

# HOUSE BILL 1132

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By: **Delegates M. Morgan, Arikan, Chisholm, Grammer, McComas, and Nawrocki**  
Introduced and read first time: February 7, 2024  
Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

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

3 FOR the purpose of authorizing pharmaceutical manufacturers and representatives of  
4 pharmaceutical manufacturers to engage in the truthful promotion of off-label uses  
5 for drugs, biological products, and devices; prohibiting certain persons from taking  
6 certain enforcement and disciplinary action against a pharmaceutical manufacturer,  
7 representative of a pharmaceutical manufacturer, or health care provider for  
8 engaging in a truthful promotion of an off-label use of a drug, biological product, or  
9 device; and generally relating to the off-label promotion of drugs, biological products,  
10 and devices.

11 BY adding to  
12 Article – Health – General  
13 Section 21–218.1  
14 Annotated Code of Maryland  
15 (2023 Replacement Volume)

16 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,  
17 That the Laws of Maryland read as follows:

18 **Article – Health – General**

19 **21–218.1.**

20 **(A) IN THIS SECTION, “OFF-LABEL” MEANS THE USE OF A DRUG,**  
21 **BIOLOGICAL PRODUCT, OR DEVICE FOR A TREATMENT OTHER THAN THOSE**  
22 **TREATMENTS STATED IN THE LABELING APPROVED BY THE FEDERAL FOOD AND**  
23 **DRUG ADMINISTRATION.**

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1           **(B) A PHARMACEUTICAL MANUFACTURER AND ANY REPRESENTATIVE OF A**  
2 **PHARMACEUTICAL MANUFACTURER MAY ENGAGE IN A TRUTHFUL PROMOTION OF**  
3 **AN OFF-LABEL USE OF A DRUG, BIOLOGICAL PRODUCT, OR DEVICE.**

4           **(C) NOTWITHSTANDING ANY OTHER STATE LAW OR REGULATION:**

5           **(1) AN OFFICIAL, EMPLOYEE, OR AGENT OF THE STATE MAY NOT**  
6 **ENFORCE OR APPLY A STATE LAW OR REGULATION TO OR OTHERWISE PROSECUTE**  
7 **A PHARMACEUTICAL MANUFACTURER, OR REPRESENTATIVE OF A**  
8 **PHARMACEUTICAL MANUFACTURER, FOR ENGAGING IN A TRUTHFUL PROMOTION**  
9 **OF AN OFF-LABEL USE OF A DRUG, BIOLOGICAL PRODUCT, OR DEVICE; AND**

10           **(2) A REGULATORY UNIT, AGENCY, COMMISSION, BOARD, OR OTHER**  
11 **INSTRUMENTALITY OF THE STATE MAY NOT TAKE DISCIPLINARY ACTION,**  
12 **INCLUDING REVOKING, SUSPENDING, OR FAILING TO RENEW A LICENSE, AGAINST**  
13 **ANY OF THE FOLLOWING SOLELY FOR ENGAGING IN A TRUTHFUL PROMOTION OF AN**  
14 **OFF-LABEL USE OF A DRUG, BIOLOGICAL PRODUCT, OR DEVICE:**

15                   **(I) A PHARMACEUTICAL MANUFACTURER;**

16                   **(II) A REPRESENTATIVE OF A PHARMACEUTICAL**  
17 **MANUFACTURER; OR**

18                   **(III) A HEALTH CARE PROVIDER, AS DEFINED IN § 4-301 OF THIS**  
19 **ARTICLE.**

20           **(D) THE STATE OR A POLITICAL SUBDIVISION OF THE STATE MAY NOT USE**  
21 **PERSONNEL OR FINANCIAL RESOURCES TO ENFORCE OR COOPERATE WITH**  
22 **FEDERAL ATTEMPTS TO ENFORCE OR APPLY 21 U.S.C. § 331 OR § 352 AGAINST OR**  
23 **OTHERWISE PROSECUTE A PHARMACEUTICAL MANUFACTURER, OR**  
24 **REPRESENTATIVE OF A PHARMACEUTICAL MANUFACTURER, SOLELY FOR**  
25 **ENGAGING IN A TRUTHFUL PROMOTION OF AN OFF-LABEL USE OF A DRUG,**  
26 **BIOLOGICAL PRODUCT, OR DEVICE.**

27           **(E) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE A CARRIER, AS**  
28 **DEFINED IN § 15-10A-01 OF THE INSURANCE ARTICLE, OR ANY OTHER PAYOR OF**  
29 **HEALTH CARE SERVICES TO PROVIDE COVERAGE FOR THE COST OF ANY OFF-LABEL**  
30 **TREATMENT.**

31           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
32 October 1, 2024.