Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 911 (Senator McKay)
Finance

Food, Drugs, and Cosmetics - Gene Structure- and Function-Modifying Products - Labeling

This bill prohibits a person from offering for sale in the State a gene structure- or function-modifying product unless the product is labeled, in a prominent and conspicuous manner, with (1) the words "gene structure- or function-modifying product" and (2) all potential risks, side effects, adverse effects, and other reasonably possible effects that the product may have on an individual who uses it or an individual who may come into contact with the individual who uses the product. A violator is guilty of a misdemeanor and on conviction is subject to imprisonment for up to one year and/or a fine of up to $10,000 for a first offense; or, for any subsequent offense, imprisonment for up to three years and/or a fine of up to $25,000. A violator is also subject to a civil penalty of up to $5,000 in an action in a District Court and may be enjoined from continuing the violation. Each day on which a violation occurs after conviction for a first offense constitutes a separate violation. The bill must be construed liberally to carry out its purpose.

Fiscal Summary

State Effect: General fund expenditures increase by $72,600 in FY 2025 for the Maryland Department of Health (MDH) to hire staff, as discussed below; future years reflect annualization and elimination of one-time costs. Potential minimal increase in general fund revenues and expenditures due to the bill's penalty provisions.

(in dollars)	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Revenues	$0	$0	$0	$0	$0
GF Expenditure	72,600	128,400	133,900	139,600	145,500
Net Effect	($72,600)	($128,400)	($133,900)	($139,600)	($145,500)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: Potential minimal increase in revenues and expenditures due to the bill's penalty provisions.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Gene structure- or function-modifying product" means a product that has been produced using modern biotechnology methods designed to alter the structure or function of one or more genes in the product and which leads to the product containing artificially engineered elements that may modify the structure or function of one or more genes in a consumer. "Modern biotechnology methods" means a recently discovered method of application of biological processes for industrial and other purposes, including gene editing, RNA interference, and transgenesis.

Current Law: Under the federal Public Health Service Act, a person may not introduce or deliver for introduction into interstate commerce any biological product unless a biologics license is in effect for the product and each package of the product is plainly marked with the proper name of the biological product and other specified information. A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except as specified) or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings.

In January 2024, the U.S. Food and Drug Administration released a guidance document for industry (*Human Gene Therapy Products Incorporating Human Genome Editing*) that provides recommendations to sponsors developing human gene therapy products incorporating genome editing of human somatic cells.

State Expenditures: According to MDH, the department does not currently have any budget, staff, or laboratory capacity to manage any product referrals that may result from the bill's requirements for gene structure- or function-modifying products. MDH advises that the department will likely require manufacturers to conduct testing on these products at private laboratories, rather than sending them to MDH for testing. Nonetheless, MDH advises that the bill necessitates the hiring of a scientist to advise the department on gene structure- and function-modifying science, including for consultation on testing and interpretation of test results.

General fund expenditures increase by $72,626 in fiscal 2025, which accounts for a 90-day start-up delay from the bill's October 1, 2024 effective date. This estimate reflects

the cost of hiring one public health scientist to support MDH's activities related to gene structure- or function-modifying products. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1.0
Salary and Fringe Benefits	$62,940
Operating Expenses	9,686
Total FY 2025 State Expenditures	**$72,626**

Future year expenditures reflect a full salary with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: HB 1421 (Delegates S. Johnson and A. Johnson) - Health and Government Operations.

Information Source(s): Judiciary (Administrative Office of the Courts); Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - March 5, 2024
rh/jc

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