Balancing Science and Policy Objectives

Balancing Vaccine Science and National Policy Objectives: Lessons From the National Vaccine Injury Compensation Program Omnibus Autism Proceedings

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The US Court of Federal Claims, which adjudicates cases for the National Vaccine Injury Compensation Program, has been confronted with more than 5000 cases submitted on behalf of children with autism spectrum disorders, seeking to link the condition to vaccination.

Through a test case process, the Omnibus Autism Proceedings have in every instance found no association between autism spectrum disorders and vaccines. However, vaccine advocates have criticized the courts for having an overly permissive evidentiary test for causation and for granting credence to insupportable accusations of vaccine harm.

In fact, the courts have functioned as intended and have allowed for a fair hearing of vaccine concerns while maintaining confidence in vaccines and providing protection to vaccine manufacturers. (*Am J Public Health.* 2011;101:2016–2021. doi:10.2105/AJPH.2011.300198)

ON MARCH 10, 2010, THE US Court of Federal Claims, the court that hears cases for the National Vaccine Injury Compensation Program (NVICP), ruled on the final test case of the US Omnibus Autism Proceedings. The proceedings were created to efficiently adjudicate more than 5000 petitions submitted on behalf of children with autism spectrum disorders. Petitioners alleged that their children's disorders were caused by, or significantly exacerbated by, 1 or more government-recommended vaccinations.[1–3] The vaccine court and the Court of Appeals have unanimously ruled in all cases that the petitioners failed to meet the evidentiary standard required for compensation.

These hearings have been the subject of much controversy, and the US Court of Federal Claims has come under criticism from both sides of the vaccine safety controversy. Not surprisingly, those arguing for a link between vaccines and autism spectrum disorders are not satisfied with the decisions and believe that the courts' processes and evidentiary standards favor the opinions of established scientific institutions, their research agendas, and their interests in promoting vaccines.[4,5] More perplexing is the criticism from vaccine advocates, many of whom argue that the courts have provided credibility to antivaccination arguments in what they believe to be a flawed system for entertaining theories of harm.[6–8] They argue that the courts' criteria for establishing a causal link between a vaccine and an injury are too permissive and that the institution operates without concern for the public health impact of its decisions.[9] These critics argue that the courts have given a hearing to alleged junk science, provided a forum for antivaccination sentiment that would otherwise have been marginalized, and triggered the waste of critical scientific research dollars defending vaccine safety against fringe biological theories of harm."[6,8,10,11]

To the contrary, the NVICP was successful in its management of these proceedings and met the intent of the original legislation to protect the integrity of the vaccine supply, maintain public confidence in immunization, and provide those injured with a fair hearing. The proceedings allowed for an exhaustive investigation of the concerns of parents of children with autism and at the same time protected the vaccine industry from a multitude of crippling lawsuits.

THE ADJUDICATION PROCESS

The NVICP was created as part of the National Childhood Vaccine Injury Act of 1986.[12] This legislation was introduced to address concerns about vaccination, in particular the whole-cell pertussis vaccine (since discontinued). Concerns that the whole-cell pertussis vaccine could cause encephalitis and seizures leading to permanent and serious disability or death led to an avalanche of lawsuits filed in US courts.[12] Many manufacturers responded to the risks of litigation by ceasing production altogether,[13,14] which resulted in a critical shortage of pertussis vaccine. This shortage, in addition to the heightened parental concerns about immunization, led to disruptions in childhood immunization schedules and in some cases to outbreaks of pertussis.[15,16] The

Vaccine Injury Act made it more difficult for plaintiffs to prevail in lawsuits asserting that health care providers failed to warn of adverse events.[17] So long as the injuries sustained were presumed to be unavoidable and the manufacturers complied with Food and Drug Administration requirements for product labeling (directions for use and sufficient warnings), manufacturers were shielded from injury liability.[17] This effectively blocked the most popular legal arguments in vaccine injury cases and made successful civil litigation less feasible and a less appealing option for injured parties. After the act was passed, nearly all those injured by vaccines were required to bring their cases before the NVICP prior to instituting actions in civil courts.[18]

The program was originally designed around a table of injuries, similar to workplace injury or disability insurance claims processes.[19] The legislation created a table of potential vaccine-related injuries that listed a set of recognized adverse events following vaccination and a period within which they would occur. If a petitioner met the case definitions for injury and was able to demonstrate that a child developed the injury within the time allowed, and no reasonable alternative medical explanation for the injury was offered, compensation would be granted without the requirement of proving in court that the vaccine caused the injury in that particular instance. For example, in the absence of an obvious alternative cause, a confirmed case of brachial neuritis occurring between 2 and 28 days following a tetanus immunization would be deemed eligible for compensation.[20] However, the original legislation was interpreted to allow claimants who did not meet the table criteria to have their case heard before a special master of the Court of Federal Claims.[19] This allowed for claimants to bring forward cases of injuries unaccounted for by the table where there might be little scientific consensus on the etiology of the type of injury and its relationship to specific vaccines.

In both table and nontable cases, compensation is $250 000 for the death of a child or life-long payments for disability. The program is financed by an excise tax of 75 cents per antigen for all routine or government-recommended vaccines. Since its inception, the NVICP has become relatively overfunded, developing a billion-dollar surplus in funds in the past decade.[21] Despite the surplus, the rates of compensation are much higher than would be seen with civil litigation, and for the past few years, more than 70% of all cases reviewed have been compensated, excluding the autism omnibus cases.[22]

THE OMNIBUS AUTISM PROCEEDINGS

The multitude of cases related to the alleged link between vaccines and the development of autism has presented perhaps the most significant challenge to the Injury Compensation Program since its creation. In the face of public and political scrutiny concerning these cases, the chief special master of the program formed a petitioners' steering committee that elected to expedite the process of adjudicating the roughly 5000 claims by pooling petitioners into discrete classes related to plaintiffs' biological theories of harm. This was not the first time this approach was used to adjudicate similar claims, but the scale of the process (creating test cases for thousands of cases) and stakes were unprecedented. Special hearings were held to assess the evidence for and plausibility of each theory put forth by the pool of claimants.[23]

The cases fell into 3 broad biological theories: (1) the combination of the measles-mumps-rubella vaccine and an ethylmercury preservative, thimerosal, was responsible for neurologic damage in infancy and early childhood, manifested as autism; (2) thimerosal alone was responsible for the development of autism; and (3) the measles-mumps-rubella vaccine was solely responsible for autism. The petitioners agreed to identify 3 test cases for each of these hypotheses, although they subsequently dropped the third hypothesis because most of the evidentiary material addressing it would be covered in the first set of test cases.[23]

Ultimately, 6 test cases were selected to provide a comprehensive vetting of the 2 biological theories put forward.[23] The presumption was that if a test case was successful in establishing a common mechanism linking vaccines to autism spectrum disorders, it would serve as a precedent for the adjudication of the remaining cases in the pool.

The omnibus hearings took place between June 2007 and July 2009; the first test case decisions were released in July 2009 and the second set in March 2010. In all 6 test cases adjudicated, the courts ruled against compensation.[1–3,24–26] Two of the cases have gone to the Court of Appeal and both decisions were upheld.[24,25] During the course of the omnibus proceedings, a separate case was settled out of court. It concerned a child with a subsequently diagnosed mitochondrial disorder who purportedly developed autism following exposure to vaccines.[27]

CONCERNS ABOUT AN OVERLY PERMISSIVE EVIDENTIARY TEST

Despite strong scientific consensus in 2009 that the evidence did not support a link between vaccines and autism,[28,29] considerable uncertainty and anxiety surrounded the outcome of the omnibus trials. Leading scientists feared that the court would find in favor of the plaintiffs because, following the spirit and intent of the original legislation, it has a unique approach to adjudicating evidence that favors compensation (Table 1).

Paul Offit, a prominent American pediatrician and vaccine expert specializing in pediatric infectious disease, became a vocal critic of the adjudication process.[7,10,30] In a commentary published in the *New York Times*, he argued,

> The system worked fine until a few years ago, when vaccine court judges turned their back on science by dropping preponderance of evidence as a standard. Now, petitioners need merely propose a biologically plausible mechanism by which a vaccine might cause harm—even if their explanation contradicts published studies.[10]

TABLE 1—Comparison of National Vaccine Injury Compensation Program and Civil Litigation Processes

Characteristic	Vaccine Injury Program	Civil Litigation
Weight of evidence to establish cause	Preponderance of evidence or meets table of injury criteria;	Preponderance of evidence
Standard to prove causation	Meet 3-part test; plaintiff must present (1) a biological theory of harm, (2) a logical sequence of events connecting the vaccine to the injury, and (3) appropriate time frame in which injury occurred; must also show that other, more likely cause of injury exists	Expert opinion based on epidemiology or rigorous scientific research establishing both general and specific causation
Rules of evidence related to the admission of scientific or expert testimony	Case is heard by a special master, a specialist in vaccine injury cases; evidence is heard at the discretion of the special master (ad hoc), evidence is usually a written deposition or brief hearing appearance	Case heard by a judge who is not a specialist, evidence must be admitted, formalized process used to vet experts and the quality of expert testimony by the Daubert standard, evidence or expert opinion is open to cross-examination
Kinds of evidence experts can give	Loosely determined: can be attending physician's notes, advice to discontinue vaccinating	Strictly determined by professional credentials and scientific norms
Burden of proof	Balanced between plaintiff and defendant (government)	Falls on plaintiff
Trier of fact	Special master	Jury, which may be influenced by sympathetic plaintiff

Echoing these concerns, physician Gilbert Ross wrote in the *Washington Times*,

> I find it unsettling that the safety of vaccines must be put on trial before three 'special masters' in a vaccine court. What the parents of the autistic children, plaintiffs in the 4,800-plus pending cases, cannot realize (though certainly their lawyers do) is that the truth about scientific and medical facts is not, ultimately, something that can be decided either by the whims of judges or the will of the masses.[6]

Although the burden of proof required in vaccine injury cases is technically a preponderance-of-evidence standard, Offit is correct that the court hears scientific evidence and testimony that would likely be inadmissible in a standard tort case to establish a preponderance of evidence (tort cases address acts in which injured persons may sue the wrongdoer for damages). For example, an attending physician's written notes in a patient's chart linking a vaccine to a reaction has been taken as prima facie evidence of harm, that is, evidence sufficient to establish a fact unless rebutted.[31]

Offit has voiced the concerns held by prominent vaccine advocates, court officials, and legal scholars that the standard of evidence to support causality is leading to compensation in injury cases where the expert scientific community would universally reject any possible (never mind probable) link between the injury and vaccines.[6–10]

One arguably egregious example is compensation in cases (1 in 2006[32] and another in 2008[33]) that alleged a link between multiple sclerosis and hepatitis B vaccine despite strong scientific consensus against a causal link.[34] The more permissive process to establish a preponderance of evidence, a legal standard in which the existence of a fact is more probable than its nonexistence,[35] grew, not from decisions issued by special masters of the court, but through case precedent set by the Court of Appeals. In keeping with the spirit of the act, which was designed to make it easy for parents who presented a reasonable case to receive compensation and to give those injured the benefit of doubt, the appellate judges tended to resist the kind of processes developed in civil courts to vet scientific evidence and expertise.[9]

The case *Althen v US Health and Human Services* created instead a 3-part sufficiency test to determine whether a vaccine causes an adverse event. The petitioner must show that the preponderance of evidence supports (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 vaccination and injury. Furthermore, the petitioner must be able to demonstrate that the preponderance of evidence does not support that the injury was caused by factors unrelated to the vaccine. The 3-prong standard can be established by circumstantial rather than "direct, objective conclusive scientific evidence," and causation can be found even in the face of contrary epidemiological evidence.[9]

During the autism omnibus case hearings, the vaccine court settled

the case of Hannah Poling, a child with a mitochondrial disorder who developed developmental regression and a seizure disorder following vaccination. Because the case was settled, no evidence was presented, and it is difficult to ascertain the exact reasons for settling the case. However, the leaked judgment suggests that there was a belief that this child's case would have met the court's criteria for establishing causation.[27] A plausible medical theory existed because children with mitochondrial disorders have been recognized to decompensate following metabolic stresses, and temporality could be established because the child developed her symptoms soon after the vaccine exposure. The kind of metabolic condition Hannah Poling had is extremely rare, and it is unlikely that epidemiological studies could have definitively ruled out vaccines as a cause of her injuries, nor would scientific evidence be able to conclusively pinpoint an alternative cause.

After the Poling concession, advocates of the link between autism and vaccines hailed it as a vindication of their viewpoint.[36,37] Many public health officials and medical experts, however, countered that no such conclusion could be drawn.[11] Although some disagreement exists among experts,[38] several mitochondrial disease specialists stated that no link between vaccines and harm has been established in these children.[39] Columbia professor Darryl Devivo stated, "After caring for hundreds of children with mitochondrial disease, I can't recall a single one that had a complication from vaccination."[39] Although research investigating this novel theory of harm is under way, the court's administrative structure allowed for a settlement in the face of scientific uncertainty.

The purpose of the NVICP is to provide just compensation to those injured by vaccines and to protect vaccine manufacturers from multiple lawsuits, which even if successfully defended could deter companies from producing vaccines and from expending money on research that could lead to new vaccines. The program must balance the directives to protect the vaccine supply (by limiting vaccine injury tort cases) and to provide just compensation to those likely injured from vaccination without giving credence to every theory of harm or bestowing undue legitimacy on vaccines' fiercest critics.

If the Court of Federal Claims had the same evidentiary standards as the civil courts, then petitioners would be more likely to take their claims to the latter, where damage awards are potentially larger.[40] It is unlikely that claimants who fail to win a settlement in the compensation program will seek recourse in the civil courts. First, a case that was unsuccessful in the relatively permissive evidentiary environment of the vaccine court will be perceived as less likely to win a settlement in a civil court (e.g., civil litigation has a much higher bar for the admission of expert testimony). Second, claimants who receive due process and a fair hearing may be persuaded that their case lacks merit. Finally, the practical constraints imposed by the time and expenses involved in mounting a civil case after losing a compensation program case are formidable.[41] Thus, the compensation program will likely divert hundreds if not thousands of autism cases from proceeding to civil litigation.[42,43] Although some of the petitioners in the omnibus hearings could, having received their decisions, launch civil suits, the early signs suggest that few if any cases will move forward.

By underwriting claimants' legal fees, even in unsuccessful cases, the court serves a democratic function that allows claimants access to the legal system to air their concerns about immunization, which in many states is a government-mandated practice (and a public good). The NVICP is thus designed to err on the side of compensating injury cases even when an evidence-based analysis or consensus medical opinion would reject a causal relationship. It is not only justified and entirely appropriate for the evidentiary standards to be comparatively permissive but also arguably necessary to fulfill the program's policy mandate.

CONCERNS THAT RULINGS SUPPORT UNGROUNDED THEORIES

Related to the causation issue is the accusation that the courts have in some way contributed to the belief that vaccines cause autism.[10,11] However, concerns about vaccines predated the establishment of the compensation program and in fact were an impetus for its creation. Fears about vaccines and autism began with 2 independent events. In the United Kingdom in 1998, media coverage of Andrew Wakefield's (now retracted) study in *Lancet* publicized the hypothesized link between chronic vaccine-related measles infection, gastrointestinal disruption, and resulting neurologic injury.[44] Around the same time, in the United States, as part of an Environmental Protection Agency safety review of the public's exposure to mercury from consumer products, the level of mercury exposure from routine infant and early childhood vaccines was identified as exceeding the agency's guidelines. The Institute of Medicine advised that thimerosal be removed from vaccines as a precautionary measure.[29]

In the United Kingdom, the measles-mumps-rubella vaccine and autism controversy had an independent life course, and arguably the media controversy over vaccine safety had as much impact on public confidence as the controversy in the United States, if not more.[45–47] Although the United Kingdom also has a no-fault compensation program for vaccine injuries, its system has a more restrictive standard for proving causation than the US program's. Subsequent evidence that the *Lancet* article may have been fraudulent provides further evidence of the vulnerability of vaccine programs to unsubstantiated accusations of harm.[48]

Far from contributing to the controversy, the courts have likely helped to bring closure to the debate, at least in some quarters. Clearly, some petitioners and others who strongly adhere to the 3 hypotheses for a mechanism linking vaccination and autism will not be persuaded by the courts' decisions. However, for the

increasingly large segment of the public who may be concerned about vaccines and who remain uncertain about how to proceed, the courts' deliberations represent a comparatively neutral exhaustive examination of the available evidence. Ultimately, only time will tell whether this will be sufficient to improve parental confidence.

What would have happened in the absence of the existence of the NVICP? The United States might have experienced a scenario similar to the controversy over the whole-cell pertussis vaccine in the 1980s. As in the case of autism and vaccines, the links between the diphtheria-pertussis-tetanus vaccine and sudden infant death syndrome were never supported by epidemiological evidence. Nevertheless, lawsuits crippled the vaccine industry and resulted in an exodus of manufacturers from the field threatening the vaccine supply. In the absence of the NVICP, manufacturers would likely have faced numerous individual and class action suits, requiring enormous defense expenditures. Innovation in vaccines would likely have been stifled by the legal environment. Vaccine shortages might have ensued, and the impact on parental confidence might have been even more negative than it is at present.

CONCLUSIONS

The US Omnibus Autism Proceedings have been the most significant test for the NVICP. Contrary to the criticisms of advocates on both sides, the courts have largely succeeded in their objectives. Those who are considering changes to how the courts function because of concerns about the proceedings should consider that such changes could alter the delicate balance the courts attempt to achieve between providing just compensation and fair hearing to those who allege injury from vaccines and providing protection to manufacturers of vaccines. ■

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Changing the Constitutional Landscape for Firearms: The US Supreme Court's Recent Second Amendment Decisions

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In 2 recent cases—with important implications for public health practitioners, courts, and researchers—the US Supreme Court changed the landscape for judging the constitutionality of firearm laws under the Constitution's Second Amendment.

In *District of Columbia v Heller* (2008), the court determined for the first time that the Second Amendment grants individuals a personal right to possess handguns in their home. In *McDonald v City of Chicago* (2010), the court concluded that this right affects the powers of state and local governments.

The court identified broad categories of gun laws—other than handgun bans—that remain presumptively valid but did not provide a standard to judge their constitutionality. We discuss ways that researchers can assist decision makers. (*Am J Public Health.* 2011;101:2021–2026. doi:10.2105/AJPH.2011.300200)

HAVING GONE ALMOST 70 years without deciding a case directly addressing the US Constitution's Second Amendment "right to keep and bear arms," beginning in 2008 the US Supreme Court decided 2 such cases with important implications for the public's health. In *District of Columbia v Heller*[1] (decided June 26, 2008), the Supreme Court concluded for the first time that the Constitution grants individuals a personal right to possess handguns in their home for protection. In its decision, the court struck down a 1976 District of Columbia law that outlawed most handgun ownership.

But the *Heller* decision left several important questions unanswered, particularly whether the Second Amendment affects state or local firearm laws or only limits the power of the federal government. In *McDonald v City of Chicago*[2] (decided June 28, 2010), the Supreme Court determined that the Second Amendment does indeed apply to laws enacted by state and local governments. Nevertheless, the *McDonald* decision also leaves critical issues undecided, issues that lower courts must now address and that may affect the risk of firearm violence for millions of Americans.

Firearms were associated with more than 240 000 deaths from 2000 to 2007, including homicides, suicides, and unintentional deaths. During that same period,