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PERSPECTIVE

## Filing vaccine injury claims under the federal Vaccine Injury Act

By Ben Riley

Imagine being a parent in the 1940s and 1950s. It's a hot summer day, and your daughter wants to go to the neighborhood pool. But Life Magazine contains terrifying photos of kids stacked up in iron lungs being fed and playing games of checkers as only their heads stick out of the wall of machines. They can't breathe on their own and many will die from paralysis — all from the deadly scourge of polio. What do you do?

This was an all-too real, life and death dilemma until the approval of Jonas Salk's "dead" polio vaccine in 1955. Before the wide-spread administration of the Salk vaccine and later the Sabin "live" vaccine, thousands of kids and adults contracted polio every summer, many dying or becoming severely disabled. Commenting about the polio and other vaccines, the United States Supreme Court noted that "the elimination of communicable diseases through vaccination is one of the greatest achievements of public health in the 20th century." *Bruesewitz v. Wyeth*, 562 US 223 (2011).

*The Need for Vaccine Injury Redress and Compensation.* By the 1970s, people started noticing the relatively few, but still often devastating, cases where healthy babies and children were severely disabled or died from childhood vaccines. In the 1980s, thousands of state court cases were filed, mostly challenging the pertussis part of the DPT vaccine. Some early studies (later discredited) posited a link between the vaccine and autism. The drug company Wyeth claimed to be subject to

potential liability of four to five times what it was earning on selling childhood vaccines. For the most part, courts dismissed the resulting design defect cases against drug companies, saying that for the greater public good, it was best to successfully vaccinate millions of children, even though a few inevitably would be injured by the vaccine. It's hard to argue otherwise — unless you're the parent of the one out of 5 million children who actually contracted polio or some other deadly disease from a vaccine.

Still, Congress was afraid that vaccine manufacturers would stop making the vaccines because of possible liability from civil injury suits. In response, Congress passed the National Vaccine Injury Act, effective in 1987, to require that claims for death or injuries from covered vaccines be brought in the United States Court of Federal Claims. The Vaccine Act was initially funded with \$80M from Congress, then by a 75-cent fee charged on each administered dose of covered vaccines. The idea was to ensure a stable supply of vaccines and development of new vaccines while limiting liability of manufacturers, and to provide a quick, no-fault compensation system for the small number of injured.

*The Vaccine Act.* Section 2101 of the Public Health Service Act (42 USC Section 300aa) establishes the National Vaccine Injury Compensation Program. If the plaintiff claims injury from a covered vaccine, he or she must bring their action in the United States Court of Federal Claims. The Vaccine Act preempts suits in other courts for properly prepared vaccines with

proper warnings (*Bruesewitz*), although separate cases may be brought for negligence or fraud.

The Vaccine Act requires that the petitioner suffered either death, or injury lasting for more than six months, either from a covered vaccine or from a person who has taken the covered vaccine. The claim must be filed within 24 months of death, or 36 months after injury. The act's Vaccine Injury Table, promulgated by the Department of Health and Human Services, lists the covered vaccines as well as the symptoms and time frame under which injuries normally manifest. For example, the polio infection normally occurs 25 to 30 days after the vaccine is administered, and manifests with high fever, lethargy, then paralysis. The Vaccine Act expressly covers babies, children and pregnant mothers. In 2005, the flu vaccines were added to the Vaccine Injury Table, and since then many more adults have filed claims under the act.

The Vaccine Act establishes a nofault system and comparatively permissive proof standard as long as the petitioner can show some connection between the injury and the vaccine. Often the Vaccine Injury Table is sufficient, given the symptoms and timing of injury. Best case, as with polio, is a specific diagnosis from the CDC. But the court will also consider expert testimony and the relevant science to establish the requisite connection.

Procedures under the act are easier and speedier, but the level of compensation is much less than normal court litigation. The respondent in the case is the Secretary of HHS, and the cases are

decided by Vaccine Compensation Special Masters from the Court of Federal Claims. The Justice Department attorneys defending the cases are specialists in these vaccine petitions.

*Injuries Under the Act; COVID Not Yet Covered.* As mentioned, to file a claim under the Vaccine Act, the vaccine alleged to have caused the injury must be specifically listed in the Vaccine Injury Table. See [https:// www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable. pdf](https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf). Included vaccines are polio, DPT, measles, mumps, meningitis, hepatitis, seasonal flu, and others.

Importantly, the COVID vaccines are not yet covered by the Vaccine Act. But in April 2021, the special master in *Wilson v. HHS*, 2021 WL 2379553, stated that "it is foreseen-

**Ben Riley** is a principal with Bartko Zankel Bunzel & Miller in San Francisco, and a member of the firm's Executive Committee. He is a trial lawyer (30 trials to verdict) specializing in Intellectual Property, Commercial, and Trust and Estate Litigation.



able that the COVID-19 vaccine will (in some form and at some time in the future) be added to the Table,” enabling filing of past and future injury claims from the vaccines.

In the 1990s and 2000s, I litigated two cases under the act, for children who contracted polio from the vaccine. Although exceedingly rare (one in 5 million?), as a result of these and other polio petitions the CDC changed its vaccine protocol. Instead of 6-week-old babies getting the live Sabin vaccine — which provides better and longer societal immunity but exposes a very young immune system to the disease — since the mid-1990s babies first get the dead Salk vaccine to start building up immunity, followed by the Sabin vaccines for lifetime immunity. It’s my understanding this protocol has greatly reduced the contraction of polio in babies with normal immune systems.

*Procedures Under the Vaccine Act.* The filed petition must establish a prima facie case for the claim. It should attach declarations and documents establishing the injury under the perimeters of the Vaccine Injury Table and detail the requested compensation. The special master will review the petition to determine if it is “complete” such that the litigation may proceed. The evidence is weighed under the preponderance of evidence standard.

In terms of compensation, the act provides actual unreimbursed expenses due to the vaccine prior to entry of judgment. In death cases, \$250,000 will be awarded in damages. In injury situations, the claimant must submit a full package proving the anticipated injury, including declarations from: a physician predicting future disability and life outcomes; a rehabilitation specialist who takes the doctor’s report and outlines the anticipated surgeries and medical equipment (for example, a new wheelchair every five years), and their cost; and an economist who compiles the monies required for each year’s medical equipment and surgeries through life expectancy, reduces those annual amounts to present value, and adds an inflation factor.

The Vaccine Act also provides “reasonable compensation” for impaired work capacity after age 18. But these awards are limited, and usually based on farm workers or entry wages. Finally, the act authorizes an award for pain and suffering up to \$250,000. The \$250,000 maximum is limited to the most serious cases; my polio clients were each awarded \$125,000.

Once deemed complete by the Special Master, a decision on the petition is required within 240 days of filing. Of my two cases, one went through a full hearing, the other settled prior to the hearing. Normally, the award pays past expenses and pain and suffering

in cash, while future medical expenses and wage loss are paid through the purchase on an annuity. For the past 20 years, the annuities have been structured as “reversionary trusts,” by which the claimant has to seek future reimbursement for any cash outlay of medical equipment and surgery authorized under the award, and any monies not spent revert to the federal vaccine fund. In other words, even after recovering an award, it’s still a rigorous process to obtain future medical expenses.

Attorney fees are also recoverable for successful claims, but at relatively low hourly rates (a 2016 case rejected \$405 per hour, granting \$325 per hour for “senior attorney”). Also, the special masters do not seem to expect or want to reimburse for a substantial amount of attorney work on these cases, even though a strong claim will likely require it.

The parties have 30 days after the Special Master’s decision to file a motion to review with the Court of Federal Claims, which evaluates any appeal under an abuse of discretion standard. Thereafter, appeal can be taken to the Federal Circuit.

*Historical Results.* Since 1986, 24,000 petitions have been filed under the Vaccine Act, with 8,000 petitions receiving compensation and a total of \$4.2 billion paid out. Between 2006 and 2019, 4 billion covered vaccines were adminis-

tered in the U.S., and 6,000 vaccine recipients have been compensated — in essence, 1.5 recognized injuries for every 1 million doses.

*Practical Points.* For vaccine injuries, first check the Vaccine Injury Table to be sure the vaccine is covered and the injuries are consistent with the time frame and manifestation of the symptoms in the chart. I’d suggest filing the petition as soon as the injury or disability is diagnosed and ongoing — six months for injury cases — and submit all necessary declarations and documents along with the petition. The COVID vaccines are likely to be added to the Vaccine Injury Table soon — especially as they obtain full approval. Note that COVID vaccine compensation cases, like all vaccine cases, will be fought over the medical conditions caused by the vaccines; the act does not cover non-vaccine injuries. Science will likely take some time to determine exactly what conditions are caused by the COVID vaccines.

Vaccine injuries present an interesting area of litigation. These cases are highly important for the victims and can make a big difference in their lives. But it is not a lucrative area for lawyers. I viewed my two cases as mostly pro bono although we were able to recover some amount in fees. I would be glad to consult with other lawyers, without charge, who are considering these cases for their clients. ■