$\begin{array}{c} \text{J1} \\ \text{CF SB 911} \end{array}$

By: Delegates S. Johnson and A. Johnson

Introduced and read first time: February 9, 2024 Assigned to: Health and Government Operations

A BILL ENTITLED

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1	AN ACT concerning
2 3	Food, Drugs, and Cosmetics – Gene Structure– and Function–Modifying Products – Labeling
4 5 6 7	FOR the purpose of prohibiting a person from offering for sale in the State a gene structure— and function—modifying product unless the product is labeled in a certain manner; and generally relating to labeling of gene structure— and function—modifying products.
8 9 10 11 12 13	BY adding to Article – Health – General Section 21–3A–01 through 21–3A–04 to be under the new subtitle "Subtitle 3A. Gene Structure– and Function–Modifying Products" Annotated Code of Maryland (2023 Replacement Volume)
14 15	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
16	Article – Health – General
17	SUBTITLE 3A. GENE STRUCTURE- AND FUNCTION-MODIFYING PRODUCTS.
18	21-3A-01.
19 20	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
21	(B) "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

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- 1 PRODUCT AND WHICH LEADS TO THE PRODUCT CONTAINING ARTIFICIALLY
- 2 ENGINEERED ELEMENTS THAT MAY MODIFY THE STRUCTURE OR FUNCTION OF ONE
- 3 OR MORE GENES IN A CONSUMER.
- 4 (C) (1) "MODERN BIOTECHNOLOGY METHODS" MEANS A RECENTLY
- 5 DISCOVERED METHOD OF APPLICATION OF BIOLOGICAL PROCESSES FOR
- 6 INDUSTRIAL AND OTHER PURPOSES.
- 7 (2) "MODERN BIOTECHNOLOGY METHODS" INCLUDES:
- 8 (I) GENE EDITING;
- 9 (II) RNA INTERFERENCE; AND
- 10 (III) TRANSGENESIS.
- 11 **21–3A–02.**
- 12 (A) A PERSON MAY NOT OFFER FOR SALE IN THE STATE A GENE
- 13 STRUCTURE- OR FUNCTION-MODIFYING PRODUCT UNLESS THE GENE
- 14 STRUCTURE- OR FUNCTION-MODIFYING PRODUCT IS LABELED IN ACCORDANCE
- 15 WITH SUBSECTION (B) OF THIS SECTION.
- 16 (B) A GENE STRUCTURE- OR FUNCTION-MODIFYING PRODUCT OFFERED
- 17 FOR SALE IN THE STATE SHALL BE LABELED, IN A PROMINENT AND CONSPICUOUS
- 18 MANNER, WITH:
- 19 (1) THE WORDS "GENE STRUCTURE- OR FUNCTION-MODIFYING
- 20 PRODUCT"; AND
- 21 (2) ALL POTENTIAL RISKS, SIDE EFFECTS, ADVERSE EFFECTS, AND
- 22 OTHER REASONABLY POSSIBLE EFFECTS THAT THE GENE STRUCTURE- OR
- 23 FUNCTION-MODIFYING PRODUCT MAY HAVE ON AN INDIVIDUAL WHO USES THE
- 24 GENE STRUCTURE- OR FUNCTION-MODIFYING PRODUCT, OR ON AN INDIVIDUAL
- 25 WHO MAY COME INTO CONTACT WITH THE INDIVIDUAL WHO USES THE GENE
- 26 STRUCTURE- OR FUNCTION-MODIFYING PRODUCT.
- 27 **21–3A–03**.
- 28 (A) A PERSON THAT VIOLATES THIS SUBTITLE:
- 29 (1) IS GUILTY OF A MISDEMEANOR AND ON CONVICTION IS SUBJECT
- 30 **TO**:

- 1 (I) FOR A FIRST OFFENSE, A FINE NOT EXCEEDING \$10,000 OR 2 IMPRISONMENT NOT EXCEEDING 1 YEAR; AND
- 3 (II) FOR A SECOND OR SUBSEQUENT OFFENSE, A FINE NOT 4 EXCEEDING \$25,000 OR IMPRISONMENT NOT EXCEEDING 3 YEARS;
- 5 (2) IS SUBJECT TO A CIVIL PENALTY NOT EXCEEDING \$5,000 IN AN 6 ACTION IN A DISTRICT COURT; AND
- 7 (3) MAY BE ENJOINED FROM CONTINUING THE VIOLATION.
- 8 (B) EACH DAY ON WHICH A VIOLATION OCCURS AFTER CONVICTION FOR A 9 FIRST OFFENSE IS A SEPARATE VIOLATION UNDER THIS SECTION.
- 10 **21-3A-04.**
- THIS SUBTITLE SHALL BE CONSTRUED LIBERALLY TO CARRY OUT ITS 12 PURPOSE.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2024.