The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Regulated Industries

BILL:	SB 408
INTRODUCER:	Senator Grall
SUBJECT:	Advertisement of a Harmful Vaccine
DATE:	January 16, 2026
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Baird	Imhof	RI	**Pre-meeting**
2.			HP	
3.			RC	

I. Summary:

SB 408 establishes a new cause of action for those who are injured or harmed by a vaccine manufacturer who advertises their products in Florida.

The bill updates the term "advertise" within ch. 499, F.S., to mean 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 manufacturer's vaccine.

It does not include any discussion between a health care provider and his or her patient or written materials regarding vaccines, or any promotional materials concerning vaccines displayed in a health care facility.

The bill provides that an injured individual may bring an action within 3 years following the accrual of the cause of action.

Finally, the bill provides that a court shall award a claimant who prevails in an action brought under this section actual damages, court costs, and reasonable attorney fees.

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

II. Present Situation:

State and Federal Regulation of Drugs, Devices, and Cosmetics

The regulation of drugs and cosmetics is addressed in ch. 499, F.S., which regulates drugs, devices, and cosmetics by the Department of Business and Professional Regulation (DBPR).[1] The Florida Drug and Cosmetic Act (the act)[2] 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 regarding the distribution of drugs.

Administration of the act must conform to the Federal Food, Drug, and Cosmetic Act[3] and the applicable portions of the Federal Trade Commission Act[4] which prohibit the false advertising of drugs, devices, and cosmetics. 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.[5] The FDA preempts the state of Florida from regulating certain areas regarding drugs and cosmetics, including generally, the pre-market approval of drugs and the post-market surveillance of cosmetics, in both instances monitoring for safety issues for the American people.

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.[6] 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.[7]

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.[8]

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[1] 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, at http://laws.flrules.org/2012/184 (last visited January 12, 2026).
[2] See ss. 499.001-499.081, F.S.
[3] 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*.
[4] *See* 15 U.S.C. ss. 41-58, as amended.
[5] Section 499.01, F.S.
[6] U.S. Food & Drug Administration, New Drug Application (NDA), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited January 15, 2026).
[7] *Id*.
[8] Sections 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

Drugs and Devices

General Prohibitions

The act prohibits any person from:[9]

- 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, 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 will raise to the level of criminal acts under s. 499.0051, F.S.

General Regulation of Vaccines

The Advisory Committee on Immunization Practices (ACIP) develops recommendations on the use of vaccines in the United States.[10] The ACIP is comprised 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 Obstetricians

[9] *See* Section 499.005, F.S.

[10] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *General Committee-Related Information*, available at https://www.cdc.gov/vaccines/acip/committee/index.html (last visited January 15, 2026). Established under Title 42 U.S.C. § 217a, ACIP members are appointed by the Secretary of the U.S. Department of Health and Human Services and consist of a mix of medical and public health experts from private industry and the public sector. There are 15 voting members (14 are industry experts and one consumer member), 6 non-voting, ex-officio members consisting of specific federal government employees, and 30 non-voting representatives from professional health care organizations.

and Gynecologists, and the American College of Physicians to develop annual childhood and adult immunization schedules.[11]

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.[12] New vaccines are considered for addition to the schedule after licensure by the FDA.[13]

The FDA 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.[14]

All vaccines must be licensed (approved) by the FDA in order to be marketed in the United States.[15] However, during public health emergencies, the FDA may authorize vaccines for emergency use, which speeds up the process of bringing a vaccine to market.[16]

Liability for Vaccine Manufacturers

In the 1980s Congress passed the National Childhood Vaccine Injury Act (NCVIA) in response to vaccine supply shortages and a destabilization of childhood immunization.[17] The NCVIA preserved the right for vaccine injured persons to bring a lawsuit in the court system *if* federal compensation is denied or is not sufficient or when there was evidence a drug company could

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[11] Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP), *ACIP Recommendations*, available at https://www.cdc.gov/vaccines/acip/recommendations.html (last visited January 15, 2026).
[12] *Id*.
[13] College of Physicians of Philadelphia, *The History of Vaccines: The Development of the Immunization Schedule,* available at http://www.historyofvaccines.org/content/articles/development-immunization-schedule (last visited January 16, 2026).
[14] U.S. Food and Drug Administration, *Vaccine Development – 101,* available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101 (last visited January 15, 2026).
[15] U.S. Food and Drug Administration, *Ensuring the Safety of Vaccines in the United States,* available at https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Ensuring-the-Safety-of-Vaccines-in-the-United-States.pdf (last visited January 15, 2026).
[16] Food and Drug Administration, *Emergency Use Authorization*, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited January 15, 2026). Medical countermeasures are FDA-regulated products (biologics, drugs, and devices) that may be used in the event of a public health emergency.
[17] National Childhood Vaccine Injury Act, 42 U.S.C. §§300aa-1-34 (1986).

have made a vaccine safe.[18] Under the NCVIA, individuals are generally prohibited from filing a civil lawsuit against a vaccine manufacturer in state or federal court without first exhausting their remedies by filing a petition in the U.S. Court of Federal Claims.[19]

Within the NCVIA the National Vaccine Injury Compensation Program (VICP) was created as an alternative to traditional products liability and medical malpractice litigation for persons injured by their receipt of one or more of the standard childhood vaccines.[20] The VICP is designed to encourage vaccination by providing a streamlined system for compensation where an injury results from vaccination.[21]

Since the program's inception in 1988, almost 9,500 people have been paid in excess of $4.5 billion.[22]

The NCVIA significantly restricts the ability to sue by granting 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.[23] There is a presumption that a vaccine manufacturer can't be held liable for punitive damages unless the plaintiff shows that the manufacturer:[24]

- 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.

This protection for vaccine manufacturers was further solidified by the U.S. Supreme Court in *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011), which ruled that the NCVIA preempts all state-law "design-defect" claims against vaccine manufactures by plaintiffs who seek compensation for injury or death caused by vaccine side effects.

Effectively, the NCVIA prevents most standard lawsuits like those for design defects or failure to warn against vaccine manufacturers for covered vaccines.

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[18] National Vaccine Information Center, *The National Childhood Vaccine Injury Act of 1986* (February 19, 2024), available at https://www.nvic.org/law-policy-federal/vaccine-injury-compensation/1986-national-childhood-vaccine-injury-act (last visited January 15, 2026).
[19] 42 U.S.C. §300aa-11(a)(2).
[20] Department of Justice Civil Division, *Vaccine Injury Compensation Program* (updated January 25, 2023), available at https://www.justice.gov/civil/vicp (last visited January 15, 2026).
[21] *Id*.
[22] *Id*.
[23] 42. U.S.C. §300aa-22(b)(1).
[24] *Id*.

Advertising of Vaccines

In 2025, healthcare and pharma digital ad spending is estimated to reach $24.8 billion, while traditional ad spending is estimated to be about $7.9 billion.[25] 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.

III. Effect of Proposed Changes:

The bill amends s. 499.0054, F.S., defining the term "advertise" to mean 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 manufacturer's vaccine.

"Advertise" does not include:

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

The bill provides that a vaccine manufacturer **is liable** to an individual if the manufacturer advertises a vaccine in this state and the advertised vaccine causes harm or injury to an individual.

Notwithstanding any other law, to the contrary, an individual may bring an action under this section within **3 years** following the accrual of the cause of action.

A court shall award a claimant who prevails in an action brought under this section actual damages, court costs, and reasonable attorney fees.

The bill provides for an effective date of July 1, 2026.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[25] Andrea Park, Fierce Pharma, *2026 forecast: Pharma ad dollars will continue shifting away from traditional TV* (December 19, 2025), available at https://www.fiercepharma.com/marketing/2026-forecast-pharma-ad-dollars-will-continue-shifting-away-traditional-tv (last visited January 1, 2026).

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

While the bill seeks to carve out a new cause of action strictly based on advertising, there likely could be arguments made that may trigger the express federal preemption under the NCVIA (federal law).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 499.0054 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.