FJRI Opposes SB 408 and HB 339 and the Creation of New Strict Liability for Vaccine Manufacturers

Senate Bill 408 and House Bill 339 propose to make a new personal injury cause of action against manufacturers of vaccines who advertise in Florida, which would impose strict liability on such manufacturers even if the vaccine was not defective. Specifically, SB 408 and HB 339 would add subsection (4) to section 499.0054 of the Florida Drug and Cosmetic Act, §§ 499.001–.94, Fla. Stat., stating that "[a] 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." The proposed legislation further states that "an individual may bring an action under this section within 3 years following the accrual of the cause of action," and "[a] court shall award a claimant who prevails in an action brought under this section actual damages, court costs, and reasonable attorney fees."

This proposed legislation is unwarranted because individuals injured by vaccines already have multiple avenues to obtain compensation for their injuries under federal vaccine compensation programs and Florida law. Because this legislation would create a new strict liability cause of action that permits plaintiffs but not defendants to be awarded attorney fees, it would needlessly generate litigation against vaccine manufacturers, increasing their costs, jeopardizing investment and innovation in vaccine development, and ultimately increasing healthcare costs for Florida residents. Moreover, SB 408 and HB 339 are ill-conceived measures that will be rejected by courts. Indeed, most claims that a person could bring against a vaccine manufacturer under this legislation would be preempted by well-established federal law.

For all these reasons, FJRI opposes SB 408 and HB 339.

Federal Compensation Programs and State-Law Claims Already Exist for Vaccine Injuries

Federal law already limits vaccine manufacturer liability in certain respects and establishes compensation programs for injuries related to many vaccines. For the few vaccines not covered by these programs, an injured person retains the right to sue the manufacturer directly in court.

Congress enacted the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), 42 U.S.C. §§ 300aa-1–300aa-34, to protect life-saving vaccine development and production in the United States while facilitating compensation to individuals injured by vaccines. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011). The Vaccine Act established the National Vaccine Injury Compensation Program (the "VICP"), a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Id.* (quoting *Shalala v. Whitecotton,* 514 U.S. 268, 269 (1995)). Compensation through the VICP is funded by vaccine manufacturers through an excise tax imposed on each vaccine dose. *In re Gardasil Products Liab. Litig.*, 724 F. Supp. 3d 474, 485 (W.D.N.C. 2024), *aff'd sub nom.*, 151 F.4th 178 (4th Cir. 2025).

Unlike in tort suits, claimants seeking compensation through the VICP "are not required to show that the administered vaccine was defectively manufactured, labeled, or designed." *In re*

Gardasil Products Liab. Litig., 724 F. Supp. 3d at 485. If a person has experienced a side effect or other injury that has been scientifically linked to the vaccine they received within the period that such injuries typically occur, that person is presumptively entitled to compensation without any showing of causation. *See id.* "Successful claimants receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering; and $250,000 for vaccine-related deaths." *Id.* Moreover, claimants are entitled to attorney fees not only for successful cases, but even for unsuccessful claims that are not frivolous. *Id.* A claimant who is not awarded compensation or is unsatisfied with the award can file a lawsuit in state or federal court. *See id.*

The VICP covers most vaccines routinely given in the United States. *See* Health Res. & Servs. Admin., *Covered Vaccines*, National Vaccine Injury Compensation Program, https://www.hrsa.gov/vaccine-compensation/covered-vaccines.

Another federal law governing vaccine liability is the Public Readiness and Emergency Preparedness Act of 2005 (the "PREP Act"). To encourage the development of countermeasures—like vaccines and drugs—the PREP Act limits the legal liability of manufacturers, distributors, health care providers, and others for losses related to the administration or use of covered countermeasures. More specifically, the PREP Act authorizes the Secretary of the Department of Health and Human Services ("HHS") to issue a PREP Act declaration. *See* 42 U.S.C. § 247d-6d. Such declaration provides immunity from liability (except for willful misconduct) 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 HHS Secretary to constitute a present or credible risk of a future public health emergency; and
- to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.

See id. For instance, the HHS Secretary invoked the PREP Act and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures in March 2020.[1]

In addition to allowing the Secretary to issue a PREP Act declaration and to limit the legal liability of manufacturers of countermeasures, the PREP Act also authorized HHS to establish the Countermeasure Injury Compensation Program (the "CICP"). *See* 42 U.S.C. § 247d-6e; 42 C.F.R. § 110.1. The CICP compensates claimants for serious physical injuries and death caused by certain covered vaccines. *See* Health Res. & Servs. Admin., Countermeasure Injury Compensation Program (CICP), https://www.hrsa.gov/cicp. Compensation under the CICP may include medical expenses, a portion of lost employment income, and a survivor death benefit. *See* 42 C.F.R. § 110.30. Injuries related to a COVID-19 vaccine could potentially be compensated under the CICP.

[1] *See* Legal Sidebar, *The PREP Act and COVID-19: Part 2: The PREP Act Declaration for COVID-19 Countermeasures* (Jan. 3, 2025), https://www.congress.gov/crs-product/LSB10730.

See Health Res. & Servs. Admin., Countermeasure Injury Compensation Program (CICP), https://www.hrsa.gov/cicp.

A Florida resident injured by a vaccine not covered by either the VICP or CICP and for which the manufacturer does not have immunity may bring a lawsuit under Florida negligence and product liability law. *See, e.g.*, *Kravitz v. Evans Med. Ltd.*, 741 F. Supp. 2d 1299, 1300–01 (S.D. Fla. 2010) (holding that plaintiff could bring Florida-law negligence and strict liability claims against a vaccine manufacturer for alleged injuries caused by a vaccine that was not covered by the Vaccine Act at the time plaintiff received the vaccine).

This Ill-Conceived Legislation Would Create Remedies Preempted by Federal Law

The Vaccine Act "pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects." *Bruesewitz*, 562 U.S. at 243. Thus, any state-law claim that an injury resulted from a vaccine's design, ingredients, formulation, development, testing, or lack of safety and efficacy is preempted. *See In re Gardasil Products Liab. Litig.*, 724 F. Supp. 3d at 487–88. The Vaccine Act also preempts vaccine-injury claims against manufacturers based on an alleged failure to directly warn the person injured regarding risks associated with the vaccine. *See id.* at 488–89.

In addition, because vaccine labeling must be approved through the onerous process prescribed by the Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301–399i, most failure to warn claims based on a drug or vaccine manufacturer's failure to include adequate warnings in its labeling are preempted by the FDCA. *See, e.g.*, *Herlth v. Merck & Co., Inc*., No. 3:21-CV-438 (JAM), 2022 WL 788669, at *3 (D. Conn. Mar. 15, 2022).

In addition, where the injury was caused by a vaccine developed and used as a countermeasure to a public health emergency, the PREP Act gives the manufacturer broad immunity from "liability under Federal and State law" for any claim based on the vaccine's "design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use[.]" 42 U.S.C.A. § 247d-6d.

Between the Vaccine Act, the FDCA, and the PREP Act, almost all claims that could be brought under the new cause of action that SB 408 and HB 339 propose to create would be preempted by federal law or subject to dismissal due to the manufacturer's immunity.[2] As courts would reject most attempts by plaintiffs to use this legislation, it is ill-conceived and would be an imprudent use of legislative power.

[2] Notably too, almost 20 years ago, Florida legislators proposed legislation that would have done the ***opposite*** of what this legislation proposes, by further insulating vaccine manufacturers from liability so that they would pursue innovation, particularly in Florida. *See* 2006 HB 311 (Sponsor: Rep. Cretul) (proposing to require Enterprise Florida, Inc., to conduct an outreach campaign to encourage vaccine production facilities to produce certain vaccines in this state and to exempt certain business entities from liability); 2006 SB 706 (Sponsor: Sen. Fasano) (identical).

The Proposed Legislation Would Needlessly Generate Litigation and Attorney Fees

A private right of action is a legal authority, granted either explicitly by statute or implied by a court, that empowers a private party—such as an individual, corporation, or class of plaintiffs—to sue another party to remedy a statutory violation. *See, e.g.*, *Fla. Wildlife Fed'n v. State Dep't of Envtl. Regul.*, 390 So. 2d 64, 66 (Fla. 1980). A new private right of action such as the one proposed in SB 408 and HB 339, which imposes strict liability and provides for one-way attorney fees, would create a powerful economic engine for litigation. The primary mechanism for calculating attorney fees is the billable hour, often formalized in fee awards as the "lodestar" amount, which is an attorney's hourly rate multiplied by the hours spent on the matter. *See, e.g.*, *Haines City HMA, Inc. v. Carter*, 948 So. 2d 904, 907 (Fla. 2d DCA 2007) (approving lodestar attorney fee award in action under Florida Civil Rights Act). The financial reality is that litigation costs for both sides in private rights of action often become untethered from the initial stakes, ultimately dwarfing the amount in controversy.

Contrary to Florida product liability law, the cause of action proposed by SB 408 and HB 339 would impose liability on vaccine manufacturers ***even if*** the vaccine was not defectively designed or manufactured and ***even if*** the manufacturer provided adequate warnings regarding risks associated with the vaccine. This expansive liability paired with a one-way attorney fee provision that insulates plaintiffs from financial risk while imposing it on defendants would encourage litigation for its own sake, rather than as a reasonable means to redress meritorious claims. Given that individuals injured by vaccines already have multiple avenues to obtain compensation for their injuries, the only real beneficiaries of this legislation are plaintiffs' attorneys.

The increase in needless litigation that this legislation would cause would impose substantial and cascading costs on vaccine manufacturers that could jeopardize investment and innovation in vaccine development and result in increased healthcare costs for Florida residents. Beyond direct expenses of litigation such as defense fees, court costs, e-discovery, and expert witnesses, vaccine manufacturers face the threat of immense settlements or adverse judgments. This risk is magnified in the context of class actions, where potential liability can be so catastrophic as to pose an existential threat, creating immense pressure to settle even non-meritorious claims. These costs are not absorbed in a vacuum; businesses must often divert resources from innovation and growth to legal defense, and they ultimately pass these expenses to users through higher prices. In this way, the proliferation of litigation through the creation of private causes of action acts as a "tort tax," imposing a hidden and inefficient burden on the broader economy.

For all these reasons, the Institute asks you to oppose SB 408 and HB 339.