**HB 1132**

# Department of Legislative Services

Maryland General Assembly
2024 Session

## FISCAL AND POLICY NOTE
**First Reader**

House Bill 1132 (Delegate M. Morgan, *et al.*)
Health and Government Operations

**Drugs, Biological Products, and Devices - Off-Label Use - Promotion**

This bill authorizes a pharmaceutical manufacturer (or a representative of a pharmaceutical manufacturer) to engage in a truthful promotion of an "off-label" use of a drug, biological product, or device. An official, employee, or agent of the State may not enforce or apply a State law or regulation to or otherwise prosecute a pharmaceutical manufacturer (or representative) for engaging in a truthful promotion of an off-label use of a drug, biological product, or device. A regulatory unit, agency, commission, board, or other instrumentality of the State may not take disciplinary action against a pharmaceutical manufacturer (or representative) or a health care provider solely for engaging in a truthful promotion of an off-label use of a drug, biological product, or device. The State or a political subdivision of the State may not use personnel or financial resources to enforce or cooperate with federal attempts to enforce or apply federal law regarding misbranded drugs and devices against a pharmaceutical manufacturer (or a representative) solely for engaging in a truthful promotion of an off-label use of a drug, biological product, or device. The bill may not be construed to require a health insurance carrier or any other payor of health care services to provide coverage for the cost of any off-label treatment.

## Fiscal Summary

**State Effect:** The bill is not anticipated to materially affect State operations or finances.

**Local Effect:** The bill is not anticipated to materially affect local government operations or finances.

**Small Business Effect:** Minimal.

## Analysis

**Bill Summary:** "Off-label" means the use of a drug, biological product, or device for a treatment other than those treatments stated in the labeling approved by the U.S. Food and Drug Administration (FDA).

**Current Law:** The federal Food, Drug, and Cosmetics Act prohibits the adulteration or misbranding of any drug or device in interstate commerce (or introduced or delivered into interstate commerce). Section 352 of the Act sets forth the circumstances under which a drug or device is deemed to be misbranded.

*Off-label Promotion of Drugs and Devices*

Off-label promotion of a drug or device is not expressly prohibited by the federal Food, Drug, and Cosmetics Act or by FDA regulations. However, introducing a drug into interstate commerce without proper labeling constitutes "misbranding" and FDA views off-label promotion as misbranding the drug because it indicates a new intended use for the drug that is not mentioned on the drug's labeling. To legally promote a new intended use for a drug or device, a pharmaceutical manufacturer must apply for and receive FDA approval of the drug for that indication.

In *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the U.S. Court of Appeals for the Second Circuit vacated the conviction of a pharmaceutical sales representative for promoting an FDA-approved drug for off-label use. The Second Circuit held that the Food, Drug, and Cosmetics Act does not criminalize the mere promotion of a drug's off-label use because doing so would violate commercial speech protections under the First Amendment. Notwithstanding the decision in *United States v. Caronia*, courts have generally endorsed the federal government's role in ensuring that drugs are only marketed for their approved indications. FDA has continued to prosecute – often successfully – pharmaceutical manufacturers and their representatives for violating the Food, Drug, and Cosmetics Act by promoting off-label uses for various drugs.

*Maryland Food, Drug, and Cosmetic Act*

The Maryland Department of Health implements the Maryland Food, Drug, and Cosmetic Act, which conforms to the federal Food, Drug, and Cosmetics Act. Among other things, a drug or device is misbranded if (1) its labeling or packaging is false or misleading in any way; (2) its labeling does not include adequate directions for the use of the drug or device and adequate warnings against specified uses, such as the use of the drug or device by a child if its use by a child may be dangerous; and (3) it is dangerous to health when used in the dosage, with the frequency, or for the duration specified, recommended, or suggested in the labeling of the drug or device. The prohibitions under the Act are subject to criminal

penalties, including (1) for a first offense, imprisonment for up to three months and/or a fine of up to $1,000 and (2) for a second violation, imprisonment for up to one year and/or a fine of up to $2,500. Additionally, a person who violates the Act is liable for a civil penalty of up to $5,000.

**Additional Comments:** Off-label use of prescription drugs is commonplace in the United States and particularly prevalent for treating psychiatric disorders and certain cancers. According to a 2021 report by the Congressional Research Service, credible researchers have estimated that off-label drug prescriptions comprise between 12% to 38% of prescriptions nationally.

## Additional Information

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

**Designated Cross File:** None.

**Information Source(s):** Office of the Attorney General; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

**Fiscal Note History:** First Reader - February 26, 2024
js/jc

Analysis by: Ralph W. Kettell

Direct Inquiries to:
(410) 946-5510
(301) 970-5510