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Health Law:*Why Anti-Vaccine Claims About NVICP Cases are Wrong*Dorit Reiss¹

This Chapter provides an introduction to the National Vaccine Injury Compensation Program and its autism jurisprudence. The Chapter also examines claims by anti-vaccine activists that certain decisions by a special administrative program created to compensate vaccine harms, and settled cases in that same program, are evidence that vaccines cause autism. The claims are mistaken, not only because extensive scientific evidence shows no such link, but also because the program the cases came from—the National Vaccine Injury Compensation Program (NVICP)—has, when examining directly whether vaccines cause autism (and at this point, there have been several cases using several theories to make the claim), found no link between vaccines and autism, and the cases used as evidence are cases that did not directly address the question. In essence, trying to claim that using off-topic cases from a program that, when it squarely faced the topic, went the other way as evidence is highly problematic.

A recurrent concern of parents who do not vaccinate is the long-standing claim—over two decades old at this point—that vaccines cause autism-spectrum disorder. Extensive studies from all around the world, covering millions of children (and reaching back for decades), have found no such link. A strong scientific consensus exists, in the United States and abroad, that vaccines do not cause autism. Nonetheless, a small but dedicated group of opponents—the Vaccines Cause Autism Community—continues to argue that vaccines cause autism. One of the tools they have used repeatedly is to claim that cases compensated by the National Vaccine Injury Compensation Program demonstrate that vaccines cause autism.

Other scholars have highlighted the tension between science and the law and suggested that legal decisions cannot overcome a scientific

1. Summarized and excerpted from Dorit Rubinstein Reiss & Rachel Heap, *Using and Misusing Legal Decisions: Why Anti-Vaccine Claims about NVICP Cases Are Wrong*, 20 MINN. J.L. SCI. & TECH. 191 (2018).

consensus.² But courts have a role in examining causation and addressing scientific uncertainty.³ While courts do not directly do science, they routinely have to rule on scientific questions and examine the limits of scientific knowledge. This Chapter addresses opponents' claims that these cases show that vaccines cause autism from a different direction. It explains that the specific cases in question, examined seriously, cannot be used to support the claim that vaccines cause autism because none of them compensated a child on the legal theory that vaccines cause autism, most of them were settlements, and many of them compensated children for specific issues that were not autism.

The National Vaccine Injury Compensation Program is a no-fault program, created in response to a crisis in the 1980s. In response to an increase of lawsuits against vaccine manufacturers, manufacturers were leaving the market, and Congress was concerned about the vaccine supply. Plaintiffs, too, were dissatisfied with the legal process, where most lawsuits were dismissed or otherwise failed. A coalition of unlikely allies—concerned health officials, doctors, anti-vaccine organizations, and manufacturers—led to the passage of the National Childhood Vaccine Injury Act, which, among other things, created the NVICP.⁴ The final result, as explained by Anna Kirkland, was a set of compromises nobody was completely happy with, but everyone could live with.⁵

The program's goals were several and included making compensating claims easier and more certain and protecting the vaccine supply. Before litigating a claim of harm from a vaccine, claimants have to go through the program. The process for obtaining compensation includes substantially less of a showing than a civil lawsuit would. As a no-fault program, petitioners do not have to show a product defect (or negligence). Causation is also relaxed. For some injuries, listed in a special table of injuries, causation is presumed. Even for those not on the table, general causation does not have to be demonstrated by scientific literature but can be supported by a plausible expert opinion. The goal was to allow scientific

2. Joelle Anne Moreno, "It's Just a Shot Away": *MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1512, 1517 (2009).

3. Joelle Anne Moreno, *Toxic Torts, Autism, and Bad Science: Why the Courts May Be Our Best Defense Against Scientific Relativism*, 40 NEW ENG. L. REV. 409 (2006).

4. 42 U.S.C. § 300aa, *et seq.*

5. ANNA KIRKLAND, *VACCINE COURT: THE LAW AND POLITICS OF INJURY* (2016).

uncertainty to be resolved in favor of claimants. Further, the special masters are not bound by the rules of evidence, reasonable lawyer fees and litigation costs are covered by the program, and contingency fees are disallowed. The program has some disadvantages for claimants compared to regular courts: there is a three-year statute of limitations that is not tolled for minors, discovery is limited and in the special master's discretion, and compensation for death and noneconomic damages is capped at \$250,000, a sum not updated since the law was enacted.

The Vaccines Cause Autism Community's claim that the program's body of cases shows that vaccines cause autism misuses those cases. Many of the cases are settlements, where the government denied causation but settled the case anyway—and those cases cannot be used as evidence of causation. In other cases, the theory of compensation was not autism. In some cases, the compensation was given for a seizure disorder, which is not autism; in others, it was given for encephalopathy—a general brain disorder that is different than the criteria used to diagnose autism. Further, because in the 1980s, when the program was created, some data suggested that the DTP vaccine, then used to protect children against diphtheria, tetanus, and pertussis, was a rare cause of brain damage and seizure disorder, in the early stages seizure disorder and encephalopathy were included in the table of injuries, and causation was presumed for these cases unless the government proved another cause.

Large studies since have not found a link between the DTP vaccine and brain damage or seizure disorder, and additional evidence suggested a genetic cause for most seizure disorders, including those initially blamed on vaccines. But studies like this take time to do, and at the time many of the cases in question were decided, the data were not yet available. Several of the cases were compensated for seizure disorder based on the then-available data and may well have gone the other way if litigated today. They were also, again, not directly about autism. In fact, in some of the cases used to allege that vaccines cause autism, the claim that the child's problem was autism was raised by the government as an argument against compensating the family—and rejected. In others, the court expressly stated that the child's problem was not autism.

Using these cases as evidence of a link between vaccines and autism is highly problematic. Only one case even comes close. In a case involving a child named Hannah Poling, the government conceded that vaccines may have aggravated and made more severe the child's encephalopathy, which was the result of a pre-existing mitochondrial disorder—of genetic origin, and that the child's encephalopathy had “features of autistic spectrum

disorder.” However, even that case cannot be convincingly used as evidence linking vaccines and autism. First, the child’s main problem was a genetic one, an extremely rare and severe one, which likely predisposed her to regress regardless of whether she was or was not given vaccines. Second, the link between the vaccines and her condition was tenuous, and later cases rejected an alleged link between mitochondrial disorders and vaccines harms. Because the Poling case was conceded by the government, we will never know the result had it been fully litigated. But the trajectory of the later cases does not support using it as evidence.

Finally, in addition to the fact that the cases in question were either never fully adjudicated or not decided on a theory that vaccines caused a child’s autism, NVICP did explicitly litigate claims that vaccines cause autism. First, in 2009-2010 it litigated a set of cases serving as test cases in the Omnibus Autism Proceedings. After extensive hearings and abundant evidence submitted, six detailed, thorough NVICP decisions rejected the alleged link based on two legal theories: that the measles, mumps, and rubella vaccine caused autism, or that thimerosal—a mercury-based preservative present in tiny amounts in vaccines until 2000—caused autism when present in vaccines. Later decisions rejected other theories trying to link vaccines and autism, such as claims of mitochondrial disorder making children vulnerable to autism if given vaccines, or the claim that fetal DNA in vaccines caused autism.

Using off-topic cases, or settled cases, from a program that looked at the issue directly and arrived at an opposite conclusion, is not a good way to support a claim. NVICP directly addressed several theories on the link between vaccines and autism, and in careful and detailed decisions explained why they are invalid. Several of these cases have been appealed up to the federal circuit courts, and the decisions were upheld. Under these circumstances, it is at best an error to try to use the other cases discussed here—where a family was not compensated based on a child’s autism, but on a different claim—to try and counter the extensive scientific evidence showing that vaccines do not cause autism.