Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

March 7, 2024

The Honorable Joseline A. Peña-Melnyk
Chair, House Health and Government Operations Committee
241 House Office Building
Annapolis, MD 21401-1991

RE: House Bill 1421 – Food, Drugs, and Cosmetics – Gene Structure– and Function–Modifying Products – Labeling – Letter of Opposition

Dear Chair Peña-Melnyk and Committee Members:

The Maryland Department of Health (Department) respectfully submits this letter of opposition for House Bill (HB) 1421 – Food, Drugs, and Cosmetics – Gene Structure – and Function – Modifying Products – Labeling. HB 1421 would prohibit the offering for sale in Maryland any gene structure- or function-modifying (hereon called simply "gene-modifying") product unless the gene-modifying product is labeled with the words "gene structure- or function-modifying product" and all potential risks, side effects, adverse effects, and other reasonably possible effects the product may have on the user, or anyone who comes into contact with the user. Violation of the requirement would be a misdemeanor accompanied by fines.

The Department is concerned that the scope of HB 1421 and the definition of gene-modifying is extremely broad. It includes a significant array of consumer products, foods, and medical therapeutics, including vaccines, cancer chemotherapy agents, antibiotics, and monoclonal antibody products essential to health care in the State. Many of these products have already been extensively tested and vetted by the U.S. Food and Drug Administration (FDA), and their labels and necessary warnings are already standardized by the FDA.

HB 1421 would also potentially affect foods that naturally contain chemicals that can alter genetic material or function. It is not clear if such products would also be covered by this bill, or to what extent.

This bill will have a fiscal impact on the Department. There is currently no budget, staff, or laboratory capacity in the Department to conduct testing on product referrals. In response, it is likely that the Department will instead require producers to conduct testing at private laboratories. In the instance of inter-state commerce, it is possible that the FDA could do the testing. Because of the unclear implication of the phrase "gene structure- or function-modifying" in the bill, the Department would require a 1.0 FTE Public Health Laboratory Principal Scientist Developmental to advise the Bureau Chief and the Department on gene structure- and

function-modifying science, testing possibilities, interpretation of test results, recommended actions, etc. at the State and national level. The State Fiscal Year 2025 salary and fringe cost is $94,181 with associated operating costs of $11,333. The total State Fiscal Year 2025 cost is $105,514.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary