# WEST VIRGINIA LEGISLATURE

## 2025 REGULAR SESSION

## Introduced

# House Bill 3477

By Delegate Worrell

[Introduced March 17, 2025; referred to the

Committee on the Judiciary then Finance]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding a new article, designated §55-7L-1, §55-7L-2, §55-7L-3, §55-7L-4, §55-7L-5, §55-7L-6, §55-7L-7, §55-7L-8, and §55-7L-9, relating to liability shield products; providing definitions; placebo-controlled studies; tracking adverse outcomes; publishing post-market surveillance data; issuing an alert about adverse consequences; requiring manufacturers of liability shield products to submit documentation and compliance reports; granting individuals the right to refuse liability shield products; action brought forth by the Attorney General or an individual; and damages and relief.

*Be it enacted by the Legislature of West Virginia:*

## ARICLE 7L. MEDICAL, PHARMACEUTICAL, BIOLOGICAL, OR TECHNOLOGICAL LIABILITY SHIELD PRODUCTS.

### §55-7L-1. Definitions.

For purposes of this article:

"Allergenicity" means the ability to provoke an allergic reaction in an individual.

"Cabinet" means the Cabinet for Health and Family Services.

"Carcinogenicity" means the ability to cause cancer in an individual.

"Department" means the Department of Health.

"Fertility impact" means the ability to adversely affect the reproductive health or fertility of an individual.

"Immunogenicity" means the ability to cause an immune response in an individual.

"Liability shield product" means a medical, pharmaceutical, biological, or technological product that has been designated as immune from liability under federal law.

"Mutagenicity" means the ability to cause a genetic mutation in an individual.

"Placebo" means a substance used as a control in a placebo-controlled study that is administered to a study participant and should not have a pharmacological effect on the participant.

"Placebo-controlled study" means a scientific study that randomly assigns a participant to receive either a product that is being studied or a placebo to measure health effects and the safety outcome metrics of the product on participants.

"Reactogenicity" means the symptoms or the outcome of a vaccine that is administered to an individual.

"Safety outcome metrics" means data that is collected and analyzed on a product concerning the allergenicity, carcinogenicity, fertility impact, immunogenicity, mutagenicity, and reactogenicity of the product.

**§55-7L-2. Placebo-controlled studies.**

(a) A manufacturer of a liability shield product shall ensure that a placebo-controlled study of the liability shield product has been completed before it is manufactured, marketed, distributed, or administered in West Virginia.

(b) The placebo-controlled study required in subsection (a) of this section shall be continued for at least five years and continuously collect safety outcome metrics during the five years.

(c) The results of the placebo-controlled study and the safety outcome metrics required under this section shall be made publicly available and accessible to the public including patients, health care providers, and state agencies, on the Department’s website.

**§55-7L-3. Tracking and publishing adverse outcomes.**

The Department shall:

(a) Monitor and track adverse outcomes of liability shield products using:

(1) The West Virginia Health Information Network; and

(2) The Vaccine Adverse Event Reporting System cosponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration in the United States Department of Health and Human Services; and

(b) Publish any post-market surveillance data that reports an adverse consequence of a liability shield product.

**§55-7L-4. Alert and bulletin concerning information about adverse consequences.**

The Department shall issue an alert and bulletin with information about any adverse consequences of a liability shield product identified under §55-7L-3 of this code.

**§55-7L-5. Establishment of policy to monitor and publish data.**

By January 1, 2026, the Department shall establish and make public a policy to monitor and publish data as required under this article.

**§55-7L-6. Documentation confirming placebo-controlled studies and submitting of compliance reports.**

(a) By July 1, 2028, all manufacturers of liability shield products that are distributed, manufactured, marketed, or administered in West Virginia shall submit documentation to the Department confirming that a placebo-controlled study has been initiated on the liability shield product and listing the safety outcome metrics being collected.

(b) Not later than December 31, 2030, all manufacturers of liability shield products that are distributed, manufactured, marketed, or administered in West Virginia shall submit a compliance report to the Department confirming that required placebo-controlled study has been completed and describing the placebo-controlled study results.

**§55-7L-7. Right to refuse a liability shield product.**

An individual may refuse a liability shield product and may not be subject to coercion or threat to use a liability shield product.

**§55-7L-8. Action brought forth by the Attorney General; relief; civil penalties; attorney's fees.**

Beginning January 1, 2031, if an entity violates §55-7L-2, §55-7L-6, or §55-7L-7 of this code, the Attorney General may bring an action to obtain the following:

(1) Injunctive relief;

(2) A civil penalty of not more than $100,000 for each violation; and

(3) Reasonable attorney's fees and costs.

**§55-7L-9. Action brough forth by an individual; relief; damages; attorney's fees.**

(a) An individual who suffers an injury due to a violation of §55-7L-3, §55-7L-4, or §55-7L-7 of this code may bring an action to obtain the following:

(1) Injunctive relief;

(2) Compensatory damages; and

(3) Reasonable attorney's fees and costs.

(b) A suit brought under this article may be filed by the individual or a personal representative on behalf of the individual.

NOTE: The purpose of this bill is to establish regulatory oversight for medical, pharmaceutical, biological, or technological liability shield products.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.