



Physicians Caring for Texans

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Act¹ (NVICA) was established as a means of diverting lawsuits away from vaccine manufacturers and health care providers who administer vaccines. This was accomplished by the NVICA's establishment of the National Vaccine Injury Compensation Program (NVICP), which provides a means by which individuals with vaccine related injuries can be compensated based on a "no-fault" system. This means that compensation is not dependent on proving that vaccine manufacturers or health care providers were at fault by their negligence in providing vaccinations.

Instead, the NVICP relies on its Vaccine Injury Table² (Table) to compensate people injured by vaccines. If a vaccine is listed in the Table, claims arising out of an alleged injury from that vaccine must pass through the NVICP's claims process. There are three ways to qualify for compensation:

1. An individual must show that a vaccine found on the Vaccine Injury Table resulted in a corresponding injury within the time frame listed on the Table.
2. For some vaccines listed on the Table, there is no corresponding injury designated; in such a case, a person filing a claim must prove that the vaccine actually caused the condition.
3. Additionally, an individual can be compensated if a vaccine listed on the Table significantly aggravates a pre-existing condition.

Compensation for vaccines is not paid by healthcare providers, but rather is derived from the Vaccine Injury Compensation Trust Fund, which is funded from an excise tax of \$.74 on every dose of covered vaccine that is purchased.³

Trivalent Influenza and Pneumococcal Immunizations Recently Added to List

As of this writing⁴ two vaccines are recent additions to the Vaccine Injury Table, thereby requiring all claims to go first through the claims process set up by NVICP. Those vaccines are:

- **Pneumococcal conjugate vaccines, and**

¹ 42 U.S.C. § 300aa-10, et seq.

² 42 U.S.C. § 300aa-14. Also see www.hrsa.gov/osp/vicp/table.htm

³ If a vaccine was administered before October 1, 1988, claim awards were derived from federal tax dollars. For vaccines administered after October 1, 1988, claims derive from the Vaccine Injury Compensation Trust Fund.

⁴ June 9, 2005

- **Trivalent Influenza vaccines.** While Influenza is not actually *listed* on the Table, it is incorporated into the Table by an administrative revision, as is permitted under the federal statute creating the Vaccine Injury Table.⁵ Individuals may file petitions for compensation related to trivalent influenza vaccine related injuries as of July 1, 2005. It is important to note that eight years retroactive coverage is provided for any vaccine or vaccine-related adverse event added for coverage under the NVICP.

Doctors' and Hospitals' Liability/risk as a Result of an Adverse Vaccine Event.

Vaccine administrators⁶ face minimal liability due to lawsuit barriers at the federal and state levels. An analysis of the federal and state laws intended to minimize physician and provider legal risk follows.

FEDERAL LAWS

If a particular vaccine is listed on the Vaccine Injury Table, all claims of injury from the administration of such vaccine *must first* go through the federal NVICP's claims process; otherwise, no civil action can be filed against any potentially liable party.

However, a court *is permitted* to preside over a lawsuit against a vaccine administrator arising out of an alleged injury caused by a vaccine listed on the Vaccine Injury Table:

1. If, after going through the NVICP, the claim is deemed non-compensable or is dismissed; or
2. If, after going through the NVICP and an award is granted, the person filing the claim rejects the award.

Of course, if a vaccine is not listed on the Vaccine Injury Table, an aggrieved individual may sue the vaccine manufacturer and/or administrator in court.

TEXAS LAWS

Vaccines Required by Law

In addition to the NVICA, Texas law provides additional protection to certain vaccine *administrators*. There are certain vaccines required by Texas law.⁷ For those healthcare providers that administer such vaccines, Texas law provides some immunity under Health and Safety Code §161.001. It provides:

⁵ 42 U.S.C. § 300aa-14. The required prerequisites to add a vaccine to the Vaccine Injury Table were satisfied (those requirements were twofold: a recommendation by the Centers for Disease Control and Prevention for routine administration of the vaccine to children, and a publication by the Secretary of the Department of Health and Human Services. This publication can be found in the Federal Register: April 12, 2005 (Volume 50, Number 69); Notices; Page 19092-19093 [which can also be viewed on the following website: www.hrsa.gov/osp/vicp/frn041205.htm])

⁶ "Vaccine Administrator"—This term is not a phrase used in any Texas statutes and is not assigned a specific statutory meaning. Rather, it is a phrase that the U.S. Department of Health and Human Services frequently uses on its website when discussing the Vaccine Injury Compensation Program and is used often in the website's Frequently Asked Questions section (see website at www.hrsa.gov/osp/vicp/). From reading the term in context, it seems to have a simple and plain meaning—an individual or an entity that administers vaccines (e.g., hospitals, physicians, nurses, etc).

⁷ These requirements are incorporated in Title 25 Health Services, paragraphs 97.61 – 97.77 of the Texas Administrative Code. 25 TX ADC § 97.61 through 25 TX ADC § 97.77

(a) A person who administers or authorizes the administration of a vaccine or immunizing agent is not liable for an injury caused by the vaccine or immunizing agent if the immunization is required by the board or is otherwise required by law or rule.

(b) A person who administers or authorizes the administration of a vaccine or immunizing agent is not liable or responsible for the failure to immunize a child because of the failure or refusal of a parent, managing conservator, or guardian to consent to the vaccination or immunization required under this chapter. Consent to the vaccination or immunization must be given in the manner authorized by Chapter 32, Family Code.

(c) A person who fails to comply with Section 161.004 [which discusses state immunization policy and the obligation placed on hospitals and physicians to immunize newborns] is not liable or responsible for that failure, and that failure does not create a cause of action.

(d) This section does not apply to a negligent act in administering the vaccine or immunizing agent.

Thus, administering vaccines required by law abrogates all risk of liability except for “a negligent act in administering the vaccine or immunizing agent.”⁸

Standard of Care

Texas Family Code §32.103 further limits a vaccine administrator’s liability for immunizations:

- First, §32.103(a) provides that a health care provider is not liable for adverse reactions to immunization or other injuries resulting from factual errors in the health history or information given by a person who is delegated the authority to consent to the immunization of a child, unless the health care provider acts in a way that is deemed to be “willful misconduct” or “gross negligence.”
- Secondly, §32.103(b) states that “a physician, nurse, or other health care provider, or a public health clinic, hospital, or other medical facility is not liable for damages from an immunization administered to a child . . . except for injuries resulting from the person’s or facility’s own acts of negligence.” Thus, if a health care provider administers a vaccine in a manner that is not consistent with the standard of care required, such provider can be found negligent and thereby be held liable for damages caused by a vaccine related injury.

Hospitals and Physicians Providing Vaccinations

A health care provider’s liability for a vaccine-related injury is minimal. With regard to vaccines listed in the Vaccine Injury Table in accordance with the National Vaccine Injury Compensation

⁸ Texas Health and Safety Code, §161.001(d).

Act, allegedly injured individuals face tremendous disincentives to pursuing, physicians, health care providers, or vaccine manufacturers and distributors.

People complaining of an injury caused by a vaccine, which is listed in the Vaccine Injury Table, must first pursue compensation through the NVICA process. The NVICP creates incentives for attorneys to bring claims there by paying attorney's fees irrespective of whether the claim succeeds or fails; fees are not based on the award amount, but rather are determined by an hourly rate, plus expenses.

Claimants who receive compensation awards through the NVICP are not likely to refuse them in order to pursue lawsuits against healthcare providers. According to statistics provided by the Department of Health and Human Services, an average award is about \$800,000, the highest being \$9,130,000. Claimants receiving such large settlements would be unlikely to reject them in favor of pursuing litigation. Moreover, even though the award for a vaccine related *death* is capped at \$250,000, the trend is that claimants are pursuing the NVICA process and accepting their awards. For example, as a result of the NVICA, "the number of lawsuits filed against vaccine manufacturers has plunged since the [NVICP] fund's inception: four suits against DTP [diphtheria, tetanus, and pertussis] makers in 1997, compared with 255 in 1985."⁹ Additionally, since the implementation of the NVICA, research has not disclosed any lawsuits against healthcare providers (with regard to the vaccines listed in the Vaccine Injury Table). In any case, in the rare case, that a lawsuit is brought alleging a vaccine related injury or death; it is usually the manufacturer that is pursued, not the physician or provider.

Prepared by:
Office of the General Counsel
Texas Medical Association
June 2005

NOTICE: This information is provided as a commentary on legal issues and is not intended to provide advice on any specific legal matter. This information should NOT be considered legal advice and receipt of it does not create an attorney-client relationship. The Office of the General Counsel of the Texas Medical Association provides this information with the express understanding that 1) no attorney-client relationship exists, 2) neither TMA nor its attorneys are engaged in providing legal advice and 3) that the information is of a general character. Although TMA has attempted to present materials that are accurate and useful, some material may be outdated and TMA shall not be liable to anyone for any inaccuracy, error or omission, regardless of cause, or for any damages resulting there from. Any legal forms are only provided for the use of physicians in consultation with their attorneys. You should not rely on this information when dealing with personal legal matters; rather legal advice from retained legal counsel should be sought.

⁹ Statistic taken from <http://www.whale.to/a/girl.html> [accessed June 10, 2005]