

In the United States Court of Federal Claims

No. 02-1183C
(Filed: April 29, 2005)

DANIEL L. AULL and FRANCIS C.
AULL as Co-Administrators of the Estate
of WILLIAM DANIEL BLAKE AULL,
Deceased,

Petitioners,

v.

National Childhood
Vaccine Injury Act; State
court negligence
proceeding.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

David L. Yewell, Owensboro, KY, for petitioners.

Julia W. McInerney, Trial Attorney, Torts Branch, Civil Division,
Department of Justice, for the United States. With her on briefs were *Peter
D. Keisler*, Assistant Attorney General, *Timothy P. Barren*, Director, *John
Lodge Euler*, Deputy Director, *Mark Rogers*, Assistant Director, *Gabrielle M.
Fielding*, Assistant Director.

OPINION

BRUGGINK, *Judge.*

This case concerns a petition for vaccine compensation brought under the National Childhood Vaccine Injury Act of 1986 (“NCVIA” or “the Act”), 42 U.S.C. §§ 300aa-10 to -34 (2000). Before the court is petitioners’ motion for review of the Special Master’s decision to dismiss for lack of jurisdiction. The Special Master concluded that the pendency in state court of a claim

against the administering physician for wrongful death bars the proceeding here. The matter has been fully briefed. Oral argument was held on March 10, 2005. While we reject the Special Master's analysis, we affirm on other grounds. The petition is dismissed without prejudice.

BACKGROUND

This case stems from the tragic death of Blake Aull on September 12, 2000. On September 10, 2001, petitioners filed a civil action in Daviess County (Kentucky) Circuit Court against David E. Danhauer, M.D., and Owensboro Pediatrics, PLLC, along with other care givers. In their complaint, they allege a series of facts beginning with “[o]n Friday, September 8, 2000, Dr. Danhauer administered to Blake Aull a series of vaccinations,” and culminating with the death of Blake Aull on September 12, 2000. Complaint at 3-5, *Aull v. Danhauer*, No. 01-CI-01055 (Ky. Daviess Cir. Ct. filed Sept. 10, 2001). None of the allegations directly reference the vaccination. The six counts of the complaint allege the following negligence by Dr. Danhauer and Owensboro Pediatrics:

a) failure to recognize or treat his pneumonia and deteriorating state in a timely manner; b) failure to diagnose pneumonia and prescribe antibiotics, or other proper medication; c) failure to admit Blake to the hospital; d) failure to act upon blood tests and laboratory results in a timely manner; e) failure to inform Mr. and Mrs. Aull of Blake's blood test results and x-ray results in a timely manner; f) failure to administer Blake's blood transfusion of September 12, 2000, at the OMHS emergency room in a timely manner; g) failure to respond to Blake's special medical needs as a child with diffuse encephalopathy and a tracheotomy.

Id. at 6.

While the Daviess Circuit Court case was pending, petitioners filed their petition on Blake's behalf for compensation under the NCVIA on September 11, 2002. In this petition, while not providing significant detail about the development of Blake's symptoms, they alleged:

Blake received the immunization on September 8, 2000. Within 2 hours, Blake started running a temperature of 104 degrees.

His parents fought to reduce his fever for the next three days, but as soon as it would break, it would rise again. Blake developed shortness of breath on September 11, 2000, and he was placed on a small flow of oxygen. On September 12, Blake continued to have a high temperature. . . . All possible measures were taken, but Blake lost his struggle to live.

Resp't Mot. to Dismiss at 6 (quoting Pet. at ¶ 24).

During oral argument on March 10, 2005, counsel for petitioners was asked whether the state action is a challenge to the decision of Dr. Danhauer to administer the vaccine. Counsel responded as follows:

Dr. Danhauer in the state case, we think, was negligent Monday, September the 11th, when this child presented to his office at 10 a.m. . . . During the office exam of September the 11th, he did not review the reports he had faxed to his office [from the hospital emergency room] that said this child has pneumonia. He did not examine the child and diagnose pneumonia. He gave the wrong medication indicated. . . .

[T]he vaccine administered September 8, 2000, though it wasn't known at the time, weakened this child's immunity system, his ability to fight whatever might attack his body. . . . And so, when he was weakened by that immunization . . . when he developed pneumonia, Sunday - Sunday night, and went to the hospital, his body was further weakened by the vaccine. The pneumonia is what really killed this child.

Tr. at 9, 11. The court also asked counsel whether the child's injuries and death are associated with the vaccine. He responded, "It appears that's true. It has to be, because the September 8th immunization, from all we can gather, further weakened this child's immunity system." Tr. at 13.

The difficult question posed by this petition for review is whether the maintenance of the state court negligence action, even though it alleges post-vaccination negligence, is nevertheless barred because it seeks damages for a "vaccine-related injury" within the meaning of the Act.

DISCUSSION

The Act created an alternative compensation program for those with vaccine-related injuries. Its twofold purpose is to provide a “fair, simple, and easy to administer” system to better serve vaccine-injured persons than the existing tort system while not deterring vaccine administrators and manufacturers from administering or producing vaccines because of potential liability. H.R. Rep. No. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6348. Suits concerning vaccine-related injuries must be brought here first, where plaintiffs benefit from simplified proof requirements.^{1/} However, once the case has proceeded to judgment, plaintiffs must choose between accepting the judgment and extinguishing traditional tort claims or rejecting the judgment and instituting a traditional tort suit.

Several interlocking provisions of the Act create this procedure. Section 300aa-11(a)(2)A precludes bringing “a civil action for damages . . . against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988” until judgment has been reached on a petition here. This is supported by a provision requiring courts to dismiss such civil actions. § 300aa-11(a)(2)(B). Section 300aa-11(a)(5)(B) provides a reciprocal limitation. It prohibits bringing a petition here while an independent civil action is pending: “If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.” The latter section provided the basis for the Special Master’s dismissal here.

Two other provisions protect petitioners. If a civil suit is dismissed under § 300aa-11(a)(2)(B) because it must be brought here first, the limitations period is tolled to ensure the petition can later be submitted here. Also, § 300aa-16(c) provides that the limitations period under state law is tolled, thereby permitting a traditional tort claim if a plaintiff chooses to reject the

^{1/}A plaintiff under the Act can benefit from a presumption of causation based on timing, which was unavailable under the tort system, or alternatively can prove actual causation. However, an affirmative showing by a preponderance of the evidence that the illness, disability, injury, or condition described in the petition is due to factors unrelated to the administration of the vaccine serves as a defense. § 300aa-13(a)(1)(B).

judgment.

The outcome turns on whether the specific claims alleged in the state court proceeding are the sort Congress intended should be brought here first. Two Federal Circuit cases aid the interpretation of this subsection in the context of the entire statute: *Schumacher v. Secretary of the Department of Health and Human Services*, 2 F.3d 1128 (Fed. Cir. 1993), and *Amendola v. Secretary of the Department of Health and Human Services*, 989 F.2d 1180 (Fed. Cir. 1993).

In *Schumacher*, the petitioner filed here, alleging injuries resulting from the administration of a DPT vaccine. Also pending in state court, however, was a tort proceeding against the manufacturer of a drug, Bentyl, that had been co-administered with the DPT vaccine. The Federal Circuit had before it the question of whether § 300aa-11(a)(5)(B) was implicated because of the pendency of that other proceeding. The Secretary argued that the reach of subparagraph B was broad enough to be triggered. The Secretary pointed out that § 300aa-11(a)(5)(B) does not include the phrase, “against the vaccine administrator and manufacturer.” Moreover, the Act elsewhere defines a “vaccine-related injury or death” as “an illness, injury condition, or death *associated with* one or more of the vaccines set forth in the Vaccine Injury Table,” § 300aa-33(5) (emphasis added). It followed, according to the government, that even claims not brought against the vaccine administrator or manufacturer could trigger the bar, so long as the injury was allegedly associated with the vaccine.

The Federal Circuit disagreed. It noted that the phrase “civil action for damages for a vaccine-related injury or death,” or its functional equivalent, “civil action,” appear throughout the Act. Sometimes they appear with the modifying phrase, “against a vaccine administrator or manufacturer.” The question in *Schumacher* was whether it should be assumed that Congress intended that the modifying phrase be implied when applying § 300aa-11(a)(5)(B). The court found that it should. It held that “when the phrase is used without clear references, such as in § 300aa-11(a)(5)(B), the meaning of the ‘civil action’ can only be determined by looking at the purpose of the provision within the general statutory scheme, as illuminated by the legislative history.” 2 F.3d at 1132. Based on an examination of the legislative history of the Act and subsequent amendments, the court concluded that “the phrase ‘civil action’ in each provision of § 300aa-11(a) other than (3), where it is clearly shown to the contrary, means a civil action against a vaccine

administrator or manufacturer.” *Id.* at 1135.

This case involves a related question. The Special Master deduced from similar distinctions of language among provisions of the Act a deliberate choice by Congress to bar some actions in this court (because of the pendency of a related state action) and yet not bar the same action in state court (despite the availability of a remedy here). The key to his analysis is the absence in § 300aa-11(a)(5)(B) of the words “associated with the administration of a vaccine,” which appears in § 300aa-11(a)(2)(A) and, by reference, in § 300aa-11(a)(2)(B). Finding the omission of the phrase from § 300aa-11(a)(5)(B) significant, he concluded that even actions not dependent on the administration of the vaccine for purposes of tort liability can preclude a petition under the Act, so long as they are “vaccine-related.” Because the state court proceeding meets that simple threshold, the action here is barred, the Special Master concluded, despite the fact that the state proceeding might not be barred under reciprocal, but differently worded provisions.

We reject this analysis, taking *Schumacher*’s interpretive approach as a model. The statute is most intelligible when it is understood to refer to the same sort of injury throughout, just as in *Schumacher* it was found to refer to the same category of defendants throughout. Consider the procedural quandary in which an alternative interpretation would place petitioners. If the action here is dismissed and, in order to revive it, the state claim against the physician must be dismissed, the distinct possibility exists that, if petitioners later wish to invoke the tolling features of § 300aa-11(a)(2)(A), they will find renewal of the state action no longer possible. The tolling provisions only protect actions related to the “administration of a vaccine.” The analysis below thus means that, although the state action is not barred (because it does not allege negligence in the administration of the vaccine), the existence of the state action bars any recovery under the NCVIA (because it involves a “vaccine-related” death). We disagree with this approach. In our view, it is quite unlikely that Congress intended to bar claims under the NCVIA because of the pendency of state claims, unless those claims could have been brought under the NCVIA.

The Special Master’s conclusion that Congress deliberately gave § 300aa-11(a)(5)(B) a broader reach than § 300aa-11(a)(2)(A) rests on the presumed deliberateness of the difference between the phrase “vaccine-related injury or death” on the one hand and “vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988” on the

other hand. We are reluctant to attach great significance to the difference in phraseology. Of the twenty times the phrase “associated with the administration of a vaccine” is used, all but one include a temporal limitation—before or after a certain date.^{2/} In our view it is apparent from the construction of § 300aa-11 that the phrase was not intended to draw a distinction between injuries generally associated with the vaccine itself and injuries associated with the *administration* of the vaccine. Each time the phrase appears, it is apparent that the intent was to focus on the dates relevant to implementation of the statute. “Administration” occurs in such usages because Congress considered it important *when* the vaccine was administered, not whether the injury came through the vaccine’s administration. Chronological distinctions would be difficult to express without use of the term “administer” or some derivation of it.

At the outset, therefore, we disagree with the Special Master that the language of § 300aa-11(a)(5)(B) is intentionally broader than that of § 300aa-11(a)(2)(A). In our judgment, Congress assumed that a “vaccine-related injury” was synonymous with an injury “associated with the administration of a vaccine.” The structure of § 300aa-11 makes it plain that Congress’ intent was to force into the NCVIA program all those claims, but only those claims, which it was designed to address. Just as there would be no incentive to bar state court proceedings to the extent they could not be handled within the vaccine program, there is no reciprocal incentive to bar actions here that would not be barred in state court.

Coming to this conclusion, however, does not resolve this case, because we also disagree with the decision below to the extent that it assumed that the outcome here turns on whether the phrase “associated with the administration of a vaccine” is to be read into § 300aa-11(a)(5)(B). Instead, the case turns on what distinguishes a “vaccine-related injury,” which must be brought here, from an injury which may be litigated without resort to the NCVIA. Specifically, does post-administration negligence in treating the effects of the vaccine come under the requirements of the statute?

^{2/}The one exception occurs in a clause requiring an advisory commission to “survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines.” § 300aa-19(f)(4).

The statute does not, on its face, provide a bright line which distinguishes the two categories. It defines a vaccine-related injury as an “illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table.” § 300aa-33(5). Concluding that this definition is synonymous with the phrase “injury or death associated with the administration of a vaccine” adds little to understanding the correct result here.

In *Amendola*, the Federal Circuit briefly addressed this question while considering a state court action in which it was alleged that “the doctor was negligent and committed malpractice by administering the #3 injection in spite of the negative reactions apparently caused by the #2 injection.” 989 F.2d at 1181. The court concluded that such an allegation concerned a vaccine-related injury and thus barred the petition under the NCVIA, but the court explicitly distinguished those facts from other possibilities: “If this were a situation in which the direct cause of the injury was a contaminated needle, or the doctor’s negligent dropping of an infant patient, or other negligence facially *unrelated to the vaccine’s effects*, then the hypotheticals posed by the Amendolas might require further examination.” *Id.* at 1186-87. The court in *Amendola* thus had in view a distinction based on whether the negligence was related to the vaccine’s effects.

This makes sense in light of the purpose of the NCVIA. Permitting a civil action against a doctor for dropping a child during the vaccination visit to proceed simultaneously in no way jeopardizes the continued supply of the vaccine or the willingness of doctors to administer a vaccine. Even a suit for negligence directly associated with administration of the vaccine, e.g., using a contaminated needle, could nevertheless proceed without offense to the Act because the negligence is “facially unrelated to the vaccine’s effects.” *Id.* at 1186-87. We draw from *Amendola* the proposition that the NCVIA looks to whether the injury alleged in the alternative proceeding flows out of the effects of the vaccine itself on the child.

In *Salceda v. Secretary of the Department of Health and Human Services*, No. 90-1304V, 1994 WL 139375 (Fed. Cl. Spec. Mstr. Apr. 6, 1994), the Special Master applied *Schumacher* to this issue. She permitted a petitioner with a pending civil suit against a vaccine administrator for negligent post-vaccination care to remain in the program. Because *Schumacher* limits the application of the NCVIA only to vaccine manufacturers or administrators, *Salceda* perceived a paradox in that anyone could be sued for negligent post-vaccination care except the individual who

also administered the vaccine. Arguing that to make vaccine administrators immune from all suits “would be to disregard medical malpractice and the public interest” contrary to Congressional intent, the Special Master concluded that a claim could proceed here so long as the allegations in state court are strictly post-vaccination negligence. 1994 WL 139375, at *4.

While agreeing with the approach taken in *Salceda*, we draw the line in a different place in light of *Amendola*. Congress clearly did not intend to immunize administrators from all suits; on the other hand, Congress created a program which specifically protects administrators from certain charges of negligence. Whether the line distinguishing these categories should be drawn at the moment of vaccination, as *Salceda* assumed, or tied to the physical effects of the vaccine, as *Amendola* suggests, has not been directly addressed before. Because it is not clear that Congress intended to divert into the program actions based on a “vaccine-related injury” only when the alleged negligence occurred immediately before the vaccination rather than soon after, we find the better rule to be grounded in the physical effects of the vaccine. Namely, if the injury is associated with the receipt of the vaccine *qua* vaccine, the petitioner either must go through the NCVIA or lose the claim. Otherwise, many, if not most, plaintiffs would retain the option to recover under the Act and simultaneously sue for alleged negligence arising from efforts to mitigate the consequences of the vaccine. This seems quite contrary to Congress’ purpose in encouraging the administration of vaccines.

Still, the present case is not simple. It is not clearly on either side of *Amendola*’s distinction. According to the “Clarification of Petitioners’ Claims” filed on July 20, 2004:

There is necessarily a factual overlap [between] this vaccine claim and the negligence case in state court. Dr. Schweller’s report of February 6, 2004, mentions that Petitioners were given assurances by the physician who administered the September 8, 2000, immunization that the immunization would not adversely affect his health. He further states that from the information the parents were given this immunization was an unwise course of conduct due to prior reactions from earlier immunizations, as well as the fact that Blake had a seizure disorder and a chronic neurologic disorder, both being contraindications for the immunization.

The fact remains, however, that the September 8, 2000, immunization directly caused a significant aggravating further injury to Blake, that being an increased strain on his metabolic system to the point that the mitochondrial system decompensated, causing the child to have seizures, fever, and a state of respiratory failure leading directly to his death.

Plainly speaking, the . . . immunization weakened Blake's ability to fight pneumonia. . . . Thus, we have a death due to an immunization which significantly aggravated a preexisting chronic encephalopathy which created an inability to fight off an undiagnosed, untreated pneumonia which was the actual and direct cause of Blake's death.

Clarification of Pet.'s Claims at 3-4.

The injury claimed therefore is not "facially unrelated to the vaccine's effects." *Amendola*, 989 F.2d at 1187. If petitioners' claim in state court were the same as the "clarification" here, in other words, the suit would be barred in state court because of § 300aa-11(a)(2)(A). The present claim would therefore appear properly to belong in this court because it alleges that the effect of the vaccine was to aggravate a pre-existing encephalopathy. The irony, of course, is that this means that it would first have to be dismissed.

Somewhat in contrast to these asserted facts, however, the state court action claims only post-vaccination negligence of Dr. Danhauer in misdiagnosing Blake's condition. The vaccination took place on September 8. Blake began to "experience difficulty breathing and developed a high temperature" on September 10. Complaint, ¶ 12, *Aull v. Danhauer*, No. 01-CI-01055 (Ky. Daviess Cir. Ct. filed Sept. 10, 2001). Blake died on September 12, allegedly because defendants failed to diagnose the pneumonia and treat it properly. During oral argument in this proceeding, counsel further explained that all the negligence alleged in the state action occurred after vaccination: "The wrong alleged of Dr. Danhauer in the civil case came three days later. The vaccine was administered Friday, September 8, 2000. The alleged negligence of Dr. Danhauer occurred Monday, September 11th." Tr. at 8. Counsel specifically disclaimed any assertion that "the injuries alleged in the state court proceeding [] flow out of either the decision to administer the vaccine or on some strict-liability theory, based on the content of the vaccine."

Tr. at 9. The injury suffered, however, is the same as the one for which the action here was brought, namely, Blake’s unfortunate death.^{3/}

In state court, petitioners would clearly be barred by *Amendola* from asserting that the decision to administer the vaccine was negligent. Although that assertion is not made, we cannot ignore the representations made here that the reason Blake was at risk from Dr. Danhauer’s alleged negligent treatment was the effect of the vaccine on his pre-existing condition. It is thus alleged that there is a causal connection between the vaccine and the post-vaccination negligence, namely that the vaccine exacerbated the pre-existing encephalopathy, which in turn led to the asserted misdiagnosis.

Applying *Amendola*’s emphasis on the relationship between the negligence and the vaccine’s effects, we hold that, where the alleged negligence concerns the physical effects of the vaccine upon the body, Congress intended resort to the NCVIA first. If it is alleged that the injury is related to the physical effects of the vaccine, whether the alleged negligence occurred before the administration of the vaccine, as in *Amendola*, or soon thereafter, as in this case, it must be brought under the NCVIA.

The injury and death in this case are associated with the physical effects of the vaccine, as petitioners’ counsel admitted during oral argument. We are required, therefore, to dismiss this action under § 300aa-11(a)(5)(B) because petitioners have pending a state action for a “vaccine-related . . . death.” Similarly, the state court will have to consider whether to dismiss the state action under § 300aa-11(a)(2)(B). If that occurs, petitioners may invoke the tolling provision of § 300aa-11(a)(2)(B) in order to refile a petition under the NCVIA within one year of the state court dismissal.

^{3/}We note, moreover, that what petitioners have identified is a set of facts which may constitute a defense to an action here—“factor[s] unrelated to the administration of the vaccine”—under § 300aa-13(a)(1)(B). There is an obvious risk to petitioners’ strategy. Judicial estoppel would open petitioners up to the defense here that, but for the post-vaccination negligence of Dr. Danhauer, the death would not have occurred.

CONCLUSION

The decision of the Special Master is affirmed on other grounds. The Clerk is directed to dismiss the petition.

ERIC G. BRUGGINK
Judge