

A Shot in the Arm: “Procedural Preemption” of Vaccine Claims

By David J. Walz

The National Childhood Vaccine Injury Act of 1986 (the “Vaccine Act” or the “Act”) dictates the compensation process for injuries resulting from covered vaccines. *See* 42 U.S.C. §§ 300aa-1 *et seq.* Generally, it sets forth an administrative no-fault compensation program for claimants alleging a vaccine-related injury. Claimants proceed under that program in the United States Court of Federal Claims (the “Vaccine Court”).

For claims filed outside of the Vaccine Court under state tort law, the Vaccine Act substantively preempts product-liability claims in several ways. For example, the Vaccine Act provides that “[n]o vaccine manufacturer shall be liable in a civil action . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.” 42 U.S.C. § 300aa-22(b)(1). Courts apply that provision to bar design-based claims under Restatement (Second) of Torts section 402A, comment k. *See, e.g., Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 241, 247-48 (3d Cir. 2009). Likewise, other provisions of the Vaccine Act create a rebuttable presumption that a warning is adequate if the manufacturer complies with FDA regulations, *see* 42 U.S.C. § 300aa-22(b)(2), and eliminate the mass-immunization exception to the learned-intermediary doctrine. *See* 42 U.S.C. § 300aa-22(c). Those substantive preemption arguments arise frequently as defenses.

Less frequently encountered and discussed are certain “procedural preemption” grounds that bar suits filed in state or federal court other than the Vaccine Court before even reaching the issue of substantive preemption. This article will focus on those procedural issues.

Seeking Compensation in the Vaccine Court is a Condition Precedent to Filing Suit under State Law

A plaintiff may file suit under state law only after first petitioning the Vaccine Court for compensation and rejecting that court’s judgment. Under the Vaccine Act, any “[s]uit in state and federal courts is barred unless and until there has been compliance with section 300aa-11(a)(2)(A) of the Act.” *Holder v. Abbott Labs., Inc.*, 444 F.3d 383, 388 (5th Cir. 2006). Compliance under that section “requires that claims ‘for a vaccine-related injury or death’ must first be brought in the United States Court of Federal Claims.” *Id.* at 387-88 (*citing* 42 U.S.C. § 300aa-11(a)(1)). As a result, “[i]f a civil action barred under section 300aa-11(a)(2)(A) is brought in state or federal court, *the court is required to dismiss the action.*” *Id.* at 388 (*citing* 42 U.S.C. § 300aa-11(a)(2)(B)) (*emphasis added*); *see also Adams v. Aventis Pasteur, Inc.*, No. Civ. 04-246-AA, 2004 WL 1724624, *2 (D. Or. July 29, 2004) (granting dismissal and holding that the “Act makes clear that any person seeking compensation for a vaccine-related injury must first file a petition in Vaccine Court [the Court of Federal Claims] as a condition precedent to filing suit”).

Simply put, a fundamental premise in vaccine-related claims is that “the Vaccine Act requires that plaintiff [file a petition for compensation under the no-fault program] before seeking relief in [] court.” *Adams*, 2004 WL 1724624 at *2. Otherwise, “the plain and mandatory language of the Vaccine Act requires [the] court to dismiss plaintiffs’ [] complaint.” *Id.* Courts around the

country apply the Vaccine Act requirements as a condition precedent to filing a lawsuit. *See, e.g., Reilly v. Wyeth*, 876 N.E.2d 740, 744, 746 (Ill. App. Ct. 2007) (affirming dismissal of a complaint “for failing to exhaust [the] remedies under the [Act]” because the Act “requires that a person seeking compensation for a vaccine-related injury must first file a petition against the United States Secretary of Health and Human Services [in the Vaccine Court] before traditional tort remedies may be pursued.”); *Cheskiewicz v. Aventis Pasteur, Inc.*, 843 A.2d 1258, 1262 (Pa. Sup. Ct. 2004) (affirming dismissal and holding that “[t]he general rule provision of the Vaccine Act mandates that a petition must be filed in Vaccine Court before initiating a civil action in either state or federal court”).

Thus, a vaccine plaintiff’s failure to exhaust the remedies available under the compensation program before filing suit under state law is a powerful defense.

Even Potentially Time-Barred Claims Must First Proceed in Vaccine Court

The Vaccine Act imposes several time limitations on claims. For vaccines already included in the list of covered vaccines, claims must be filed in the Vaccine Court within 36 months of the claimant’s “first symptom or manifestation of onset or of the significant aggravation of such injury.” 42 U.S.C. § 300aa-16(a)(2); *see* 42 U.S.C. § 300aa-14(a) (listing covered vaccines). Occasionally, the list of covered vaccines is revised to include additional vaccines. When a vaccine is added to the list, a savings provision in the Vaccine Act allows claimants two years from the date of the revision to file a claim. *See* 42 U.S.C. § 300aa-16(b). That savings provision applies as long as the vaccine-related death or injury occurred no more than eight years before the date of the revision that added the vaccine to the list of covered vaccines.

Those time bars do not, however, alter the requirement that a claimant first proceed in Vaccine Court. Indeed, even claims that are potentially barred, outside of, or untimely under the Vaccine Act must still first proceed by petition through the claims process to allow the Vaccine Court to make that determination. *See Cheskiewicz*, 843 A.2d at 1264 (“We acknowledge that . . . [the] Vaccine Act claim likely will be adjudged untimely. Nonetheless, [plaintiffs] must await a determination from the Vaccine Court and cannot anticipate its decision and proceed prematurely to state court.”). Courts applying the Vaccine Act hold that “the question of whether plaintiffs are barred from filing petitions for compensation is one that must be decided first by the Vaccine Court.” *Adams*, 2004 WL 1724624, *4-*5 (rejecting the argument that a court could “rewrite the statute to allow plaintiffs their day in court without first exhausting their remedies under the [p]rogram established by the Vaccine Act.”); *see also Reilly*, 876 N.E.2d at 751-52 (recognizing that Congress may require a party to exhaust its remedies prior to filing suit and rejecting the argument that presumably ineligible claims need not resolve that issue first under the claims process).

Plaintiffs typically argue that, by falling outside of the time requirements in the Vaccine Act, they also fall outside of the provisions barring civil suits. That argument fails, though, because the Vaccine Court determines its own jurisdiction, including the assessment of a claimant’s eligibility. Indeed, the Vaccine Court possesses exclusive jurisdiction over such matters:

The United States Court of Federal Claims and the United States Court of

Federal Claims special masters *shall*, in accordance with this section, *have jurisdiction* over proceedings to determine if a petitioner under section 300aa-11 of this title is *entitled to compensation* under the Program and the amount of such compensation.

42 U.S.C. § 300aa-12(a) (emphasis added). Courts applying that provision treat the Vaccine Court’s jurisdiction as exclusive. *See Culbertson v. Peoples Bank*, 375 F. Supp. 2d 824, 827-28 (S.D. Iowa 2005) (noting “that the exclusivity provision” of section 300aa-12(a) extends “to the questions of entitlement and initial amounts of compensation.”). Thus, the Vaccine Court determines whether the Vaccine Act covers a claim and whether a petitioner is eligible for relief – not any other federal or state court.

For that matter, the general restrictions that bar skipping over the Vaccine Court to file suit in federal or state court under 42 U.S.C. § 300aa-11(a)(2)(A), (B) are broad and unrelated to the claim’s underlying validity. Section 300aa-11(a)(2)(A) expansively restricts and bars all “civil action[s] 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” The Vaccine Act’s plain language applies that mandatory restriction to any “civil action for damages” involving “a vaccine-related injury or death.” It does not draw any connection to whether a claim is covered, timely, or barred. In fact, a “proper claimant” under the Vaccine Act is simply “any person who has sustained a vaccine-related injury,” or the legal representative of such person.” *Strauss v. Am. Home Prods. Corp.*, 208 F. Supp. 2d 711, 713 n.4 (S.D. Tex. 2002) (*quoting* 42 U.S.C. § 300aa-11(b)(1)(A)). Accordingly, as long as the plaintiff alleges a vaccine-related injury, the plaintiff is subject to all of the Vaccine Act requirements, including the restrictions that bar a premature suit in federal or state court.

Another typical plaintiffs’ argument is that they are not “qualified petitioners” under 42 U.S.C. § 300aa-11(a)(9) and, as a result, the general restrictions in the rest of section 300aa-11 do not apply. The provision that plaintiffs rely upon in section 300aa-11(a)(9) limits the general restrictions elsewhere in section 300aa-11 so that those restrictions “appl[y] only to a 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) (emphasis added). That limitation, though, is a narrow one and does not apply as plaintiffs usually contend. In *Cheskiewicz*, the plaintiffs argued that they were not “qualified” under section 300aa-11(a)(9) because their claim was untimely and not covered under the Vaccine Act. *See* 843 A.2d at 1263. The court rejected that argument, holding that 42 U.S.C. § 300aa-11(c)(1)(A)-(E) defines a qualified litigant in the Vaccine Court and essentially requires only that a person received a vaccine and was allegedly injured as a result. *See id.* The court concluded that those simple requirements “are the requisites for filing, not including, as [claimants] maintain, that the purported claim is timely.” *Id.*

Likewise, “eligibility” to file a petition in Vaccine Court is not the high burden that plaintiffs often contend. Rather, it requires only that a petitioner “suffers a specified injury after receiving a vaccine” or “is the legal representative of such a person.” *Strauss*, 208 F. Supp. 2d at 714; *see Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 5 (1st Cir. 1994) (explaining that “qualified” under

section 300aa-11(a)(9) means only that the claimant actually “received a vaccine” and does not entail some broader limitation based on actual eligibility or timeliness); *Nestlen v. Wyeth*, No. 0201-00126, 0106-05780, 2003 WL 23531954, *2 (Or. Cir. Ct. Mar. 20, 2003), *aff’d* 194 P.3d 367 (Or. Ct. App. 2004) (rejecting argument that “qualified” under section 300aa-11(a)(9) “creates an exception to the general rule that potential state court litigants first proceed through Vaccine Court.”).

Even the Vaccine Court itself holds that a petitioner may not use section 300aa-11(a)(9) to escape the general Vaccine Act requirements. In *Zwick*, the petitioner argued that the general requirements and prohibitions in section 300aa-11(a) did not apply because the vaccine administered to him was not listed on the Vaccine Injury Table at the time that he received the vaccine. *See* 2007 WL 5172434 at *4. In particular, the petitioner argued that, as a result, he was not “qualified” under section 300aa-11(a)(9). *See id.* The Vaccine Court wholeheartedly rejected that argument, holding that “[a]lthough there are only a few decisions interpreting subsection 11(a)(9), none of those decisions read that subsection to mean what [the petitioner] contends that it does.” *Id.*

In the end, plaintiffs cannot argue around the Vaccine Court’s jurisdiction by claiming that their claim is not covered, or that they are not qualified, under the Vaccine Act.

The Failure to File a Timely Claim in the Vaccine Court Bars a Subsequent Tort Action

Finally, even if a plaintiff files a petition in the Vaccine Court first, but fails to do so within the Vaccine Act’s limitations periods, any subsequent tort action under state law is barred. *See, e.g., Strauss*, 208 F. Supp. 2d at 715-16; *McDonald v. Lederle Labs*, 775 A.2d 528, 532-33 (N.J. Super. Ct. App. Div. 2001). Untimely claims in the Vaccine Court are not saved by longer statutes of limitation or delayed-discovery rules under state law. *See, e.g., Hebert v. Sec’y of Health & Human Servs.*, 66 Fed. Cl. 43, 46-47 (Fed. Cl. 2005) (no application of tolling provisions under state law); *Strauss*, 208 F. Supp. 2d at 716 n.10. Thus, the limitations provisions in the Vaccine Act control and dictate the timeliness of product-liability claims outside of the Vaccine Court.

Overall, “procedural preemption” of vaccine claims offers several options to build up an immunity against product-liability claims under state law. Used wisely as a defense, it will inoculate manufacturers before a case even gets to the substantive issues.

David J. Walz is an associate in the Tampa, Florida office of Carlton Fields. His practice focuses on product-liability claims, primarily pharmaceutical litigation and the defense of actions involving prescription and over-the-counter products and devices. He may be contacted at dwalz@carltonfields.com and wishes to thank Allison L. Kirkwood, a 2009 Summer Associate at Carlton Fields, for her assistance in preparing this article.