2021 PA Super 191

LISA SULLIVAN	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
HOLY REDEEMER HOSPITAL AND MEDICAL CENTER AND HOLY REDEEMER HEALTH SYSTEM	:	No. 1990 EDA 2020
Appellants	:	

Appeal from the Order Entered March 11, 2020
In the Court of Common Pleas of Montgomery County Civil Division at No(s): 2019-07502

BEFORE: DUBOW, J., MURRAY, J., and COLINS, J.*

OPINION BY COLINS, J.: **FILED SEPTEMBER 24, 2021**

This is an interlocutory appeal by permission from an order denying the motion of Appellants Holy Redeemer Hospital and Medical Center and Holy Redeemer Health System (Defendants) to dismiss a medical malpractice action filed by Lisa Sullivan (Plaintiff) pursuant to the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), 42 U.S.C. §§ 300aa–1 to 300aa–34. Because Plaintiff's action is barred by the exhaustion of remedies requirement of the Vaccine Act, we reverse the trial court's order and remand this case to the trial court with instructions to dismiss Plaintiff's complaint for lack of subject matter jurisdiction.

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* Retired Senior Judge assigned to the Superior Court.

This action arises out of Defendants' administration of a tetanus vaccination. The complaint in this action avers the following facts. Plaintiff, a nurse manager who works in Defendants' operating room, received a tetanus vaccination from Defendants' Emergency Department on June 16, 2017, following an exposure to human tissue and blood the previous day. Complaint ¶¶9-11, 18. The tetanus vaccine was injected into the subacromial bursa of Plaintiff's left shoulder and Plaintiff experienced severe burning and tingling pain in the back of her shoulder and her neck immediately after the shot. ***Id.*** ¶¶11-12. Plaintiff was unable to complete her work shift that day due to pain and sought medical treatment for continued pain on June 17, 2017. ***Id.*** ¶¶18-23. Plaintiff continued to experience shoulder pain and receive medical treatment through 2017 and 2018 and in 2019. ***Id.*** ¶¶26-29.

On April 22, 2019, Plaintiff filed this action against Defendants in the Court of Common Pleas of Montgomery County (trial court). In her complaint, Plaintiff avers that Defendants were negligent in their injection of the tetanus vaccine and that the negligent administration of the vaccine caused her to suffer shoulder bursitis, subacromial inflammation, rim rent tear, shoulder impingement, and reflex sympathetic dystrophy syndrome (RSD). Complaint ¶¶11, 35, 43, 49. On September 16, 2019, Defendants filed an answer and new matter, in which they pled that Plaintiff's action is barred by the Vaccine Act's provision, 42 U.S.C. § 300aa–11, that prohibits actions for damages exceeding $1,000 for vaccine-related injuries unless the plaintiff has first filed

a petition for compensation under the National Vaccine Injury Compensation Program (the Program) and exhausted her remedies under the Program. Answer and New Matter at 8-9 ¶24. Plaintiff admitted in response to a request for admission that she has not filed a petition for compensation under the Program with respect to the tetanus vaccination that is at issue in this action. Defendants' Motion to Dismiss Ex. B.

On January 23, 2020, Defendants filed a motion to dismiss this action for lack of subject matter jurisdiction on the ground that it is barred by the Vaccine Act. Plaintiff opposed the motion to dismiss, arguing that her injury is not a vaccine-related injury because the negligence was in the injection, rather than the content of the vaccine, and that the Vaccine Act therefore did not apply. On March 11, 2020, the trial court entered an order denying Defendants' motion to dismiss. Defendants timely filed a motion to certify the order for interlocutory appeal. Following the trial court's denial of that motion, Defendants filed a petition for permission to appeal in this Court in accordance with Pa.R.A.P. 1311. On November 4, 2020, this Court granted Defendants' petition for permission to appeal.

Defendants raise one issue in this appeal:

> Does the trial court lack subject matter jurisdiction over the plaintiff's alleged vaccine-related injury claims because the plaintiff failed to exhaust her administrative remedies pursuant to the National Childhood Vaccine Injury Act of 1986 prior to initiating the underlying litigation against the defendants?

Appellants' Brief at 6 (unnecessary capitalization omitted). We agree that the Vaccine Act applies to Plaintiff's claims and compels dismissal of this action for lack of subject matter jurisdiction.[1]

The Vaccine Act was enacted in 1986 and provides a federal administrative compensation program outside traditional tort law for vaccine injuries. ***Ashton v. Aventis Pasteur, Inc.***, 851 A.2d 908, 910 (Pa. Super. 2004); ***Cheskiewicz v. Aventis Pasteur, Inc.***, 843 A.2d 1258, 1260 (Pa. Super. 2004). Its purpose is two-fold: to expedite compensation for vaccine injuries and to protect vaccine manufacturers from litigation that jeopardized the vaccine supply. ***Ashton***, 851 A.2d at 912; ***Cheskiewicz***, 843 A.2d at 1263. The United States Supreme Court has described the Vaccine Act as covering "injuries and deaths traceable to vaccinations" and claims that "damages resulted from a vaccination." ***Shalala v. Whitecotton***, 514 U.S. 268, 269-70 (1995).

A person who claims to have suffered an injury after receiving a vaccine covered by the Vaccine Act may obtain compensation from the Program without proving any negligence or defect either by proving that the vaccine caused the injury or by demonstrating that her injury is an injury listed as associated with that vaccine in the Vaccine Injury Table created under the

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[1] This is a question of law as to which our standard of review is *de novo* and our scope of review is plenary. ***Mazur v. Trinity Area School District***, 961 A.2d 96, 101 (Pa. 2008) (whether a court has subject matter jurisdiction is a question of law).

Vaccine Act, which creates a presumption of causation. 42 U.S.C. § 300aa–11(a)(1), (c)(1)(C); 42 U.S.C. § 300aa–13; ***Shalala***, 514 U.S. at 270-71. The Vaccine Act applies both to claims against vaccine manufacturers and to medical malpractice actions against health care providers who administered a vaccine that it covers where the action asserts a claim for a "vaccine-related injury." 42 U.S.C. § 300aa–11(a)(2)(A); ***Harman v. Borah***, 720 A.2d 1058, 1060-64 (Pa. Super. 1998), ***rev'd on other issue***, 756 A.2d 1116 (Pa. 2000); ***Crucen v. Leary***, 867 N.Y.S.2d 49 (N.Y. App. Div. 2008).

The Vaccine Act provides in Section 300aa–11(a):

> (2)(A) **No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount 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**, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, **unless a petition has been filed**, in accordance with section 300aa-16 of this title, **for compensation under the Program for such injury or death** and --
> (i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and
> (II) such person elects under section 300aa-21(a) of this title to file such an action, or
> (ii) such person elects to withdraw such petition under section 300aa-21(b) of this title [permitting withdrawal of a petition where the special master fails to make a decision or the United States Court of Federal Claims fails to enter judgment on the petition within certain time limits] or such petition is considered withdrawn under such section.
> (B) **If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action.** If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the

> date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

42 U.S.C. § 300aa–11(a)(2) (emphasis added).

This exhaustion requirement applies to any "person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program." 42 U.S.C. § 300aa–11(a)(9). A person is "qualified to file a petition for compensation" and therefore subject to Section 300aa–11(a)(2)'s exhaustion requirement if the following five requirements are met: (1) the person received a vaccine set forth in the Vaccine Injury Table; (2) the vaccination was in the United States; (3) the person "sustained … any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine … and the first symptom or manifestation of the onset … occurred within the time period after vaccine administration set forth in the Vaccine Injury Table" or the person "sustained … any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by [the] vaccine;" (4) the person suffered residual effects or complications for more than six months after the vaccination; and (5) the person has not previously collected an award or settlement in a civil action for damages for the injury. 42 U.S.C. § 300aa–11(b)(1)(A), (c)(1)(A)–(E).

The language of Section 300aa–11(a)(2) is clear and must be enforced in accordance with its terms. ***Ashton***, 851 A.2d at 912.

> If statutory language is clear, the court's sole function is to enforce its terms …. The language of the [Vaccine Act] relative to wherein jurisdiction lies is clear: a claimant's exhaustion of the [Vaccine Act's] statutory remedy is a condition precedent to subject matter jurisdiction of a state or federal court to resolve the merits of a claim filed by an individual seeking damages for a vaccine-related injury.

Id.

It is undisputed here that this action is "a civil action for damages in an amount greater than $1,000." 42 U.S.C. § 300aa–11(a)(2)(A). Plaintiff in her complaint seeks damages in excess of the arbitration limit. Complaint at 7, 9, 10. ***See*** 42 Pa.C.S. § 7361(b)(2) (providing that no claim in excess of $50,000 shall be referred to arbitration). It is also an action "against a vaccine administrator." 42 U.S.C. § 300aa–11(a)(2)(A). Plaintiff avers that Defendants' agents, for whose actions she seeks to impose liability on Defendants, injected the tetanus vaccine. Complaint ¶¶31, 33-35, 39, 41-43. A health care provider that injected a vaccine is a vaccine administrator. ***Amendola v. Secretary, Department of Health & Human Services***, 989 F.2d 1180, 1186 (Fed. Cir. 1993); ***Hallowell v. Safeway, Inc.***, 2018 WL 294497 at *3 (W.D. Wash. No. C16-972 TSZ Jan. 4, 2018); ***Crucen***, 867 N.Y.S.2d at 49. Plaintiff has admitted that she has not filed a petition for compensation, as is required by Section 300aa–11(a)(2). Defendants' Motion to Dismiss Ex. B.

In addition, Plaintiff is a person "qualified to file a petition for compensation under the Program." 42 U.S.C. § 300aa–11(a)(9). The vaccine

that Plaintiff received, a tetanus vaccine, is a vaccine listed in the Vaccine Injury Table. 42 C.F.R. § 100.3(a). Plaintiff received the vaccine in the United States, as she avers that she received the tetanus shot in Montgomery County, Pennsylvania. Complaint ¶8. The injuries that Plaintiff avers that she sustained include injuries or conditions "set forth in the Vaccine Injury Table in association with the vaccine" of which the first symptoms "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). The Vaccine Injury Table lists "Shoulder Injury Related to Vaccine Administration" (SIRVA) as an injury associated with the tetanus vaccine if the first symptoms or manifestations occur within 48 hours after the vaccination. 42 C.F.R. § 100.3(a). Plaintiff avers that she suffered shoulder injuries as a result of the vaccine injection, including shoulder bursitis, shoulder inflammation, and shoulder impingement and she avers that she experienced symptoms of these injuries on the day that she received the vaccine and day after. Complaint ¶¶11-14, 18-22, 49. Plaintiff avers that she has suffered effects from these injuries for more than six months, as she avers that her pain has continued from the date of the vaccination through the date that the complaint was filed, over a year and one-half after the vaccination. ***Id.*** ¶¶28-29, 49-51. There is no contention that Plaintiff has received any damages award or settlement for her injuries.

Indeed, dismissal of this action pursuant to Section 300aa–11(a)(2) will not bar Plaintiff from recovering under the Vaccine Act. The Vaccine Act

provides that "no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation." 42 U.S.C. § 300aa–16(a)(2). Section 300aa–11(a)(2), however, provides that if civil action is dismissed for failure to comply with the Vaccine Act's exhaustion requirement, "the date such dismissed action was filed shall … be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action." 42 U.S.C. § 300aa–11(a)(2)(B). Plaintiff filed this action less than two years after the vaccination and first symptoms, well inside the Vaccine Act's three-year statute of limitations and Plaintiff would therefore be able to file a timely petition for compensation under the Vaccine Act following the dismissal of this action.

Whether the Vaccine Act requires dismissal of this action therefore turns on whether Plaintiff has asserted a claim for a vaccine-related injury. 42 U.S.C. § 300aa–11(a)(2)(A), (9) (requirement that claimant exhaust Vaccine Act remedy applies to actions "for damages arising from a vaccine-related injury or death" and "applies only to a person who has sustained a vaccine-related injury or death"). The trial court held, and Plaintiff argues that the injuries here are not vaccine-related because the negligence that she alleges does not relate to the vaccine or its components. That, however, is not the test for whether an injury is vaccine-related. An injury is vaccine-related and is subject to the Vaccine Act if the vaccine was a cause of the injury, even if

the only tortious conduct alleged against the defendant is unrelated to the content of the vaccine. ***Aull v. Secretary of Health & Human Services***, 462 F.3d 1338, 1343-44 (Fed. Cir. 2006) (medical malpractice action for negligent treatment of injury caused by vaccine was vaccine-related action because it was not "facially unrelated to the vaccine's effects") (quoting ***Amendola***); ***Amendola***, 989 F.2d at 1186-87 (claim against physician was vaccine-related because "the injury resulted from the administration of the vaccine," even though only negligence alleged was in decision to give the vaccine) (emphasis omitted); ***Stenberg v. Kalansky***, 996 N.Y.S.2d 306, 307 (N.Y. App. Div. 2014) (lack of informed consent claim concerning vaccine was subject to the Vaccine Act); ***Quigley v. Rider***, 593 S.E.2d 476, 477-79 (S.C. 2003) (medical malpractice action for negligence in decision to give vaccinations was claim for vaccine-related injury). The fact that the plaintiff claims that the person administering the vaccine injected it in the wrong way does not remove an action from the Vaccine Act's coverage. ***Hallowell***, 2018 WL 294497 at *1-*3 (Vaccine Act applied even though complaint alleged that "the nurse jammed the needle in the wrong way").[2]

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[2] ***Shyface v. Secretary of Health & Human Services***, 165 F.3d 1344 (Fed. Cir. 1999), on which Plaintiff relies, is not to the contrary. The issue in ***Shyface*** was the standard for proving causation where the injury is not one listed on the Vaccine Injury Table as associated with the vaccine in question, not whether claims of negligence unrelated to the components of the vaccine prevent an injury from being vaccine-related.

Here, Plaintiff's averments include claims that the presence of the tetanus vaccine in her subacromial bursa caused her injuries, not merely that the hypodermic needle itself damaged her shoulder. Plaintiff avers in her complaint that her injuries were caused by "the failure to inject a tetanus shot into an appropriate and safe location of [her] arm/shoulder," and that Defendants were negligent because they "failed to inject a tetanus shot at an appropriate and safe location on the arm/shoulder," and "failed to follow the warnings and directions of the tetanus shot instructions." Complaint ¶¶35(g), 39, 43(g), 47. Injury caused by the presence of tetanus vaccine in the wrong part of Plaintiff's shoulder is an injury caused by the vaccine and is therefore a claim for a vaccine-related injury, even though the only negligence or other basis for tort liability is in the injection method.

Moreover, even if Plaintiff did not make any averments that the tetanus vaccine's interaction with her shoulder contributed to her injuries, her complaint makes a claim for a vaccine-related injury because it asserts claims for injuries listed in the Vaccine Injury Table as associated with her vaccine. The Vaccine Act defines "vaccine-related injury" as "an illness, injury, [or] condition … associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, [or] condition … associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa–33(5). An injury that the Vaccine Injury Table lists as covered for that vaccine is a vaccine-related injury

and an action for damages for such an injury is barred if the plaintiff has not complied with Section 300aa–11(a)(2)(A)'s exhaustion requirement. ***Hallowell***, 2018 WL 294497 at *2-*3 (action for shoulder injury from flu shot was for vaccine-related injury and was barred by the Vaccine Act because Vaccine Injury Table listed SIRVA as a flu vaccine injury).

As was discussed above, the Vaccine Injury Table lists shoulder injury, SIRVA, as an injury associated with the tetanus vaccine if the first symptom or manifestation occurs within 48 hours after the vaccination and Plaintiff avers that she suffered shoulder injuries as a result of the vaccine injection and experienced symptoms of these injuries on the day that she received the vaccine and day after. 42 C.F.R. § 100.3(a); Complaint ¶¶11-14, 18-22, 49. The Vaccine Injury Table describes SIRVA as follows:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).

42 C.F.R. § 100.3(c)(10). Plaintiff's claims of shoulder bursitis, shoulder inflammation, and shoulder impingement, Complaint ¶49(a), (b), (d), meet this definition.

The Vaccine Injury Table further provides:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
> (ii) Pain occurs within the specified time-frame;
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10). There is no dispute that Plaintiff's claims meet the first three of these requirements.

The trial court concluded that the fourth requirement was not met because Plaintiff's RSD claim is an uncovered condition or abnormality that would explain Plaintiff's symptoms. Trial Court Opinion at 11. This ruling was not a valid basis for concluding that Plaintiff's shoulder bursitis, shoulder inflammation, and shoulder impingement do not constitute SIRVA. RSD is an injury that follows another injury. Merriam-Webster's Medical Desk Dictionary 705 (2002) (defining RSD as "a painful disorder that usu. follows a localized injury, that is marked by burning pain, swelling and motor and sensory disturbances esp. of an extremity, and that is associated with sympathetic nervous system dysfunction"). Plaintiff does not aver that she suffered from RSD before she suffered her other injuries. It is therefore not an "other condition or abnormality … that would explain" Plaintiff's diagnosed shoulder bursitis and impingement that, according to Plaintiff's complaint, were

clinically documented the day after Plaintiff's tetanus vaccination. Complaint ¶¶20-21.

Plaintiff contends that her claim of RSD does not constitute SIRVA because it is a neurological injury and that this excludes her action from the Vaccine Act. This claim fails for two reasons.

First, the contention that RSD is excluded from compensation under the Vaccine Act is inaccurate. RSD is a dysfunction caused by another injury and not a direct neurological injury. Merriam-Webster's Medical Desk Dictionary 705 (2002). If Plaintiff's RSD is a complication or sequela of her SIRVA, it can also qualify as an injury associated with the tetanus vaccine under the Vaccine Injury Table. 42 C.F.R. § 100.3 (b)(1). RSD has in fact been held to be compensable under the Vaccine Act. ***Fullerton v. Secretary of Health & Human Services***, 2019 WL 1894574 at *1 (Fed. Claims, Office of Special Masters No. 15-182 Apr. 24, 2019); ***Sloan v. Secretary of Health***, 2019 WL 1556706 a *1 (Fed. Claims, Office of Special Masters No. 16-1561V Feb. 1, 2019); ***Dedon v. Secretary of Health & Human Services***, 2014 WL 7495978 at *1 (Fed. Claims, Office of Special Masters No. 14–553V Dec. 17, 2014); ***Garrett v. Secretary of Department of Health & Human Services***,

2004 WL 528312 at *10 (Fed. Claims, Office of Special Masters No. 01–452V Mar. 3, 2004).[3]

More importantly, even if Plaintiff's RSD is not a vaccine-related injury, that does not negate the fact that the other injuries for which Plaintiff seeks damages are Vaccine Injury Table injuries and are therefore vaccine-related. Because Plaintiff's complaint seeks damages for the vaccine-related injury of SIRVA in its shoulder bursitis, shoulder inflammation, and shoulder impingement claims, this action is an action "for damages arising from a vaccine-related injury" subject to the requirement that she exhaust her remedies under the Program prior to bringing a tort action, regardless of the status of her RSD claim. 42 U.S.C. § 300aa–11(a)(2)(A); ***Hallowell***, 2018 WL 294497 at *2-*3.

The trial court also held and Plaintiff contends that two decisions of other states' courts, ***Nwosu v. Adler***, 969 So.2d 516 (Fla. App. 2007) and ***Neddeau v. Rite Aid of Connecticut***, 2015 WL 5133151 (Conn. Super. July 28, 2015), and subsequent regulatory action with respect to the Vaccine Injury Table show that this action does not seek damages for a vaccine-related injury. These arguments are likewise without merit.

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[3] If Plaintiff's RSD were held not to be a condition set forth in the Vaccine Injury Table, that would not prevent Plaintiff from recovering compensation for that injury from the Program, as she could recover for any injury not listed in the Vaccine Injury Table by proving causation without the benefit of the Vaccine Injury Table presumption. 42 U.S.C. § 300aa–11 (c)(1)(C)(ii); 42 U.S.C. § 300aa–13(a); ***Shyface***, 165 F.3d at 1350.

These cases relied on by the trial court and Plaintiff are inapplicable here because they did not involve any Vaccine Injury Table injury. In ***Nwosu***, the court held that there was no vaccine-related injury and reversed dismissal of a damages action where the plaintiff claimed that a diphtheria-tetanus-pertussis vaccination caused a nerve injury to the lower part of the body and alleged that the injury was caused by the needle hitting a nerve, not that presence of the vaccine at the injection site caused injury. 969 So.2d at 517-19. The Vaccine Injury Table does not list nerve injury to the lower part of the body as an injury associated with the diphtheria-tetanus-pertussis vaccine. 42 C.F.R. § 100.3(a). In ***Neddeau***, the court held that there was no vaccine-related injury and denied a motion to dismiss where the plaintiff sued the pharmacy that gave her a flu shot for shoulder and arm injuries allegedly caused because the pharmacist who injected the vaccine "'improperly stuck the needle too high' in the plaintiff's arm." 2015 WL 5133151 at *1-*3. While this would appear to allege SIRVA and SIRVA is currently listed on the Vaccine Injury Table as associated with the flu vaccine, SIRVA was not added to the Vaccine Injury Table until 2017. 82 F.R. 6294-01; 82 FR 11321-01; ***see generally*** 86 F.R. 21209-01 at 21209-10. The injury in ***Neddeau*** therefore was not a Vaccine Injury Table injury in 2015 when the court held that the plaintiff's injury was not a vaccine-related injury. Here, in contrast, Plaintiff has alleged shoulder injuries that are Vaccine Injury Table injuries and that are therefore necessarily vaccine-related injuries.

The subsequent regulatory actions concerning the Vaccine Injury Table not only do not support the trial court's order, they confirm that claims for shoulder injuries from a negligently injected vaccine are claims for vaccine-related injuries that are subject to the Vaccine Act. Following a July 20, 2020 notice of proposed rulemaking, the Department of Health and Human Services (HHS) issued a regulation that was to become effective February 22, 2021 that would have revised the Vaccine Injury Table to remove SIRVA as a vaccine-related injury. 86 F.R. 6249-01. The revision concluded that SIRVA damages claims should be addressed through tort actions rather than compensated through Program because they involve vaccination technique and administration of the vaccine, rather than the components of the vaccine. 86 F.R. 6249-01 at 6252-56, 6259-62, 6264-65.[4]

This revision, however, never became law. HHS delayed the effective date of the revision for 60 days to April 23, 2021, 86 FR 10835-01 and, on April 22, 2021, rescinded the revision and left SIRVA listed in the Vaccine Injury Table as an injury associated with the tetanus vaccine and other

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[4] HHS in this revision did recognize that injuries classified as SIRVA can "occur when an immunologically active substance designed to trigger an inflammatory response (i.e., the vaccine antigen) is injected into an area where the inflammatory response can cause joint damage (i.e., the bursa or tendons) as opposed to an area where the inflammatory response will not cause joint damage or permanent harm (i.e., the deltoid muscle)," but nonetheless would have removed SIRVA from the Vaccine Injury Table because poor injection technique was also a cause. 86 F.R. 6249-01 at 6256, 6261.

vaccines. 86 F.R. 21209-01. In rescinding the revision, HHS stated that it did so "because it is concerned that [the revision] would have a negative impact on vaccine administrators," noting that the removal of conditions from the Vaccine Injury Table "could negatively impact the vaccine administrators carrying out this massive COVID-19 vaccination campaign by increasing their exposure to liability for administering non-COVID vaccines." ***Id.*** at 21211, 21213.

Because Plaintiff's complaint asserts claims for damages for a vaccine-related injury, it is subject to the Vaccine Act's exhaustion of remedies requirement and this action must be dismissed for lack of subject matter jurisdiction. Accordingly, we reverse the trial court's order and remand this case with instructions to dismiss the action without prejudice to any right that Plaintiff may have to bring an action after she has filed a petition for compensation under the Program and has exhausted her remedies under the Vaccine Act.

Order reversed. Case remanded with instructions. Jurisdiction relinquished.

Judgment Entered.

Joseph D. Seletyn, Esq.
Prothonotary

Date: 9/24/2021