FLORIDA HOUSE OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: CS/HB 339	**COMPANION BILL:** SB 408 (Grall)None
TITLE: Advertisement of a Harmful Vaccine	**LINKED BILLS:** None
SPONSOR(S): Miller	**RELATED BILLS:** None

Committee References

Civil Justice & Claims
12 Y, 4 N, As CS
➤ Health Professions & Programs
➤ Judiciary

SUMMARY

Effect of the Bill:
CS/HB 339 creates a civil cause of action against a vaccine manufacturer by an individual who was harmed after receiving a vaccine, if the manufacturer advertised the vaccine in Florida. The bill clarifies that the term "advertise" includes traditional methods of advertisement as well as newer, "direct-to-consumer" media communications, such as product placement, social media ads, and paid promotion by influencers. The bill specifically exempts materials, discussions, and print advertisements traditionally obtained and exchanged in a medical office from the definition of advertisement.

Under the bill, a vaccine-injured individual may bring suit against a vaccine manufacturer within three years from the date the injury accrued. The court must award actual damages, costs, and attorney fees to a prevailing claimant.

The bill has an effective date of October 1, 2026.

Fiscal or Economic Impact:
None.

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ANALYSIS

EFFECT OF THE BILL:

CS/HB 339 amends s. 499.0054, F.S., creating a cause of action against a vaccine manufacturer in certain situations. The bill allows an individual to bring a civil action in state court against a manufacturer of a vaccine if the manufacturer advertised the vaccine in Florida. The action must be brought within three years from the date such vaccine caused him or her harm or injury. (Section 1).

For purposes of meeting the requirement that the vaccine manufacturer must have advertised the vaccine, the bill defines the term "advertise" as a media communication, including, but not limited to:

- Television;
- Radio;
- Print;
- The Internet;
- Digital or electronic media;
- Product placement;
- Promotion by an influencer in exchange for compensation; or
- Any other manner of paid promotion that a vaccine manufacturer purchases to promote the vaccine in question. (Section 1).

The bill specifically exempts the following from the definition of an advertisement:

- Any discussion between a health care provider and the patient;
- Any written materials that a health care provider provides to a patient concerning a vaccine; or
- Any posters, decorations, or other materials that are displayed in or made available by a health care facility, health care provider's office, or other clinical setting. (Section 1).

The bill imposes a three-year limitation to file an action against a manufacturer from the date the action accrued. (Section 1).

Further, the bill requires a court to award a prevailing claimant actual damages, court costs, and reasonable attorney fees. (Section 1).

The effective date of the bill is October 1, 2026. (Section 2).

FISCAL OR ECONOMIC IMPACT:

PRIVATE SECTOR:

The bill may have an indeterminate economic impact on private individuals who seek to recover against a vaccine manufacturer, as well as on vaccine manufacturers, under the provisions established in the bill.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Civil Liability

The main purpose of Florida's civil justice system is to properly and fairly redress the civil wrongs caused throughout the state, whether such wrongs be in the form of tortious conduct, breaches of contract, or other non-criminal harm for which the law provides a remedy. The civil justice system accomplishes this goal by providing a neutral court system empowered to decide the amount of monetary damages required to make each wronged person whole again. A functioning civil justice system, when it operates justly:

- Provides a fair and equitable forum to resolve disputes;
- Discourages persons from resorting to self-help methods to redress wrongs;
- Appropriately compensates legitimately harmed persons;
- Shifts losses to responsible parties;
- Provides incentives to prevent future harm; and
- Deters undesirable behavior.[1]

Tort Law

One of the goals of the civil justice system is to redress tortious conduct, or "torts." A tort is a wrong for which the law provides a remedy. Torts are generally divided into two categories, as follows:

- An intentional tort, examples of which include an assault, battery, or false imprisonment.
- Negligence, which is a tort that is unintentionally committed. To prevail in a negligence lawsuit, the party seeking the remedy, the "plaintiff," must demonstrate that the:
  - Defendant had a legal duty of care requiring the defendant to conform to a certain standard of conduct for the protection of others, including the plaintiff, against unreasonable risks;
  - Defendant breached his or her duty of care by failing to conform to the required standard;
  - Defendant's breach caused the plaintiff to suffer an injury; and
  - Plaintiff suffered actual damage or loss resulting from such injury.[2]

[1] *Cf.* Am. Jur. 2d Torts s. 2.

Accrual of a Claim

An important date for the purpose of a civil tort action is the date the claim accrues. Under s. 95.031(1), F.S., a claim accrues when the last element constituting the cause of action occurs. In a negligence claim, the cause of action accrues "upon the happening of an accident and the attendant injuries."[3]

Negligence

Duty of Care

The first of the four elements a plaintiff must show to prevail in a negligence action is that the defendant owed the plaintiff a "duty of care" to do something or refrain from doing something. The existence of a legal duty is a threshold requirement that, if satisfied, "merely opens the courthouse doors."[4] Whether a duty sufficient to support a negligence claim exists is a matter of law[5] determined by the court.[6] A duty may arise from various sources, including:

- Legislative enactments or administrative regulations;
- Judicial interpretations of such enactments or regulations;
- Other judicial precedent; and
- The general facts of the case.[7]

In determining whether a duty arises from the general facts of the case, courts look to whether the defendant's conduct foreseeably created a "zone of risk" that posed a general threat of harm to others—that is, whether there was a likelihood that the defendant's conduct would result in the type of injury suffered by the plaintiff.[8] Such zone of risk defines the scope of the defendant's legal duty, which is typically to either lessen the risk or ensure that sufficient precautions are taken to protect others from the harm the risk poses.[9] However, it is not enough that a risk merely exists or that a particular risk is foreseeable; rather, the defendant's conduct must create or control the risk before liability may be imposed.[10]

Breach of the Duty of Care

The second element a plaintiff must prove is that the defendant "breached," or failed to discharge, the duty of care. Whether a breach occurred is generally a matter of fact for the jury to determine.[11]

Causation

The third element a plaintiff must prove is that the defendant's breach of the duty of care "proximately caused" the plaintiff's injury. Whether or not proximate causation exists is generally a matter of fact for the jury to determine.[12] Florida follows the "more likely than not" standard in proving causation; thus, the inquiry for the factfinder is

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[2] 6 *Florida Practice Series* s. 1.1; *see Barnett v. Dept. of Fin. Serv.*, 303 So. 3d 508 (Fla. 2020).
[3] *Dep't. of Transp. v. Soldovere*, 519 So. 2d 616 (Fla. 1988).
[4] *Kohl v. Kohl*, 149 So. 3d 127 (Fla. 4th DCA 2014).
[5] A matter of law is a matter determined by the court, unlike a matter of fact, which must be determined by the jury. Matters of law include issues regarding a law's application or interpretation, issues regarding what the relevant law is, and issues of fact reserved for judges to resolve. Legal Information Institute, *Question of Law*, https://www.law.cornell.edu/wex/question_of_law (last visited Jan. 22, 2026); Legal Information Institute, *Question of Fact*, https://www.law.cornell.edu/wex/Question_of_fact (last visited Jan. 22, 2026).
[6] *Kohl*, 149 So. 3d at 135; *Goldberg v. Fla. Power & Light Co.*, 899 So. 2d 1110 (Fla. 2005).
[7] *Goldberg,* 899 So. 2d at 1105 (citing *Clay Elec. Co-op., Inc. v. Johnson*, 873 So. 2d 1182 (Fla. 2003)).
[8] *Kohl*, 149 So. 3d at 135 (citing *McCain v. Fla. Power Corp.*, 593 So. 2d 500 (Fla. 1992); *Whitt v. Silverman*, 788 So. 2d 210 (Fla. 2001)).
[9] *Kohl*, 149 So. 3d at 135; *Whitt*, 788 So. 2d at 217.
[10] *Bongiorno v. Americorp, Inc.*, 159 So. 3d 1027 (Fla. 5th DCA 2015) (citing *Demelus v. King Motor Co. of Fort Lauderdale*, 24 So. 3d 759 (Fla. 4th DCA 2009)).
[11] *Wallace v. Dean*, 3 So. 3d 1035 (Fla. 2009).
[12] *Sanders v. ERP Operating Ltd. P'ship*, 157 So. 3d 273 (Fla. 2015).

whether the defendant's negligence probably caused the plaintiff's injury.[13] In making such a determination, the factfinder must analyze whether the injury was a foreseeable consequence of the danger created by the defendant's negligent act or omission.[14] It is not required that the defendant's conduct must be the exclusive cause, or even the primary cause, of the plaintiff's injury suffered; instead, the plaintiff must only show that the defendant's conduct substantially caused the injury.[15]

Damages

The final element a plaintiff must show to prevail in a negligence action is that the plaintiff suffered some harm, or "damages." Actual damages, also called compensatory damages, are damages the plaintiff actually suffered as the result of the injury.[16] Juries award compensatory damages to compensate an injured person for a defendant's negligent acts.[17] Compensatory damages consist of both:

- "Economic damages," which typically consist of financial losses that can be easily quantified, such as lost wages, the cost to replace damaged property, or the cost of medical treatment; and
- "Non-economic damages," which typically consist of nonfinancial losses that cannot be easily quantified, such as pain and suffering, inconvenience, physical impairment, mental anguish, disfigurement, and loss of the capacity to enjoy life.[18]

In certain limited situations, a court may also award "punitive damages," the purpose of which is to punish a defendant for bad behavior and deter future bad conduct, rather than to compensate the plaintiff for a loss.[19]

Products Liability in General

A "products liability action" is a civil action based upon a theory of strict liability, negligence, defective design, failure to warn, or other similar theories for damages caused by the manufacture, construction, design, formulation, installation, preparation, or assembly of a product or the failure to warn that the product is potentially dangerous.

Products liability suits are based on the premise that companies have a duty to protect consumers from potential hazards caused by their products.[20] Generally, a product must meet the ordinary expectations of a consumer; when a product has an unexpected defect or danger, the product cannot be said to meet those expectations.[21] However, Florida courts have held that:

- A manufacturer has no duty to design the safest possible product;
- A manufacturer cannot be held liable for the misuse of a product;
- There is no duty to warn of an obvious danger or a danger about which the user is aware;
- A legally sufficient warning does not need to prevent a user from misusing a product; and
- A product manufacturer, distributor, or seller does not owe a duty to a third party who is injured as a result of a buyer's use of a product for unintended purposes.[22]

A manufacturer, although liable for injuries caused by a defect in its product, is not an insurer for all physical injuries caused by its product.[23] Additionally, the Fourth DCA has repeatedly held that "products liability does not make the manufacturer an insurer of all foreseeable accidents which involve its product…the availability of an

[13] *Ruiz v. Tenent Hialeah Healthsystem, Inc.*, 260 So. 3d 977 (Fla. 2018).
[14] *Id.* at 981-982.
[15] *Id.* at 982.
[16] *Birdsall v. Coolidge*, 93 U.S. 64 (1876).
[17] *St. Regis Paper Co. v. Watson*, 428 So. 2d 243 (Fla. 1983).
[18] *Cf.* s. 766.202(8), F.S.
[19] *See* ss. 768.72, 768.725, and 768.73, F.S. (providing standards and requirements for awarding punitive damages).
[20] *See* Legal Information Institute, *Products Liability*, https://www.law.cornell.edu/wex/products_liability (last visited Jan. 29, 2026).
[21] *Id.*
[22] *Michael Grieco v. Daiho Sangyo., Inc.,* 344 So. 3d 11 (Fla. 4th DCA 2022).
[23] *Houdaille Indus., Inc. v. Edwards*, 374 So. 2d 490 (Fla. 1979).

alternative design does not translate into a legal duty in products liability. An action is not maintainable in products liability merely because the design used was not the safest possible."[24]

Products Liability Theories

Strict Liability

A products liability action based on the theory of strict liability exists when a defendant is liable for committing an action, regardless of what his or her intent or mental state was when committing the action. In the products liability context, strict liability may apply when a defective product for which a defendant holds responsibility causes injury to a plaintiff.[25]

Negligence

"Negligence" is the failure to act with the level of care that a reasonable person would have exercised under the same circumstances. The elements required to prove negligence are duty, breach, causation, and damages.[26] Specifically, with respect to a claim based on negligence involving firearms, the injured party may be required to show that a defendant owed not merely a general duty to society, but a specific duty to the injured party.[27]

Breach of Warranty

"Breach of warranty" is the violation of an express or implied contract of warranty, and thus it is a breach of contract. Essentially, it occurs when the warrantor fails to provide the assurances warranted.[28]

Defective Design

Defective product design is a theory often cited in products liability cases. A "design defect" means that the product was manufactured correctly, but a defect is inherent in the design of the product itself, which makes the product dangerous to consumers.[29] In a products liability case, a plaintiff can only establish a design defect when he or she proves there is a hypothetical alternative design that would be:

- Safer than the original design;
- As economically feasible as the original design; and
- As practical as the original design, retaining the primary purpose behind the original design despite the changes made.[30]

Manufacturing Defects

Unlike a flawed or defective design, a product may also fail due to a manufacturing defect, that is, a defect that occurred during the production or manufacturing of the product.[31] In contrast to a design defect which impacts the entire line of products, a manufacturing defect is a flaw that occurs only to some of the products during manufacture.[32]

Failure to Warn

[24] *Grunow v. Valor Corp. of Florida*, 904 So. 2d 551 (Fla. 4th DCA 2005).
[25] Legal Information Institute, *Strict Liability*, https://www.law.cornell.edu/wex/strict_liability (last visited Jan. 26, 2026).
[26] Legal Information Institute, *Negligence*, https://www.law.cornell.edu/wex/negligence (last visited Jan. 26, 2026).
[27] *See Grunow*, 904 So. 2d at 556.
[28] Legal Information Institute, *Breach of Warranty*, https://www.law.cornell.edu/wex/breach_of_warranty (last visited Jan. 26, 2026).
[29] Legal Information Institute, *Design Defect*, https://www.law.cornell.edu/wex/design_defect (last visited Jan. 27, 2026).
[30] *Id.*
[31] Legal Information Institute, *Manufacturing Defect*, https://www.law.cornell.edu/wex/manufacturing_defect (last visited Jan. 30, 2026).
[32] *Id.*

In addition to an action based on a manufacturing defect or design defect of a product, a plaintiff may also commence a products liability action based on a failure to warn or warning defect. A claim based on a failure to warn does not assert that the physical product was flawed, but rather that the manufacturer failed to provide adequate warning or instructions about the safe use of the product and the consumer was injured due to such undisclosed risk.[33]

Attorney Fees

The traditional "English rule" on attorney fees entitled a prevailing party in a lawsuit to recover his or her attorney fees and costs from the losing party as a matter of right. However, Florida and a majority of other United States jurisdictions have adopted the "American rule" on attorney fees, under which each party bears its own attorney fees and costs unless a contract or a "fee-shifting statute" provides a specific entitlement to such fees and costs.

In Florida, several fee-shifting statutes create a "one-way" attorney fee structure, typically entitling a specific type of prevailing plaintiff to recover his or her attorney fees and costs from a losing respondent.[34] Certain other fee-shifting statutes create a "two-way" attorney fee structure, entitling the prevailing party in a lawsuit to recover his or her attorney fees and costs from the losing party.[35]

Vaccines

A vaccine is a substance or group of substances meant to cause the immune system to respond to a tumor or microorganisms, such as bacteria or viruses.[36] Vaccination is a simple, safe, and effective way of protecting a person against harmful diseases before he or she comes into contact with them.[37] A vaccine uses the body's natural defenses to build resistance to specific infections and strengthens the person's immune system to better fend off certain diseases and infections.[38] Vaccines train the immune system to create antibodies, just as it does when it is exposed to a disease.[39] However, because vaccines contain only killed or weakened forms of germs like viruses or bacteria, they do not cause the disease in the vaccinated individual or generally put the vaccinated individual at a heightened risk of infection or complications.[40] However, as with all pharmaceuticals and biologics, the possibility of an adverse reaction still exists.

State Regulation of Vaccines

Chapter 499, F.S., regulates drugs, devices, and cosmetics, and specifically grants the Department of Business and Professional Regulation (DBPR) authority over such items.[41] The Florida Drug and Cosmetic Act (the Act)[42] is intended to safeguard public health and promote public welfare by protecting against injuries and merchandising deceit involving drugs, devices, and cosmetics or the use of such products. The Division of Drugs, Devices, and Cosmetics (the Division) under the DBPR handles Florida regulations. Within the Division, s. 499.01211, F.S., created the Drug Wholesale Distributor Advisory Council that provides input to the division and the DBPR regarding all proposed rules for the distribution of drugs.

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[33] Justia: Products Liability Law Center, *Failures to Warn Supporting Products Liability Legal Claims*, https://www.justia.com/products-liability/types-of-products-liability-claims/failure-to-warn/ (last visited Jan. 29, 2026).
[34] *See, e.g.*, s. 400.023, F.S. (nursing home resident); s. 440.34, F.S. (claimant in a workers' compensation case in certain situations); s. 501.2105, F.S. (plaintiff in specified FDUTPA actions); and s. 790.33, F.S. (plaintiff in a suit to enforce his or her firearm rights).
[35] *See, e.g.*, s. 713.29, F.S. (prevailing party in action to enforce a lien); s. 83.48, F.S. (prevailing party in action to enforce rental agreement or the Florida Residential Landlord and Tenant Act).
[36] National Cancer Institute, *Vaccine*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/vaccine (last visited Feb. 6, 2026).
[37] World Health Organization, Vaccines and Immunization: What is Vaccination?, https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-what-is-vaccination (last visited Feb. 6, 2026).
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] The Drug, Device, and Cosmetic program was transferred to the Department of Business and Professional Regulation from the Department of Health effective November 1, 2012. See ch. 2012-184, Law of Fla., s. 122.
[42] Sections 499.001-499.081, F.S.

The DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[43]

The Florida Drug and Cosmetic Act

Generally, the Florida Drug and Cosmetic Act prohibits any person from:[44]

- Offering for sale any drug, device, or cosmetic, that is adulterated or misbranded.
- Disseminating any false or misleading advertisement of a drug, device, or cosmetic.
- Refusing to allow the DBPR to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held.
- Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.
- Committing an alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.
- Forging, counterfeiting, simulating, or falsely representing any drug, device, or cosmetic, or without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.
- Using, on the labeling of any drug or in any advertisement relating to such drug, any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.
- Possessing any drug in violation of part I, ch. 499, F.S.
- Failing to maintain records as required by law and rules adopted under ch. 499, F.S.
- Providing the DBPR with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of the act.
- Failing to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by the act for that activity.
- Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

Some of these prohibitions may rise to the level of criminal acts under s. 499.0051, F.S.

Federal Regulation of Vaccines

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee which operates under the Centers for Disease Control (CDC) and is composed of medical and public health experts.[45] The ACIP develops recommendations on the use of vaccines in the United States to advise and guide the Director of the CDC.[46] The ACIP is composed of medical and public health experts, and works with professional organizations, such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of

[43] Sections 499.051, F.S., s. 499.062, F.S., s. 499.065, F.S., s. 499.066, F.S., s 499.0661, F.S., and s. 499.067, F.S.
[44] Section 499.005, F.S.
[45] Centers for Disease Control and Prevention, *Advisory Committee on Immunization Practices*, https://www.cdc.gov/acip/index.html#:~:text=Vaccines%20&%20Immunizations-,ACIP,4%2D5%2C%202025%20meeting. (last visited Feb. 8, 2026).
[46] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *Advisory Committee on Immunization Practices Policies and Procedures* (June 2022), https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf (last visited Feb. 8, 2026).

Obstetricians and Gynecologists, and the American College of Physicians to develop annual childhood and adult immunization schedules.[47]

The Centers for Disease Control and Prevention (CDC) reviews the ACIP's recommendations; once approved by the CDC Director and the U.S. Department of Health and Human Services, they are published as the CDC's official recommendations for immunizations of the U.S. population.[48] New vaccines are considered for addition to the schedule after licensure by the FDA.[49]

Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is a federal agency under the U.S. Department of Health. The FDA was created in 1906 by the Federal Food and Drug Act.[50] It oversees the safety, effectiveness, and quality of vaccines used in the United States. Once a vaccine is developed, the pre-clinical phase begins, which consists of laboratory research and testing on animals. If the pre-clinical phase shows the vaccine is likely to be safe and work well in humans, it is tested on humans through clinical trials. While clinical trials are underway, the FDA assesses the manufacturing process to ensure that the vaccine can be produced reliably and consistently. Once a manufacturing process is developed and pre-clinical and clinical trials are successfully completed, developers submit a Biologics License Application to the FDA, which includes details on the manufacturing process and data from pre-clinical and clinical trials. The FDA evaluates the application and decides whether to license the vaccine for use in the United States. The FDA continues to monitor and regulate vaccines and manufacturers after licensing.[51]

All vaccines must be licensed (approved) by the FDA in order to be marketed in the United States.[52] However, during public health emergencies, the FDA may authorize vaccines for emergency use, which speeds up the process of bringing a vaccine to market.[53]

Administration of the Florida Drug and Cosmetics Act must conform to the Federal Food, Drug, and Cosmetic Act and the applicable portions of the Federal Trade Commission Act[54] which prohibit the false advertising of drugs, devices, and cosmetics.[55] The Florida Drug and Cosmetic Act conforms to the United States Food and Drug Administration's (FDA) drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[56] The FDA preempts the state of Florida from regulating certain areas regarding drugs and cosmetics, including the pre-market approval of drugs and the post-market surveillance of cosmetics.[57]

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[47] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, https://www.cdc.gov/vaccines/acip/recommendations.html (last visited Feb. 6, 2026).
[48] *Id*.
[49] College of Physicians of Philadelphia, *The History of Vaccines: The Development of the Immunization Schedule,* http://www.historyofvaccines.org/content/articles/development-immunization-schedule (last visited Feb. 6, 2026).
[50] 21 U.S.C. s. 1.
[51] U.S. Food and Drug Administration, *Vaccine Development – 101,* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited JanuFeb.6, 2026).
[52] U.S. Food and Drug Administration, *Ensuring the Safety of Vaccines in the United States,* https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (last visited Feb. 6, 2026).
[53] Food and Drug Administration, *Emergency Use Authorization*, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited Feb. 6, 2026). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency.
[54] *See* 15 U.S.C. ss. 41-58, as amended.
[55] Section 499.003(20), F.S., defines the federal act referencing 21 U.S.C. ss. 301 *et seq.* and 52 Stat. 1040 *et seq*.
[56] S. 499.01, F.S.
[57] 39 A.L.R. Fed. 2d 155, *Construction and Application of Preemption Provisions of National Childhood Vaccine Injury Compensation Act of 1986* (2009) (providing that it is "universally agreed that the Act does not completely or expressly preempt state law, except in specific instances…the Act does preempt state law in action involving design defect claims, claims of failure to warn the public, claims to recover medical expenses, and medical malpractice claims.") *See also Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

The FDA process for new or innovative drugs is rigorous and requires an extensive series of clinical trials, first on animals and then on humans, before the new drug application can be formally filed with the FDA.[58] The company then sends the FDA the evidence from these trials to prove the drug is safe and effective for its intended use. The FDA's physicians, statisticians, chemists, pharmacologists, and other scientists review the company's data and proposed labeling. The FDA will only approve a new drug application if it determines that the drug is safe and effective for its proposed use and that the benefits of the drug appear to outweigh the known risks.[59]

National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act of 1986 ("NCVIA")[60] created a streamlined, no-fault compensation scheme making it faster and easier for injured vaccine recipients to recover damages while discouraging costly and difficult litigation that threatened to force manufacturers out of the market.[61] The NCVIA applies to most vaccines routinely given in the U.S.[62] For a vaccine to be covered, the CDC must recommend the category of vaccine for routine administration to children or pregnant women, and it must be subject to an excise tax by federal law.[63] The list of covered vaccines is provided by the "Vaccine Injury Table"[64] published by the NCVIA. The NCVIA was passed in response to vaccine supply shortages and a destabilization of childhood immunization.[65] The NCVIA preserved the right for a person injured by a vaccine to bring a lawsuit in the court system if federal compensation was denied or was not sufficient, or when there was evidence a drug company could have made a vaccine safe.[66]

Under the NCVIA, an individual is generally prohibited from filing a civil lawsuit against the manufacturer of a covered vaccine in state or federal court without first exhausting his or her remedies by filing a petition in the U.S. Court of Federal Claims, commonly referred to as "Vaccine Court."[67]

The NCVIA significantly restricts the ability of an individual to bring a traditional liability suit by granting covered vaccine manufacturers broad immunity from liability for injuries resulting from unavoidable side effects, provided the vaccine was properly prepared and accompanied by proper directions and warnings.[68] Pursuant to the NCVIA, there is a presumption that a vaccine manufacturer cannot be held liable for punitive damages unless the plaintiff shows that the manufacturer:

- Failed to exercise due care by clear and convincing evidence;
- Engaged in fraud or intentional wrongful withholding of information during any phase of a proceeding for approval of the vaccine;
- Engaged in intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval; or
- Engaged in other criminal or illegal activity relating to the safety and effectiveness of vaccines.[69]

National Vaccine Injury Compensation Program

[58] U.S. Food & Drug Administration, New Drug Application (NDA), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited Feb. 6, 2026).
[59] *Id.*
[60] 42 U.S.C. sec. 300aa-1, et seq. (1986).
[61] 39 A.L.R. Fed. 2d 155, *Construction and Application of Preemption Provisions of National Childhood Vaccine Injury Compensation Act of 1986*.
[62] Health Resources & Services Administration, *Covered Vaccines*, https://www.hrsa.gov/vaccine-compensation/covered-vaccines (last visited Feb. 8, 2026).
[63] *Id.*
[64] Health Resources & Services Administration, *Vaccine Injury Table Effective for Claims Filed on or After Jan. 3, 2022*, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf (last visited Feb. 8, 2026).
[65] National Childhood Vaccine Injury Act, 42 U.S.C. sec. 300aa-1, et seq. (1986).
[66] National Vaccine Information Center, *The National Childhood Vaccine Injury Act of 1986* (Feb. 19, 2024) https://www.nvic.org/law-policy-federal/vaccine-injury-compensation/1986-national-childhood-vaccine-injury-act (last visited Feb. 6, 2026).
[67] 42 U.S.C. ss. 300aa-11(a)(2).
[68] 42 U.S.C. s. 300aa-22(b)(1).
[69] *Id.*

The National Vaccine Injury Compensation Program ("VICP") is a compensation program created under the NCVIA. The VICP is a no-fault alternative to the traditional legal system for resolving vaccine injury petitions.[70] VICP was created in 1986 (but did not become operational until 1988) with the goal to:

- Ensure an adequate supply of vaccines;
- Stabilize vaccine costs; and
- Establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines.[71]

Under the VICP, any individual, of any age, who received a covered vaccine and believes he or she was injured as a result, can file a petition.[72] Additionally, a parent, legal guardian, or legal representative has standing to file on behalf of a child, disabled adult, or a deceased individual.[73]

From the inception of the VICP in October of 1988 and January 1, 2026, 29,460 total petitions were filed alleging a vaccine-related injury or death.[74] Of the total petitions filed, 25,652 have been adjudicated. Of the petitions that have been adjudicated, 12,567 (approximately 43%) were compensated and 13,167 (approximately 45%) were dismissed.[75]

Federal Public Readiness and Emergency Preparedness (PREP) Act

In addition to the longstanding federal vaccine safety and compensation programs, the PREP Act, enacted in 2005,[76] authorizes the Secretary of the Department of Health and Human Services to issue a PREP Act declaration which provides immunity from liability for claims:

- Of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats, and conditions.
- Determined by the Secretary to constitute a present, or credible rise of a future public health emergency.
- To entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.[77]

A PREP Act declaration is specifically enacted for the purpose of providing immunity from liability, and is different from, not dependent on, other emergency declarations.[78] Currently, there are PREP Act declarations for illnesses and diseases including, but not limited to, Smallpox, Zika Virus, Anthrax, and Covid-19.[79]

Federal Preemption of State Law

The NCVIA expressly preempts cerain design-defect claims against vaccine manufacturers brought by a plaintiff who seeks compensation for injury or death caused by vaccine side effects.[80] Specifically, the NCVIA preempts all state law products liability claims of design defect and failure to warn arising out of vaccine-related injury or death

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[70] U.S. Health Resources & Services Administration, National Vaccine Injury Compensation Program, https://www.hrsa.gov/vaccine-compensation (last visited Feb. 2, 2026).
[71] U.S. Health Resources & Services Administration, About the National Vaccine Injury Compensation Program, https://www.hrsa.gov/vaccine-compensation/about (last visited Feb. 2, 2026).
[72] U.S. Health Resources & Services Administration, National Vaccine Injury Compensation Program, https://www.hrsa.gov/vaccine-compensation (last visited Feb. 6, 2026).
[73] *Id.*
[74] U.S. Health Resources & Services Administration, Data & Statistics, at p. 5, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-01-01-26.pdf (last visited Feb. 5, 2026).
[75] *Id.*
[76] Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, December 30, 2005, 119 Stat. 2680.
[77] U.S. Administration for Strategic Preparedness & Response, *Public Readiness and Emergency Preparedness (PREP) Act*, https://aspr.hhs.gov/legal/PREPact/pages/default.aspx (last visited Feb. 8, 2026).
[78] *Id.*
[79] *Id.*
[80] 13 Fed. Proc., L. Ed. S. 35:889, *Effect of National Childhood Vaccine Injury Act* (Dec. 2025), *citing to Bruesewitz v. Wyeth, LLC.*, 562 U.S. 223, 131 S. Ct. (2011).

caused by a vaccine listed on the Vaccine Injury Table.[81] Additionally, no state may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by the NCVIA.[82]

Advertisement of Vaccines

In 2025, healthcare and pharmaceutical digital advertising spending was estimated to reach $24.8 billion, while traditional ad spending (tv, radio, etc.) was estimated to be about $7.9 billion.[83] This highlights a shift from traditional advertising methods to direct-to-consumer digital methods that consumers will see on their social media platforms as well as internet browsers. Section 499.0054(1)(a), F.S., prohibits the dissemination of false or misleading advertisements for any drug or device.

First Amendment Protections for Vaccine Advertising

The United States Supreme Court has established that commercial speech, including pharmaceutical advertising, is afforded significant protection under the First Amendment.[84] Under the *Central Hudson* framework, the government generally may not prohibit or unduly burden truthful, non-misleading advertisements for lawful products unless the regulation is narrowly-tailored to serve a substantial government interest.[85]

OTHER RESOURCES:

National Vaccine Injury Compensation Program.

U.S. Food and Drug Administration: Vaccines.

The National Childhood Vaccine Injury Act of 1986.

U.S. Health Resources & Services Administration, National Vaccine Injury Compensation Program: Monthly Statistics Report, Data & Statistics.

The National Vaccine Injury Compensation Program (VICP), Infographic.

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Civil Justice & Claims Subcommittee	12 Y, 4 N, As CS	2/11/2026	Jones	Mathews
THE CHANGES ADOPTED BY THE COMMITTEE:	Amended the effective date of the bill to October 1, 2026.			
Health Professions & Programs Subcommittee				
Judiciary Committee				

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[81] *Id. See also Kravitz v. Evans Medical Ltd.*, 741 F. Supp. 2d 1299 (S.D. Fla. 2010).
[82] 42 U.S.C. s. 300aa-22(e).
[83] Andrea Park, Fierce Pharma, *2026 forecast: Pharma ad dollars will continue shifting away from traditional TV* (December 19, 2025), https://www.fiercepharma.com/marketing/2026-forecast-pharma-ad-dollars-will-continue-shifting-away-traditional-tv (last visited Feb. 6, 2026).
[84] *Virginia State Board of Pharmacy v. Viriginia Citizens Consumer Council*, 425 U.S. 748 (1976).
[85] *Central Hudson Gas & Elec. Corp v. Public Service Commission*, 447 U.S. 557 (1980).

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.
