

Litigating On-Table and Off-Table Vaccine Cases in Federal Claims Court

I. Introduction

Starting in the early 1980s, parents of children harmed or killed by certain vaccines, especially the DTP vaccine (diphtheria/tetanus/pertussis), began bringing lawsuits against the manufacturers and health care providers that administered these vaccines. Fearful that these lawsuits would cause vaccine shortages, deter the production and development of additional vaccines, and reduce vaccination rates in the United States, Congress enacted the National Vaccine Injury Compensation Program (NVICP) in 1986.¹ NVICP is a federal no-fault program dedicated to the adjudication of vaccine injury claims.

Under the NVICP, rather than filing a lawsuit against the vaccine manufacturer or vaccine administrator in the civil tort system, individuals claiming vaccine-related injury or death must file a petition for “no-fault” compensation with the United States Court of Federal Claims.² The petition is served upon the Secretary of Health and Human Services (“HHS”), which functions as the “respondent” and decides whether to concede or defend the claim.³ Although the system is designed to be non-adversarial, HHS very much conducts itself like a civil tort defendant, and the process is generally as adversarial as it would be in the civil tort system. The U.S. Department of Justice (“DOJ”) serves as HHS’s counsel through its Tort Branch in the Civil Division.

The NVICP also features the Office of Special Masters, often referred to as “vaccine court,” which is an adjunct to the United States Court of Federal Claims. The Special Masters serve as the trial judges in vaccine cases, including having final decision authority. Claimants under the NVICP need not prove negligence, failure to warn, or other tort causes of action. Rather, claimants must only prove: 1) that the vaccine(s) at issue is one covered under the NVICP; 2) causation; and 3) damages. Litigation is bifurcated such that causation, or “entitlement,” is litigated first, followed by damages.

The NVICP is funded by an excise tax of \$0.75 on each vaccine dose. This fund is almost exclusively used to fund the compensation awarded to claimants as well as their attorneys. The NVICP has a unique framework for awarding attorney’s fees and costs. Attorneys may be eligible for reasonable attorneys’ fees, which are determined by the Special Masters, but by statute may not charge any other fees, including a contingency fee, for their services in representing a petitioner in the NVICP.

Although well-intentioned, the NVICP system has become rather complicated and inefficient. There is currently a perfect storm taking place in the NVICP which has resulted in a significant backlog of cases: More vaccine cases are being filed than ever before, and in recent years the DOJ has been taking a much harder line with respect to settlement. At an entitlement hearing I argued in Washington, D.C. in July of 2018, the Special Master noted that it would likely take him more than 12 months to issue his order. True to his word, we have yet to receive the order. It took three years from the date we filed our initial petition to reach that entitlement hearing, which again is only the first stage of litigation. If entitlement is awarded in our client’s favor, it will then proceed to the damages phase and take no less than another year before

¹ H.R.Rep. No. 99–908, at 6–7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347–48; 42 U.S.C. § 300aa–1.

² 42 U.S.C. § 300aa–12.

³ 42 U.S.C. § 300aa-11.

reaching full and final resolution, assuming there are no appeals. There are plenty of instances in which a single case has taken more than 10 years to be fully adjudicated.

II. Initial Considerations and Pre-Requisites to Filing a Petition

Before filing a petition for vaccine injury, one must first ensure that the vaccines at issue are covered under the NVICP. In total, sixteen vaccines are now covered.⁴ If the vaccine at issue is covered, then the next step is to ensure that the effects of the injury either: 1) lasted for more than six months after the vaccination; 2) resulted in inpatient hospitalization and surgical intervention; or 3) resulted in death.⁵ There are also filing deadlines to consider.⁶ For instances of injury, petitions generally must be filed within three years after the first symptom or manifestation of onset or of the significant aggravation of the injury. For instances of death, petitions generally must be filed within two years of passing and within four years of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

If the above pre-requisites are met, one should next refer to the Vaccine Injury Table to determine whether the injuries at issue will be considered “on-table” or “off-table.”⁷ The NVICP provides two separate mechanisms through which a party may establish that an injury was caused by a vaccine. First, a causal connection between vaccine and injury is rebuttably presumed if the administration of the vaccine and the particular injury are related in time as specified in the Vaccine Injury Table of 42 U.S.C. § 300aa–14.⁸ This is commonly referred to as an “on-table” case. Conversely, if the injury is not listed in the Table, or if its symptoms are not evident within the time frame specified by the Table, the petitioner faces a more demanding evidentiary burden and a much lengthier and complicated road to recovery. This is commonly referred to as an “off-table” case. An “off-table” petitioner bears the burden of proving that the vaccine was the actual cause of the injury.⁹ As the United States Court of Appeals has noted, “[g]iven the vagaries of human illnesses, particularly in young children, that is not always an easy burden to carry.”¹⁰

III. Litigating Off-Table Cases and the Three *Althen* Factors

To prove actual causation in an off-table injury case, the petitioner must show by a preponderance of evidence that the vaccination brought about the injury by providing: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury.”¹¹ Establishing causation via these three *Althen* factors is often the main challenge in any off-table vaccine case; however, be aware that HHS will often challenge diagnosis as well.

An off-table petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be “legally

⁴ <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html>.

⁵ 42 U.S.C. § 300aa-11.

⁶ 42 U.S.C. § 300aa–16(a)(2).

⁷ <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>.

⁸ 42 U.S.C. §§ 300aa–11(c)(1)(C)(i), 300aa–13(a)(1).

⁹ 42 U.S.C. § 300aa–11(c)(1)(C)(ii).

¹⁰ *Munn v. Sec. of Dep't of Health and Human Servs.*, 970 F.2d 863, 865 (Fed.Cir.1992).

¹¹ *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed.Cir.2005).

probable, not medically or scientifically certain.”¹² Proof of causation must be established by a preponderance of the evidence.¹³ Expert testimony is almost always required to prove causation in an off-table case. Vaccine Rules of the United States Court of Federal Claims Rule 8(b)(1) “provides that the special master will ‘consider all *relevant and reliable* evidence.’ (emphasis added). By inclusion of the terms ‘relevant and reliable,’ Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters.”¹⁴ While Special Masters may look to the *Daubert* standards in evaluating expert testimony, be aware that they do not control the Special Master’s analysis.

It is especially important in vaccine cases to carefully review the medical records before filing a petition because the records are given great weight in vaccine court. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”¹⁵ “[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether ‘a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’”¹⁶

Regarding the three *Althen* prongs, Petitioners cannot be required to show “epidemiologic studies...the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.”¹⁷ Causation is determined on a case-by-case basis, with “no hard and fast *per se* scientific or medical rules.”¹⁸ Close calls regarding causation must be resolved in favor of the petitioner.¹⁹

If the petitioner can establish a prima facie case by meeting the three *Althen* factors, then the petitioner is entitled to compensation unless the respondent can put forth preponderant evidence that petitioner’s injury was in fact caused by factors unrelated to the vaccine.²⁰ As the *Althen* court noted, Congress’s intent was that vaccine awards be made “quickly, easily, and with certainty and generosity” even if this results in “compensation to some children whose illness is not, in fact-vaccine-related.”²¹ “This purpose would not be served by allowing the Secretary to avoid an award by offering ‘speculative or hypothetical matters or explanations’ of alternate causation...”²²

Causation, or “entitlement,” can be established by concession or via court order after a contested hearing. Once established, the case then proceeds to the damages phase. The damages available in NVICP fall generally into four categories: 1) pain and suffering, which is

¹² *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed.Cir.1994).

¹³ 42 U.S.C. § 300aa–13(a)(1)(A).

¹⁴ *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338–39 (Fed. Cir. 2010).

¹⁵ *Murphy v. Sec’y, HHS*, 23 Cl.Ct. 726, 733 (1991), *aff’d*, 968 F.2d 1226 (Fed.Cir.1992) omitted); *see also Cucuras v. Sec’y, HHS*, 993 F.2d 1525, 1528 (Fed.Cir.1993) (medical records are generally trustworthy evidence).

¹⁶ *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

¹⁷ *Capizzano*, 440 F.3d at 1325.

¹⁸ *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed.Cir.1994).

¹⁹ *Althen*, 418 F.3d at 1280.

²⁰ *Whitcotton v. Sec’y of HHS*, 17 F. 3d 374, 376 (Fed. Cir. 1994) *rev’d on other grounds sub nom. Shalala v. Whitcotton*, 514 U.S. 268 (1995); *see also Walther v. Sec’y of HHS*, 485 F. 3d 1146, 1151 (Fed. Cir. 2007).

²¹ H.R.Rep. No. 908, 99th Cong.2d Sess. 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344.

²² *Whitcotton*, 17 F.3d 374, 378.

capped at \$250,000.00; 2) lost wages; 3) past out-of-pocket medical expenses; and 4) future medical needs.²³ Wrongful death cases are hard capped at \$250,000.00. The damages phase also often requires expert testimony, including a life care planner and economist.

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²³ 42 U.S.C. § 300aa-15(a)