

Syllabus

SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES *v.* WHITECOTTON ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 94-372. Argued February 28, 1995—Decided April 18, 1995

Respondents, Margaret Whitecotton and her parents, filed a claim for compensation under the National Childhood Vaccine Injury Act of 1986, alleging that Margaret had suffered encephalopathy as a result of her vaccination against diphtheria, pertussis, and tetanus (DPT). Under the Act, a claimant who, like Margaret, does not attempt to prove actual causation must make out a prima facie case by showing that “the first symptom or manifestation of the onset . . . of any . . . [listed] condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.” 42 U. S. C. § 300aa-11(c)(1)(C)(i). That table specifies a 3-day period for encephalopathy following a DPT vaccination. § 300aa-14(a). The Special Master ruled that Margaret had failed to make out a prima facie case, finding, *inter alia*, that by the time she received her vaccination she was “clearly microcephalic,” that this condition evidenced pre-existing encephalopathy, and that, accordingly, “the first symptom or manifestation” of her condition’s onset had occurred before her vaccination and the 3-day table period. The Court of Federal Claims affirmed, but the Court of Appeals for the Federal Circuit reversed, holding, among other things, that a claimant satisfies the table requirements whenever she shows that any symptom or manifestation of a listed condition occurred within the table time period, even if there was evidence of the condition before the vaccination.

Held: A claimant who shows that she experienced symptoms of an injury after receiving a vaccination does not make out a prima facie case for compensation under the Act where the evidence fails to indicate that she had no symptoms of that injury before the vaccination. The Court of Appeals’ assertion that the Act does not “expressly state” that a claimant relying on the table must show that the child sustained no injury prior to her vaccination—*i. e.*, that the first symptom of the injury occurred after vaccination—simply does not square with § 300aa-11(c)(1)(C)(i)’s plain language. If a symptom or manifestation of a table injury has occurred before the vaccination, a symptom or manifestation thereafter cannot be the first, or signal the injury’s onset. There cannot be two first symptoms or onsets of the same injury. Thus, a demonstration that the claimant experienced symptoms of an injury during

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the table period, while necessary, is insufficient to make out a prima facie case. The claimant must also show that no evidence of the injury appeared before the vaccination. The Court of Appeals misread language in §§300aa-14(a), 300aa-14(b)(2), and 300aa-13(a)(2)(B) in coming to the contrary conclusion. Pp. 273-276.

17 F. 3d 374, reversed and remanded.

SOUTER, J., delivered the opinion for a unanimous Court. O'CONNOR, J., filed a concurring opinion, in which BREYER, J., joined, *post*, p. 276.

Irving L. Gornstein argued the cause for petitioner. With him on the briefs were *Solicitor General Days*, *Assistant Attorney General Hunger*, *Deputy Solicitor General Kneedler*, *Barbara C. Biddle*, *Richard A. Olderman*, and *Karen P. Hewitt*.

Robert T. Moxley argued the cause for respondents. With him on the brief were *Richard Gage*, *Peter H. Meyers*, and *John S. Capper IV*.*

JUSTICE SOUTER delivered the opinion of the Court.

The question in this case is whether a claimant who shows that she experienced symptoms of an injury after receiving a vaccination makes out a prima facie case for compensation under the National Childhood Vaccine Injury Act of 1986, 100 Stat. 3755, 42 U. S. C. §300aa-1 *et seq.* (1988 ed. and Supp. V), where the evidence fails to indicate that she had no symptoms of that injury before the vaccination. We hold that the claimant does not make out a case for compensation.

I

For injuries and deaths traceable to vaccinations, the Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system. H. R. Rep.

**Stephan E. Lawton* and *Anne M. Dellinger* filed a brief for the American Academy of Pediatrics as *amicus curiae* urging reversal.

Curtis R. Webb filed a brief for Dissatisfied Parents Together et al. as *amici curiae* urging affirmance.

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No. 99-908, pp. 3-7 (1986). Special masters in the Court of Federal Claims hear vaccine-related complaints, 42 U. S. C. § 300aa-12(c) (1988 ed., Supp. V), which they adjudicate informally, § 300aa-12(d)(2), within strict time limits, § 300aa-12(d)(3)(A), subject to similarly expeditious review, § 300aa-12(e)(2). A claimant alleging that more than \$1,000 in damages resulted from a vaccination after the Act's effective date in 1988 must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any *de novo* civil action in state or federal court. 42 U. S. C. § 300aa-11(a) (1988 ed. and Supp. V).

The streamlining does not stop with the mechanics of litigation, but goes even to substantive standards of proof. While a claimant may establish *prima facie* entitlement to compensation by introducing proof of actual causation, § 300aa-11(c)(1)(C)(ii), she can reach the same result by meeting the requirements of what the Act calls the Vaccine Injury Table. The table lists the vaccines covered under the Act, together with particular injuries or conditions associated with each one. 42 U. S. C. § 300aa-14 (1988 ed., Supp. V). A claimant who meets certain other conditions not relevant here makes out a *prima facie* case by showing that she (or someone for whom she brings a claim) "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a] vaccine . . . or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U. S. C. § 300aa-11(c)(1)(C)(i). Thus, the rule of *prima facie* proof turns the old maxim on its head by providing that if the *post hoc* event happens fast, *ergo propter hoc*. The Secretary of Health and Human Services may rebut a *prima facie* case by proving that the injury or death was in fact caused by "factors unre-

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lated to the administration of the vaccine” § 300aa-13(a)(1)(B). If the Secretary fails to rebut, the claimant is entitled to compensation. 42 U. S. C. § 300aa-13(a)(1) (1988 ed. and Supp. V).

Respondents, Margaret Whitecotton and her parents, filed a claim under the Act for injuries Margaret allegedly sustained as a result of vaccination against diphtheria, pertussis, and tetanus (or DPT) on August 18, 1975, when she was nearly four months old. They alleged that Margaret (whom we will refer to as claimant) had suffered encephalopathy after the DPT vaccination, and they relied on the table scheme to make out a prima facie case. The Act defines encephalopathy as “any significant acquired abnormality of, or injury to, or impairment of function of the brain,” 42 U. S. C. § 300aa-14(b)(3)(A), and lists the condition on the Vaccine Injury Table in association with the DPT vaccine. Under the Act, a claimant who does not prove actual causation must show that “the first symptom or manifestation of the onset or of the significant aggravation” of encephalopathy occurred within three days of a DPT vaccination in order to make out a prima facie right to compensation. § 300aa-11(c)(1)(C)(i); 42 U. S. C. § 300aa-14(a) (1988 ed., Supp. V).

The Special Master found that claimant had suffered clonic seizures on the evening after her vaccination and again the following morning, App. to Pet. for Cert. 24a, 27a, and accepted those seizures as symptoms of encephalopathy. He also found, however, that by the time claimant received the vaccination she was “clearly microcephalic” (meaning that she had a head size more than two standard deviations below the mean for a girl her age) and that her microcephaly was a symptom or evidence of encephalopathy that existed before the vaccination. *Id.*, at 32a-33a. Accordingly, the Master concluded that the first symptom or manifestation of the onset of claimant’s encephalopathy had occurred before the vaccination and the ensuing 3-day period provided for in the table. *Id.*, at 34a.

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The Master then considered whether the series of seizures was “the first symptom or manifestation . . . of [a] significant aggravation” of the claimant’s encephalopathy, 42 U. S. C. §300aa–11(c)(1)(C)(i), and again decided that it was not. The Act defines “significant aggravation” as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” §300aa–33(4). The Master found that “[t]here is nothing to distinguish this case from what would reasonably have been expected considering [claimant’s] microcephaly. . . . [T]here was nothing that occurred in temporal relationship to the DPT vaccination which indicates that it is more likely than not that the vaccine permanently aggravated her condition. . . . [T]he seizures did not continue and there was no dramatic turn for the worse in her condition Thus, there is no basis for implicating the vaccine as the cause of any aspect of [claimant’s] present condition.” App. to Pet. for Cert. 41a–43a. Because he found that claimant had failed to satisfy the table requirements, and had not tried to prove actual causation, the Master denied her compensation for failure to make out a *prima facie* case.

The Court of Federal Claims found the Master’s decision neither arbitrary nor otherwise unlawful, see 42 U. S. C. §300aa–12(e)(2) (1988 ed., Supp. V), and affirmed. The Court of Appeals for the Federal Circuit then reversed, holding that a claimant satisfies the table requirements for the “first symptom or manifestation of the onset” of an injury whenever she shows that any symptom or manifestation of a listed condition occurred within the time period after vaccination specified in the table, even if there was evidence of the condition before the vaccination. Because claimant here showed symptoms of encephalopathy during the 3-day period after her DPT vaccination, the Court of Appeals concluded for that reason alone that she had made out a *prima facie* entitlement to recovery. 17 F. 3d 374, 376–377 (1994).

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The Court of Appeals went on to say that the Secretary had failed to rebut this prima facie case because she had not shown that claimant's encephalopathy was caused by "factors unrelated to the administration of the vaccine," 42 U. S. C. § 300aa-13(a)(1)(B). The Court of Appeals relied on the provision that a "facto[r] unrelated" cannot include an "idiopathic" condition, § 300aa-13(a)(2)(A), which the court read to mean that even when the Secretary can point to a specific factor, unrelated to the vaccine, as the source of a claimant's injury, she does not defeat a prima facie case when the cause of the identified factor is itself unknown. Taking the Secretary to have relied on claimant's microcephaly as the unrelated factor (or as associated with it), the court ruled the Secretary's evidence insufficient on the ground that the cause of microcephaly is unknown. 17 F. 3d, at 377-378.*

We granted certiorari to address the Court of Appeals's construction of the Act's requirements for making and rebutting a prima facie case. 513 U. S. 959 (1994). Because we hold that the court erroneously construed the provisions defining a prima facie case under the Act, we reverse without reaching the adequacy of the Secretary's rebuttal.

II

The Court of Appeals declared that nowhere does the Act "expressly state" that a claimant relying on the table to establish a prima facie case for compensation must show "that the child sustained no injury prior to administration of the vaccine," that is, that the first symptom of the injury

*The Court of Appeals's language can also be read as casting doubt on the Special Master's conclusion that claimant's microcephaly evidenced a pre-existing encephalopathy. We express no view as to the validity of that conclusion.

The Secretary has recently issued new regulations that may affect the Court of Appeals's definition of an idiopathic condition in future cases. These regulations apply only to petitions for compensation filed after March 10, 1995, and accordingly have no application to the present case. 60 Fed. Reg. 7678-7696 (1995).

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occurred after vaccination. 17 F. 3d, at 376. This statement simply does not square with the plain language of the statute. In laying out the elements of a *prima facie* case, the Act provides that a claimant relying on the table (and not alleging significant aggravation) must show that “the first symptom or manifestation of the onset . . . of [her table illness] . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.” § 300aa-11(c)(1)(C)(i). If a symptom or manifestation of a table injury has occurred before a claimant’s vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury’s onset. There cannot be two first symptoms or onsets of the same injury. Thus, a demonstration that the claimant experienced symptoms of an injury during the table period, while necessary, is insufficient to make out a *prima facie* case. The claimant must also show that no evidence of the injury appeared before the vaccination.

In coming to the contrary conclusion, the Court of Appeals relied on language in the table, which contains the heading, “Time period for first symptom or manifestation of onset . . . after vaccine administration.” 42 U. S. C. § 300aa-14(a) (1988 ed., Supp. V). The Court of Appeals saw a “significant” distinction, 17 F. 3d, at 376, between this language and that of 42 U. S. C. § 300aa-11(c)(1)(C)(i), which is set forth above. We do not. The key to understanding the heading is the word “onset.” Since the symptom or manifestation occurring after the vaccination must be evidence of the table injury’s onset, an injury manifested before the vaccination could qualify only on the theory that it could have two onsets, one before the vaccination, one after it. But it cannot: one injury, one onset. Indeed, even if the language of the heading did conflict with the text of § 300aa-11(c)(1)(C)(i), the latter would prevail, since the table heading was obviously meant to be a short form of the text preceding it.

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The Court of Appeals sought to shore up the contrary conclusion with two further arguments. As the court read the Act, Congress “expressly made the absence of preexisting injury an element of the prima facie case” for residual seizure disorder (another table injury), 17 F. 3d, at 376; thus, the court reasoned, Congress had implicitly rejected any need to negate the pre-existence of other injuries like encephalopathy. This argument rests on a misreading of the language in question. The statutory notes explaining the table provide that a claimant “may be considered to have suffered a residual seizure disorder if [she] did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved” §300aa-14(b)(2). But this is not the language that requires a claimant alleging a seizure disorder to demonstrate the absence of pre-existing symptoms. This provision specifies instead that certain types of seizures (those accompanied by a high fever) may not be considered symptoms of residual seizure disorder, and, so, do not preclude a prima facie case even when a claimant suffered them before vaccination. The language carries no implication about a claimant’s burden generally and does nothing to undermine Congress’s global provision that a claimant who has actually suffered symptoms of a listed injury before vaccination cannot make out a prima facie case of the injury’s onset after vaccination.

Finally, we cannot accept the Court of Appeals’s argument that because the causal “factors unrelated” on which the Secretary may rely to defeat a prima facie case can include occurrences before vaccination, see §300aa-13(a)(2)(B), such occurrences cannot bar the establishment of a prima facie case in the first instance. The “factors unrelated” provision is wholly independent of the first-symptom and onset provisions, serving the distinct purpose of allowing the Secretary to defeat a claim even when an injury has not manifested

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itself before vaccination. It does not relieve a claimant of the clear statutory requirements for making out a prima facie case.

III

The judgment of the Court of Appeals for the Federal Circuit is accordingly reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE O'CONNOR, with whom JUSTICE BREYER joins, concurring.

Margaret Whitecotton was born in 1975 with a condition known as microcephaly, defined commonly (but not universally) as a head size smaller than two standard deviations below the norm. At the age of four months, she received a diphtheria, pertussis, and tetanus (DPT) vaccination. Prior to receiving her vaccine, Margaret had never had a seizure. The day after receiving her vaccine, she suffered a series of seizures that required three days of hospitalization. Over the next five years, Margaret had intermittent seizures. She now has cerebral palsy and hip and joint problems and cannot communicate verbally. In 1990, Margaret's parents applied for compensation for her injuries under the National Childhood Vaccine Injury Act of 1986. The Special Master denied compensation, and the Court of Federal Claims agreed. The Court of Appeals for the Federal Circuit reversed, 17 F. 3d 374 (1994), finding that the Whitecottons had made out a prima facie case for compensation.

Although I join the Court's opinion rejecting the Court of Appeals' reading of the pertinent statutory provision, I write separately to make two points. First, I wish to indicate an additional factor supporting my conclusion that the Court of Appeals' reading of 42 U. S. C. § 300aa-11(c)(1)(C)(i) is inconsistent with congressional intent. Second, I wish to underscore the limited nature of the question the Court decides.

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Examining the language of §300aa-11(c)(1)(C)(i), the Court properly rejects the Court of Appeals' determination that a claimant may make out a *prima facie* "onset" case simply by proving that she experienced a symptom of a "table illness" within the specified period after receiving a vaccination. *Ante*, at 273-274. To establish a table case, the statute requires that a claimant prove by a preponderance of the evidence either (1) that she suffered the first symptom or manifestation of the onset of a table condition within the period specified in the table or (2) that she suffered the first symptom or manifestation of a significant aggravation of a pre-existing condition within the same period. As the Court rightly concludes, proof that the claimant suffered a symptom within the period is necessary but not sufficient to satisfy either burden; the word "first" is significant and requires that the claimant demonstrate that the postvaccine symptom, whether of onset or of significant aggravation, was in fact the very first such manifestation.

The Court relies on a commonsense consideration of the words "first" and "onset" in reaching this conclusion: "If a symptom or manifestation of a table injury has occurred before a claimant's vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury's onset." *Ante*, at 274. I find equally persuasive the observation that the Court of Appeals' reading deprives the "significant aggravation" language in the provision of all meaningful effect. The term "significant aggravation" is defined in the statute to mean "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U. S. C. §300aa-33(4). If, as the Court of Appeals determined, a claimant makes out an "onset" case any time she can demonstrate that *any* symptom occurred within the relevant period, all cases in which children experience postvaccine symptoms within the table period become "onset" cases. The phrase "significant aggravation,"

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and any limitations Congress sought to impose by including language like “*markedly* greater disability” and “*substantial deterioration* of health,” are altogether lost.

To the extent possible, we adhere to “the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.” *Department of Revenue of Ore. v. ACF Industries, Inc.*, 510 U. S. 332, 340 (1994) (internal quotation marks omitted); *Pennsylvania Dept. of Public Welfare v. Davenport*, 495 U. S. 552, 562 (1990). The construction adopted by the Court of Appeals contravenes this principle. Our reading gives effect to the “onset” and the “significant aggravation” language while according “first” its commonsense meaning.

Today’s decision is quite limited. The Court of Appeals had no occasion to address the Whitecottons’ challenges to the Special Master’s factual findings with respect to their daughter’s condition. We assume, *arguendo*, the soundness of his conclusions that Margaret Whitecotton suffered a pre-existing encephalopathy that was manifested by her prevaccine microcephaly. But this may not be the case, and the Whitecottons of course may challenge these findings as clearly erroneous on remand. The Court of Appeals also did not address the Whitecottons’ argument, rejected by the Special Master, that their daughter suffered a significant aggravation of whatever pre-existing condition she may have had as a result of the vaccine. This factual challenge appears to be open as well, as does a challenge to the legal standard used by the Special Master to define “significant aggravation.”

We also do not pass on the Secretary’s argument that the Court of Appeals misstated petitioner’s burden under 42 U. S. C. §300aa-13(a)(1)(B) (1988 ed. and Supp. V) in rebutting a claimant’s prima facie case. Given our holding with respect to the claimant’s burden, it is speculative at this time whether any effort on our part to evaluate the Court of Appeals’ approach to the “facto[r] unrelated” standard will find

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concrete application in this case. That said, the approach taken by the Court of Appeals, under which the Secretary may not point to an underlying condition that predated use of a vaccine and obviously caused a claimant's ill health, if the cause of that underlying condition is unknown, may well warrant our attention in the future.