, Dr. Nigro based his opinion on Osler's unity of diagnosis principle, which the special master stated to be as follows: "An attempt should be made to try to put all the symptoms into one unified diagnosis to explain what a person's illness may be." [A19-A20] According to Dr. Nigro the single thing that could explain all of Debra's symptoms and injuries was a viral infection.

The special master weighed the evidence and found Dr. Nigro's testimony more persuasive than that of Drs. Smith, Beeler, and Lohr. The special master found that the unity of diagnosis principle was a valid basis for Dr. Nigro's opinion and that only viral infection could explain all of Debra's symptoms including encephalopathy. The special master found that Dr. Beeler's testimony did not favor DTP vaccine as the cause, and that Dr. Lohr's testimony was merely conclusory and not supported by his opinion at the time of Debra's encephalopathy. The special master found credible Dr. Nigro's opinion regarding the MRI films, the clinical picture, and the spinal fluid, and discounted Dr. Smith's opposing view for reasons expressed on the record. The special master noted that Dr. Boysen had not testified, and that his diagnoses in Debra's medical records showed a retreat from a belief that DTP "most likely" caused the encephalopathy to a belief that DTP "possibly" caused the encephalopathy. Finally, the special master found that encephalopathies caused by DTP vaccine occur less frequently than encephalopathies caused by viral infection, and that therefore Debra's

encephalopathy was less likely to have been caused by the DTP vaccine than by the viral infection.

The special master found that Debra suffered an encephalopathy one day after receipt of the DTP vaccine, and therefore there was a presumption of causation. However, the special master concluded that, at the time Debra suffered the encephalopathy, she was also suffering from a systemic viral infection, and that the viral infection in fact caused the encephalopathy and the DTP vaccine did not. The special master therefore denied the Knudsens' petition for compensation.

On review to the Court of Federal Claims, the court upheld the findings and decision of the special master.[2] The Knudsens, on behalf of their daughter, appeal.

III.

A. The Court of Federal Claims "having upheld the determination of the special master, 'we review de novo [the court's] determination as to whether or not the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Jay v. Secretary of the Dep't of Health and Human Servs., 998 F.2d 979, 982 (Fed. Cir. 1993) (quoting Hines v. Secretary of the Dep't of Health and Human Servs., 940 F.2d 1518, 1524 (Fed. Cir. 1991)); see 42 U.S.C. § 300aa-12(e)(2). This case raises the question of what evidence is relevant to determining under the Vaccine Act that a condition or injury is unrelated to administration of the DTP vaccine, a question of law which we review de novo.

B. It is undisputed that on April 22, 1956, one day following receipt of DTP vaccine, Debra Arm Knudsen suffered an encephalopathy, and that Debra's current neurological problems are, at least in part, sequelae of the encephalopathy. Therefore, pursuant to the Vaccine Act, the law presumes that the DTP vaccine caused the encephalopathy and resulting disorders, see 42 U.S.C. § 300aa-13(a)(1)(A) (petitioner's burden of proof), -11(c)(1)(C)(i) (proving a table injury), -14(a)(I) (DTP table injuries and time frames), and the Knudsens are presumptively entitled to compensation.

The petitioners' successful showing of legal causation does not, however, end the question of compensation. "Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of the evidence, they are entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Secretary of the Dep't of Health and Human Servs., 17 F.3d 374, 376 (Fed. Cir. 1994); see 42 U.S.C. § 300aa-13(a)(1)(B).

The special master found that the government proved by a preponderance of the evidence that a factor unrelated to the vaccine--i.e., a viral infection--in fact caused Debra's table injury, encephalopathy. Accordingly, the special master denied compensation.

C. The Knudsens' primary challenge to the special master's finding of alternative causation based on

"viral infection" is that it is erroneous as a matter of law because a "viral infection" is an "unexplained, unknown and hypothetical" cause. The Knudsens argue that, as a matter of law, a viral infection cannot be found to be an alternative causation unless the virus is specifically identified by type. The parties agree that the alleged viral infection suffered by Debra has not been and cannot be specifically identified. Thus, the legal issue is whether a viral infection can be found to be an alternative causation if the specific viral type is not identified.

As a preliminary matter, the parties agree that as a general proposition it is more often than not impossible to specifically identify viral infections, and that in 1956, when Debra suffered the encephalopathy, it would have been virtually impossible to identify the specific type of virus. The government cites this difficulty of proof in support of its argument against a per se rule that the type of viral infection must be specified in order to be a possible alternative cause. The Court of Federal Claims, in upholding the special master's decision, accepted the government's argument. The Knudsens' response to this argument is that a lack of medical technology or understanding that prejudices the government's ability to prove alternative causation cannot be a basis for a rule to ease the government's burden of proof. We agree with the Knudsens on this particular point. The Vaccine Act in appropriate cases removes the petitioner's difficult burden of proving actual causation by allowing the petitioner to rely on a table injury and a presumption of causation. The Vaccine Act however gives no corresponding benefit to the government. Thus, if a petitioner has proved actual causation or obtained the benefit of a presumption, and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation.

Section 300aa-13(a)(1)(B) of the Vaccine Act provides that compensation shall not be paid to petitioners if the court finds by a preponderance of evidence on the record as a whole "that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." 42 U.S.C. § 300-13(a)(1)(B) (emphasis added). According to the statute, however, "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" may not be considered a "factor[] unrelated to the administration of the vaccine" and therefore cannot defeat a petitioner's right to recovery. Id. § 300aa-13(a)(2); see, e.g., Koston v. Secretary of the Dep't of Health and Human Servs., 974 F.2d 157, 160-61 (Fed. Cir. 1992) ("Rett Syndrome" is an idiopathic illness and therefore cannot be a factor unrelated to the administration of a vaccine and cannot be shown to be an alternative cause of an injury).

The Knudsens argue simply that if the virus is not identified by type, it is as a matter of law an "unexplained, unknown, hypothetical" illness or condition. Therefore, in the Knudsens' view, it is not a "factor[] unrelated to the administration of the vaccine" that could be considered an alternative cause and it cannot be used by the government to preclude the Knudsens' recovery. In support of their argument, the Knudsens cite to the following language in the legislative history of the Vaccine Act:

In its determination that the injury was not caused by factors unrelated to the vaccine, the court may rely on evidence of other infections, traumas, or conditions but is not to include speculative or hypothetical matters of explanations. If the injury is not demonstrated to have been caused by other, defined illnesses or factors and the injury is demonstrated to have met the other requirements [of the Vaccine Act], the injury is deemed to be vaccine-related.

H.R. Rep. No. 99-908, 99th Cong., 2d Sess. 18, reprinted in 1986 U.S.C.C.A.N. 6344, 6359 (emphasis added).

The government's position is that the statute does not require the government to identify specifically the viral infection as a per se condition to proving alternative causation, and that a non-specified "viral infection" can possibly be a "factor[] unrelated to administration of the vaccine" assuming such a finding is otherwise supported.

For its part the government relies on two sections of the Vaccine Act. First, the Vaccine Act provides that "factors unrelated to the administration of the vaccine" which can defeat a petitioner's right to recover

may, as documented by . . . material in the record, include infection. . . which has no known relation to the vaccine involved, but which in the particular case [is] shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Id. § 300aa-13(a)(2) (emphasis added). Second, the table of injuries expressly states that if "it is shown by a preponderance of the evidence that an encephalopathy was caused by infection. . . the encephalopathy shall not be considered to be a condition set forth in the table." Id. § 300aa-14(b)(3)(B) (emphasis added).

Thus in the government's view the statute expressly contemplates that proof of an infection--here viral--could potentially defeat recovery, and there is nothing in the statute that requires as a matter of law that the government always prove the specific type of viral infection. The government further contends that the alternative causation was in this case a "defined illness": the "illness" causing the encephalopathy was an "infection," specifically "viral," and was shown by medical testimony and records to be the cause of the encephalopathy.

We agree with the government's position. In the context of an off-table case, where a petitioner is attempting to prove that a certain vaccine in fact actually caused a particular injury, we have stated that proof of actual causation in fact generally requires "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Jay, 998 F.2d at 984 (quoting Grant v. Secretary of the Dep't of Health and Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). This "logical sequence of cause and effect" must be supported by a sound and reliable medical or scientific explanation. Id.; see Daubert v. Merrell Dow Pharmaceuticals, Inc., 125 L. Ed. 2d 469, 113 S. Ct. 2786,

2795-97 (1993) (analyzing use of expert scientific testimony at trial).

Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain. See Bunting v. Secretary of the Dep't of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991) ("scientific certainty" is not the standard of proof); Hodges, 9 F.3d at 966-68 (Newman, J., Dissenting). Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms. E.g., Jay, 998 F.2d at 984.

Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344. The program is supposed to be "fair, simple, and easy to administer." Id. at 7, 1986 U.S.C.C.A.N at 6348; Koston, 974 F.2d 161. The program stems from Congress's recognition that "while most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured." Id. at 4, 1986 U.S.C.C.A.N. at 6345. And "it is not always possible to predict who they will be or what reactions [to the immunizations] they will have." Id. at 6, 1986 U.S.C.C.A.N at 6347.

The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury or that the child's injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13 (a)(1), (b)(1). Our extremely deferential standard of review as to factual issues in vaccine cases is justified by the notion that these are not appeals from judgments in tort lawsuits, but are appeals in the federal administration of a fund for children shown to have been injured by vaccines.

As the Knudsens agree, the standards that apply to a petitioner's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact. Alternative causation is not automatically proved simply by the mere fact that a child is infected with a virus, even of a specifically identified type, at the time of vaccination or

injury. Likewise, there is nothing in the Vaccine Act that requires a per se rule that alternative causation cannot be proved when the specific virus is not identified. Accordingly, we hold that a "viral infection" can be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name. Thus, the government may defeat a petitioner's claim with a theory of viral infection so long as it proves that there was in fact a viral infection, and that the viral infection "in the particular case [was] . . . principally responsible for causing the petitioner's illness, disability, injury, condition, or death," 42 U.S.C. § 300aa-13(a)(2) (emphasis added).

Although we conclude that the government need not as a per se rule specifically identify the type of virus in order to prove alternative causation, we emphatically reject the government's contention that the government "needed only to prove the existence of an infection to defeat petitioners' presumed vaccine-induced encephalopathy." Government Brief at 21. The government was required not only to prove the existence of an infection (here viral), but also to prove by a preponderance of the evidence that the particular viral infection present in the child actually caused the table injury complained of. Were the government's argument accepted, a child could never recover under the Vaccine Act if the government demonstrated that the child had a viral infection at the time of vaccination or injury. The Vaccine Act, however, expressly recognizes that a child may have an infection at the time of vaccination and injury and still recover--this situation occurs where the government does not prove that the "infection" was "principally responsible for causing" the injury complained of.

Similarly, we reject the government's assertion of a "unity" theory against the petitioners in support of its proof of alternative causation, which was relied on in the special master's decision. Under this "unity" theory, as Dr. Nigro reasoned, the only single thing that could explain all of Debra's symptoms, encephalitic and non-encephalitic, was a systemic viral infection. The doctor believed, and the special master found, that DTP does not cause many of the problems accompanying the encephalopathy that Debra suffered. However, even assuming this finding to be adequately supported, there is no requirement under the Vaccine Act that petitioners prove that DTP caused symptoms or injuries other than the table injury or injury complained of. Petitioners need not explain all other symptoms or injuries by reference to the DTP vaccination, and the issue in vaccine cases is not to diagnose all the injuries and symptoms of the child in order to ascertain whether that diagnosis is DTP vaccine or something else. It is entirely plausible, and contemplated by the statute, that DTP may cause an encephalopathy at the same time that a virus or something else causes non-encephalopathic symptoms or injuries. So long as it has not been shown that the virus or other unrelated factor caused the encephalopathy or injury complained of, compensation is not foreclosed.

We also reject the government's argument, which again was relied on in the special master's decision, that evidence that there are more occurrences of encephalopathies caused by viral infections than there are encephalopathies caused by DTP vaccines is relevant. Viral infections themselves occur infinitely more often than do DTP vaccinations. Moreover, as the witnesses testified, in the 1950s doctors rarely explained an encephalopathy as being caused by a DTP

vaccination. The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

D. Having concluded that a "viral infection" can be an alternative causation even if not identified by specific type, we come to the Knudsens' challenge to the special master's finding in this case that the unspecified viral infection was in fact an alternative causation.

Based on the testimony of the government's and petitioners' witnesses, and the medical documentation, the government offered the following legitimate evidence of alternative causation: Debra had a systemic viral infection, the specific type of virus being unidentified; in general, viral infections can cause encephalopathy; and the clinical picture in Debra's case, her particular MRI films, and the contemporaneous conduct of the doctors prove that the viral infection caused the encephalopathy and prove that the encephalopathy was not caused by the DTP immunization.

Based on the testimony of Drs. Lohr, Smith, and Beeler, and the medical records, the petitioners offered the following evidence countering the government's evidence of alternative causation: Debra did not have a systemic viral infection; however, although in general viral infections can cause encephalopathy, if Debra did have a systemic viral infection, in this case the temporal association, clinical picture, spinal fluid, and the MRI films show that the DTP vaccine caused the encephalopathy and it was not caused by the viral infection.

This conflicting record evidence does not in our view either compel a finding of viral alternative causation nor preclude one. If the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded. The special master did not specifically find whether the above evidence preponderated in favor of alternative causation due to the special master's heavy reliance on grounds we have rejected: the mere presence of a viral infection in Debra, the "unity" theory, and the fact that viral encephalopathies are reported more often than DTP encephalopathies. But because the special master has found causation between the vaccine and the injury, he is required under the Vaccine Act to make a further finding on the question of alternative causation or etiologies. Grant, 956 F.2d at 1149-50. We will not speculate as to whether, on the above evidence, the special master would have found alternative causation by a preponderance of the evidence, especially in view of the presumption in this case that the DTP vaccine caused Debra's encephalopathy and residual seizure disorder and the "generosity" of the Vaccine Act. Accordingly, we vacate the decision of the Court of Federal Claims upholding the decision of the special master, and remand the case for a finding consistent with this opinion on the issue of alternative causation.

VACATED and REMANDED

Disposition

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VACATED and REMANDED.

1. Chief Judge Archer assumed the position of Chief Judge on March 18, 1994.

2. The special master issued two decisions denying compensation. On July 7, 1992, the special master first denied compensation finding that the encephalopathy was caused by a viral infection. On review to the Court of Federal Claims, the court remanded the case on November 18, 1992, to the special master for specific findings on causation between the viral infection and the encephalopathy, and a full Discussion of the weight accorded the testimony of the experts. The special master rendered a lengthy decision on remand on December 17, 1992, again denying compensation, and the Court of Federal Claims upheld this decision on February 2, 1993, from which the Knudsens appeal. The facts set forth in our opinion are taken primarily from the special master's decision on remand.