Legal Implications of Vaccines

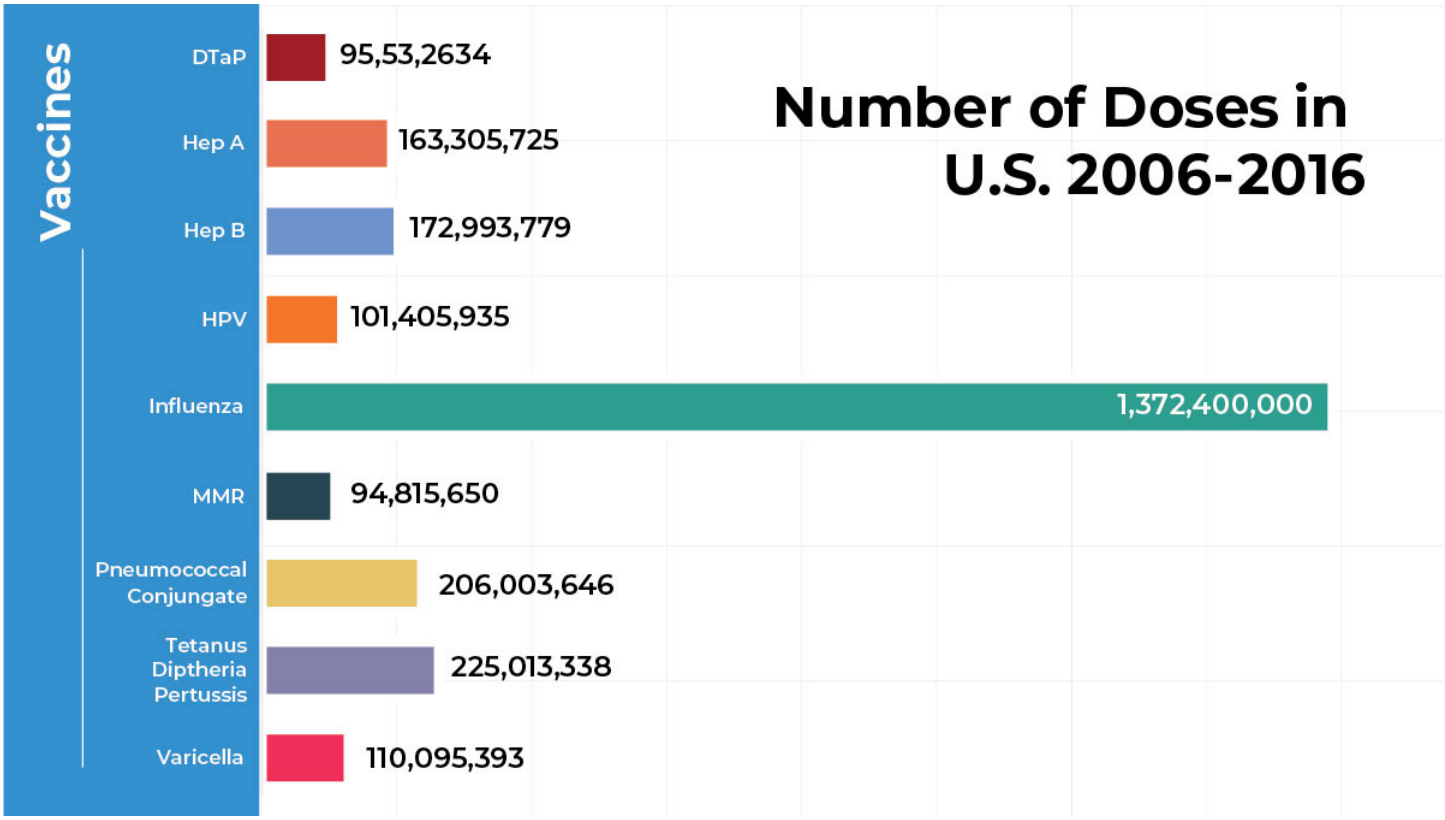
A White Paper

CONWAY HOMER, P.C.

Introduction

One of the most controversial public health issues in recent years has been the safety of commonly administered vaccines, particularly those given to children. Complaints range from their efficacy to possible deleterious side effects. The most common allegations involve side effects from the widely circulated flu vaccine administered at doctors' offices and chain drugstores nationwide [see chart below]. Some recipients assert that they have suffered nerve damage, severe shoulder pain, and autoimmune disorders shortly after immunization.

Despite the complaints, vaccines have been repeatedly proven to be generally effective, and in many cases, genuine lifesavers. Consider, for example, the tetanus vaccine, which is second only to the flu vaccine in number of administered doses. According to Science Online, the injury rate from the tetanus vaccine is just 0.0006 percent.



Still, injuries do happen, and legal redress is available. For many of the most common vaccines, the process for legal claims related to vaccine injuries differs from the usual court remedies. Complainants must use a system established by Congress that is designed to provide a "no fault" process for vaccine-related complaints. That system is administered by the National Vaccine Injury Compensation Program, or NVICP.

The process and law are far from static. The specialized forums for those who allege vaccine-related injuries have endeavored to adapt to recent developments and research. Occasional changes are made to the covered vaccines and the permitted time to make a complaint.

The Complaint Process

In 1986, Congress passed and President Reagan signed the National Childhood Vaccine Injury Act to help shield pharmaceutical companies from financially ruinous mass tort actions over vaccine injuries. The government agreed to the program partly because it feared an inadequate supply of vaccines if drug makers were to withdraw from the market.

The NVICP, which was established under the Act, provides for a separate "no fault" process for handling vaccine complaints. Commonly dubbed the "vaccine court," it is an alternative to the traditional legal system and allows vaccine-injured petitioners to seek monetary compensation on an individual basis. It does not, however, allow for classes of individuals to bring actions.

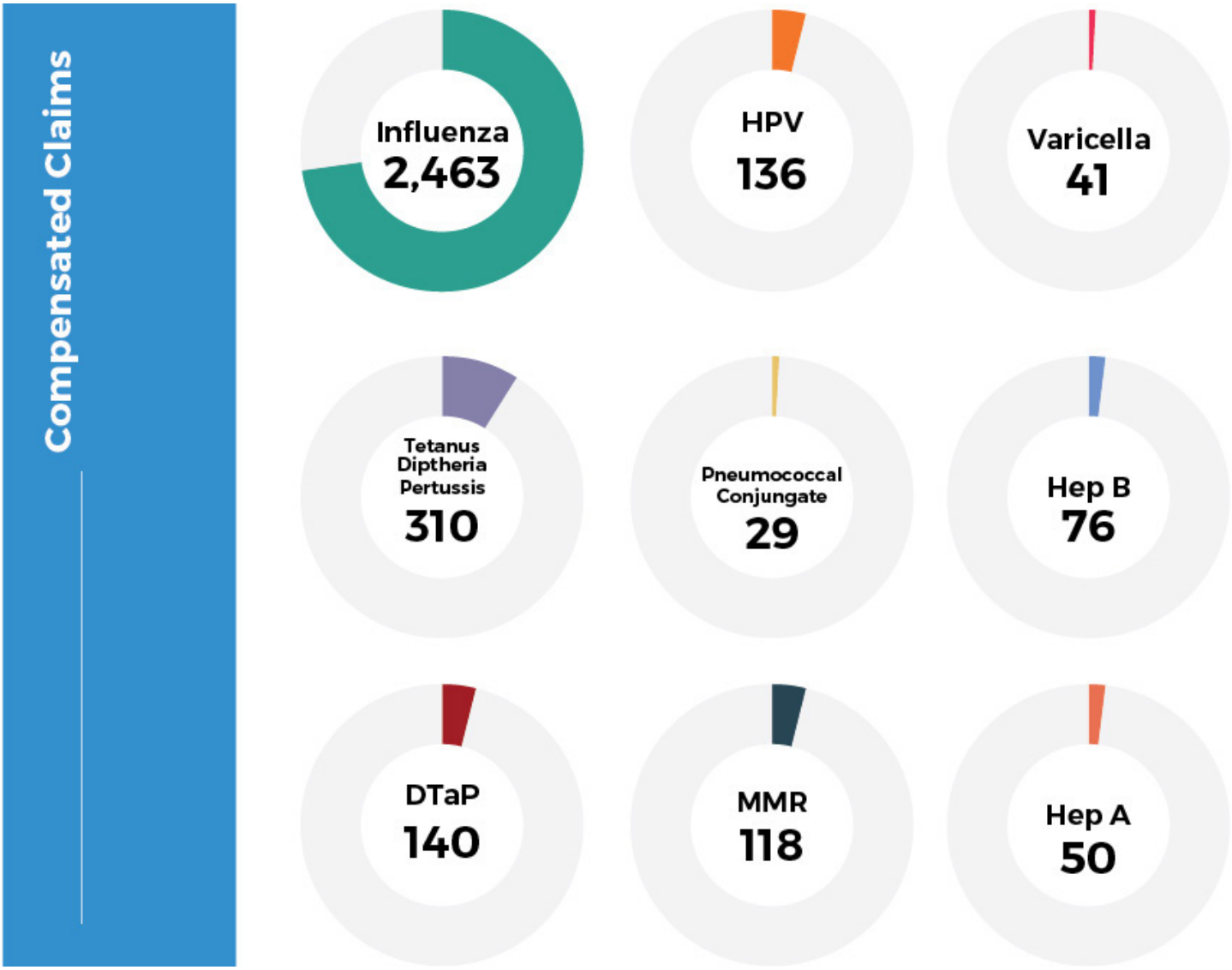
Vaccines covered under the NVICP include those for tetanus, pertussis, diphtheria, hepatitis A and B, seasonal flu, measles/mumps/rubella, polio, human papillomavirus and rotavirus, among others. An official list of the vaccines covered is available at https://www.hrsa.gov/vaccine-compensation/index.html

Not all vaccines administered in the United States are covered by the NVICP. Specifically, vaccines administered exclusively to adults are not covered in the NVICP and can be the subject of a civil complaint. Controversy over a widely administered vaccine for shingles, for example, is currently being played out in the civil courts. Also, occasional disputes arise over which vaccines should and should not be covered, especially as new vaccines are formulated.

Filing a NVICP complaint differs from filing a traditional lawsuit. Complainants must file within three years of the first symptoms of the injury, or two years of death and within four years of the first symptom if it resulted in death. Injured parties have to file in the U.S. Court of Federal Claims. While there is a $400 fee to file a claim, which may be reimbursed at the conclusion of a claim, petitioners do not pay their attorneys' fees. The fee structure is somewhat unique – attorneys' may recover their fees from the Vaccine Program itself, not the injured petitioner.

To qualify, the effects of the injury must have lasted for more than six months after the vaccination, resulted in death or resulted in inpatient hospitalization and surgery. Parents, guardians, and legal representatives of deceased persons can file. The vaccine must have been administered or made in the United States and the affected person must have returned to the U.S. within six months of receiving it. (Exceptions exist for armed forces dependents.)

So far, nearly 17,000 cases have been adjudicated under the program. Injured complainants do face a lengthy procedure, with some receiving compensation and some being dismissed without compensation.



What has changed

Two federal agencies, the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), periodically review the list of vaccines that are covered under the NVICP. Occasionally, via rule changes published in the Federal Register, the program will add or modify covered vaccines or injuries that have been firmly associated with those covered vaccines.

The agencies also periodically commission research work groups to study vaccines and review medical reports from reputable sources. In 2015, as a result of a report by the Institute of Medicine, some injuries previously not covered by the NVICP came under its aegis. The program, for example, added Guillain-Barré Syndrome, and shoulder injuries suffered as a result of improper vaccine administration to the vaccine injury table.

According to the Mayo Clinic, Guillain-Barré syndrome is a rare disorder in which the body's immune system attacks the peripheral nerves. Weakness and tingling or numbness in the extremities are usually the first symptoms. These sensations can spread quickly, eventually paralyzing the whole body. In its most severe form, Guillain-Barré syndrome is a medical emergency. Many people with the condition must be hospitalized to receive treatment.

The exact cause of Guillain-Barré syndrome is not always known, but it is often preceded by an infectious illness. Mayo Clinic also adds that, in rare cases, recent immunizations can trigger the condition. Guillain-Barré syndrome has been linked to vaccines for influenza and others, including diphtheria, tetanus and acellular pertussis (DTaP), hepatitis A and B and meningitis.

For those who have suffered GBS following a flu vaccine since March 21, 2009 and who meet the minimum criteria outlined on the Vaccine Injury Table, the strict time limits to file a claim have been relaxed. They can file for compensation under the NVICP after the effective date of the rule change if the injury occurred up to eight years before the vaccine table's revision. All claims that fall within these circumstances must now be filed by March 21, 2019. This applies even if the complainants had previously filed a claim alleging a Guillain-Barré injury, but were dismissed due to the statute of limitations, which, up to this point, had not been permitted.

The method, not the vaccine?

The rule change that gave Guillain-Barré sufferers more time to file claims also introduced another injury to the NVICP list. This addition has allowed complainants to take action for shoulder injuries caused by the way any covered vaccine was administered, not just by the vaccine itself. The same time limits apply, —along with the temporary extensions for claimants post-rule change.

In the last few years, shoulder injuries have become one of the most, if not the most, common complaint. In fact, 50 percent of alleged vaccine injuries are delivery related. Shoulder injuries are so common that they have received an acronym of their own, SIRVA, or shoulder injury resulting from vaccine administration.

In cases involving improper administration, injured petitioners generally allege the that injection was given too high on the arm. Vaccines are supposed to be administered in the deltoid muscle, or the thick part of the upper arm, but can be problematic if they are given too close to the shoulder.

The American Academy of Pediatrics examined SIRVA injuries recently. It describes SIRVA as "a specific condition that is associated with vaccine inadvertently administered into the deltoid bursa or joint space. Patients with SIRVA experience a shoulder injury that is more severe than would be expected from just needle trauma." One theory is that improperly administered vaccines trigger an inflammatory reaction that is responsible for SIRVA complaints. In 13 adult cases reported by NVICP, shoulder pain and a limited range of motion was noted immediately.

In Conclusion

The NVICP, in effect since 1988, remains the sole vehicle of legal redress for covered vaccines. Despite rigorous time limits and scrutiny of claims, the government body supervising the programs makes occasional changes as research identifies previously unknown symptoms. While an injured party can file a claim in the NVICP without assistance of an attorney, the unique procedures in the Vaccine Program can be nuanced and difficult to manage. Potential claimants can benefit greatly with the assistance of an attorney experienced in vaccine law at no cost to them.

About Conway Homer, P.C.

For over 28 years, we have represented thousands of people from all 50 states in the National Vaccine Injury Compensation Program ("NVICP"). Our practice is, and always has been, focused exclusively on vaccine law. Within the professional community, our attorneys have been chosen to serve on vaccine-related panels for the American Bar Association, American Association for Justice, the United States Court of Federal Claims, the Office of Special Masters, and the Vaccine Injured Petitioners Bar Association. We have also been chosen to educate the public about the Vaccine Program by film producers, television stations and print publications.

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