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February 27, 2024

To: Joseline A. Pena-Melnyk, Chair
House Health and Government Operations Committee

From: Heather Forsyth, Deputy Director, Health Education and Advocacy Unit

RE: HB 1132 – Drugs, Biological Products and Devises – Off-Label Use – Promotion
(**Oppose**)

The Consumer Protection Division and the HEAU write in opposition to HB 1132. This bill authorizes pharmaceutical manufacturers and representatives to engage in the off-label promotion of drugs, biological products, and devices; prohibits State officials, employees, and agents from enforcing state laws or regulations or prosecuting pharmaceutical manufacturers or representatives for off-label promotion; prohibits State government units from taking disciplinary action, including licensure action, for off-label promotion; and prohibits Maryland and its political subdivisions from using personnel or resources to enforce, or cooperate with federal attempts to enforce, or apply federal laws that implicate off-label marketing.

An approved drug has been evaluated by the FDA's Center for Drug Evaluation and Research (CDER), which has determined that the drug's benefits outweigh its known and potential risks for the intended population. An "off-label" use refers to the use of an FDA-approved drug (1) for a disease or medical condition that it is not approved to treat, (2) in a different form than approved; (3) in a different dose; or (4) for a different population. Physicians may prescribe drugs off-label in their clinical judgment. Off-label promotion, however, presents risks to public health. When manufacturers engage in off-label promotion, they are promoting a drug for a use that they have not demonstrated is safe or effective.

Allowing manufacturers to promote their drugs off-label would provide a disincentive to conduct clinical trials, which undermines the regulatory framework in place to safeguard public health. For example, a manufacturer may seek the narrowest and easiest-to-prove use in a clinical trial, and then turn around and promote the drug for an unapproved use for which it would never be able to garner FDA approval. Conversely, conducting clinical trials for additional uses could reveal risks and issues with effectiveness or side effects.

The Office of the Attorney General has investigated and reached settlements with a number of pharmaceutical manufacturers over their promotion of off-label claims because that behavior threatens the health and well-being of Marylanders. This bill would explicitly permit such conduct and prohibit our Office from stopping that conduct.

Because we believe the potential harm to Marylanders outweighs any benefit to pharmaceutical manufacturers, we respectfully request an unfavorable report for HB 1132.