The National Vaccine Injury Compensation Program (NVICP) and Vaccine Manufacturer Liability

Vaccines, like other medicines, can have side effects, as no medical intervention is completely risk free. When side effects do occur from vaccination, they are typically mild; serious adverse events following vaccination are very rare. In the event that a vaccine causes a serious adverse event and injury to the recipient, the United States (U.S.) has created the National Vaccine Injury Compensation Program (NVICP), which provides financial compensation to individuals that have been injured by a NVICP-covered vaccination.

The NVICP was the result of nearly two decades of controversy over whether and how adverse reactions to childhood vaccines should be addressed. Before the program became law, the only legal option for parents who felt that their children had been harmed by a vaccine was to sue the vaccine manufacturer, which was an expensive and time-consuming process. The NVICP was set up by the Department of Health and Human Services in the 1980s and provides financial compensation to individuals who have been injured by a NVICP-covered vaccine.

How the National Vaccine Injury Compensation Program came to be.

The NVICP was created in response to concerns about the pertussis portion of the DPT (diphtheria, pertussis, and tetanus) vaccine. The DPT vaccine was very reactogenic; it was known to cause significant injection site reactions, high fevers, and serious systemic reactions (febrile seizures, persistent crying, and whole-limb swelling). Although none of these side effects were associated with serious long-term sequelae (an aftereffect of a disease, condition, or injury), these side effects contributed to increasing public concerns about the safety of the DPT vaccine. Some claimed the pertussis component of the vaccine caused "pertussis vaccine encephalopathy", a permanent brain injury; further studies showed no true association between DTP and permanent brain injury. The alleged vaccine-induced brain damage proved to be an unrelated condition, infantile epilepsy. The whole-cell pertussis vaccine was also featured in a TV documentary and was blamed for causing various intellectual and physical disabilities.

Through the 1970s and 1980s, the number of lawsuits brought against vaccine manufacturers increased dramatically. Manufacturers made large payouts to individuals claiming vaccine injury, many of these claims tied to the DPT vaccination. For example, in 1978 only one lawsuit was filed, whereas 73 lawsuits were filed in 1984. During the seven-year period from 1978 to 1984, the average amount claimed per suit rose from $10 million to $46.5 million.

By 1985, vaccine manufacturers were still liable for any unforeseen and potentially rare injury linked to the vaccines they produced. While a successful vaccine could prevent hundreds of thousands of cases of deadly disease, it could also lead to a few rare incidences of side effects that could lead to multimillion-dollar lawsuits (In many cases, damages were awarded despite the absence of scientific evidence.). Manufacturers had difficulty obtaining liability insurance. The incentive for creating vaccines became highly unfavorable in the eyes of pharmaceutical companies; low profit margins and lawsuits related to vaccine safety led several manufacturers to withdraw their DPT vaccines from the market. The price of DPT vaccine skyrocketed, leading providers to curtail purchases, limiting vaccine availability. By the end of 1985, only one company was still manufacturing pertussis vaccine in the U.S. At the time, public health officials and vaccine experts noted that if the current lawsuit trend continued, it would pose an increasing threat to the development of new vaccines and availability of current vaccines in the U.S.

In 1986, in response to vaccine shortages and concerns about the return of vaccine-preventable diseases, Congress passed and President Ronald Reagan signed into law the NCVIA. The purpose of the NCVIA was to eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims, to ensure a stable supply of vaccines, to stabilize vaccine costs, and to provide cost-effective arbitration for vaccine injury claims.


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The National Vaccine Injury Compensation Program (NVICP)

The NVICP is funded by an excise tax added on vaccines recommended by the CDC for routine administration. This program provides liability protection to vaccine manufacturers and vaccine administrators who administered covered vaccines. There are four key things to understand about NVICP:

1. Compensation doesn't prove causation.
2. People not happy with the outcome can still take their case to civil court.
3. Although the Act provides liability protections to vaccine manufacturers and vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute.
4. The requirements for claims filed with the NVICP are two-fold: the events (vaccine administration and injury) have to be temporally related AND some biologically-plausible explanation why the events could be related must be accounted for.

Under the NCVIA, the NVICP was created to compensate those injured by vaccine on a "no fault" basis. The program began accepting petitions (also called claims) in 1988. Individuals can appeal in civil court if their claim is unsuccessful under NVICP, but few do because it is widely considered harder for a petitioner to win in civil court. The NCVIA also created the Vaccine Adverse Event Reporting System (VAERS), established the National Vaccine Program Office (NVPO), and required healthcare providers to provide Vaccine Information Statements (VISs) to vaccine recipients or their parent/legal guardian.

Although the NVICP provides liability protections to vaccine manufacturers and vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute. Both vaccine manufacturers and administrators are still liable for negligence.

Unfortunately, misconceptions around this program make it an easy source of misinformation and is commonly used in efforts to convince parents that vaccines are not safe. If you look closely at data from the compensation program, you will see that the ratio of number of settlements awarded compared to the number of vaccines given annually shows that vaccines are extremely safe.

According to the CDC, from 2006 to 2019 over 4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 8,941 petitions were adjudicated by the court, and of those, 6,390 were compensated. This means for every one million doses of vaccine that were distributed, approximately one individual was compensated.

Since 1988, over 25,152 petitions have been filed with the NVICP. Over that 30-year time period, 21,220 petitions have been adjudicated, with 9,070 of those determined to be compensable, while 12,150 were dismissed. Total compensation paid over the life of the program is approximately $4.8 billion.

The PREP Act and Countermeasures Injury Compensation Program

The Public Readiness & Emergency Preparedness (PREP) Act authorizes the Secretary of Health & Human Services to issue a declaration that provides immunity from liability (except for willful misconduct) for claims of loss resulting from administration or use of counter measures to diseases, threats and conditions determined to constitute a present or credible risk of a future public health emergency. This limited immunity from liability applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. PREP Act declarations have been issued for various anthrax, botulism, COVID-19, smallpox, and other medical countermeasures. The PREP Act and the NCVIA are similar in balancing liability protections for manufacturers with a clearer pathway for petitioners.

The PREP Act also authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits in case of physical injury due to covered countermeasures. With CICP, benefits must be requested within 1 year from the date of administration or use of the covered countermeasure alleged to have caused the injury. Examples of covered countermeasures in the case of the COVID-19 pandemic include specified diagnostic tests, treatments, and vaccines. For more information, see www.hrsa.gov/cicp.

References:

Some of the content of this handout was taken directly from the following resources:

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