

HOUSE BILL 1477

J2

9lr0003

By: **Chair, Health and Government Operations Committee (By Request – Departmental – Health and Mental Hygiene)**

Introduced and read first time: March 2, 2009

Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

2 **Health – Pharmaceutical Manufacturer Advertising and Gifts to Health Care**
3 **Providers – Reports**

4 FOR the purpose of requiring pharmaceutical manufacturers to report to the Secretary
5 of Health and Mental Hygiene on the costs of marketing and advertising
6 prescription drugs in the State; requiring pharmaceutical manufacturers to
7 report to the Secretary on certain gifts or other economic benefits provided to
8 health care providers in the State; authorizing the Department to adopt certain
9 regulations; defining certain terms; and generally relating to reports.

10 BY adding to
11 Article – Health – General
12 Section 21–228
13 Annotated Code of Maryland
14 (2005 Replacement Volume and 2008 Supplement)

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

17 **Article – Health – General**

18 **21–228.**

19 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
20 MEANINGS INDICATED.

21 (2) “AUTHORIZED PRESCRIBER” MEANS A LICENSED PHYSICIAN,
22 CERTIFIED NURSE PRACTITIONER TO THE EXTENT PERMITTED UNDER § 8–508

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 OF THE HEALTH OCCUPATIONS ARTICLE, OR OTHER INDIVIDUAL AUTHORIZED
2 BY LAW TO PRESCRIBE DRUGS.

3 (3) (I) "MANUFACTURER" MEANS A MANUFACTURER OF
4 PRESCRIPTION DRUGS AS DEFINED IN 42 U.S.C. § 1396R-8(K)(5).

5 (II) "MANUFACTURER" INCLUDES A SUBSIDIARY OR
6 AFFILIATE OF A MANUFACTURER.

7 (4) "TRADE SECRET" MEANS INFORMATION AS DEFINED IN
8 § 11-1201(E) OF THE COMMERCIAL LAW ARTICLE.

9 (B) (1) EACH MANUFACTURER THAT OPERATES IN THE STATE SHALL
10 DISCLOSE TO THE SECRETARY THE COSTS OF MARKETING ITS PRESCRIPTION
11 DRUGS IN THE STATE.

12 (2) EACH MANUFACTURER'S DISCLOSURES SHALL CONTAIN THE
13 FOLLOWING INFORMATION:

14 (I) ALL COSTS ASSOCIATED WITH MARKETING,
15 ADVERTISING, AND DIRECT PROMOTION OF PRESCRIPTION DRUGS THROUGH
16 RADIO, TELEVISION, MAGAZINES, NEWSPAPERS, DIRECT MAIL, AND TELEPHONE
17 COMMUNICATIONS; AND

18 (II) ALL COSTS ASSOCIATED WITH EDUCATIONAL
19 PROGRAMS, SEMINARS, ENTERTAINMENT, TRIPS, REMUNERATION FOR
20 PROMOTING OR PARTICIPATING IN INFORMATIONAL SESSIONS REGARDING
21 PRESCRIPTION DRUGS, AND PROMOTIONAL GIFTS IN EXCESS OF \$25.

22 (3) (I) MANUFACTURERS SHALL COMPLETE THE REQUIRED
23 DISCLOSURES ON A FORM AND IN A MANNER PRESCRIBED BY THE SECRETARY.

24 (II) THE INITIAL DISCLOSURES SHALL BE MADE ON OR
25 BEFORE JANUARY 1, 2010, FOR THE 12-MONTH PERIOD ENDING JUNE 30, 2009.

26 (III) ON OR BEFORE JUNE 1 OF EACH YEAR, THE SECRETARY
27 SHALL SUBMIT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE
28 STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY, A REPORT ON THE
29 DISCLOSURES MADE UNDER THIS SECTION.

30 (C) (1) EVERY MANUFACTURER THAT OPERATES IN THE STATE
31 SHALL DISCLOSE TO THE SECRETARY THE VALUE, NATURE, AND PURPOSE OF
32 ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT PROVIDED
33 IN CONNECTION WITH DETAILING, PROMOTIONAL, OR OTHER MARKETING

1 ACTIVITIES IN THE STATE BY THE MANUFACTURER, EITHER DIRECTLY OR
2 THROUGH ITS REPRESENTATIVES, TO AN AUTHORIZED PRESCRIBER.

3 (2) (I) MANUFACTURERS SHALL COMPLETE THE REQUIRED
4 DISCLOSURES ON A FORM AND IN A MANNER PRESCRIBED BY THE SECRETARY.

5 (II) THE INITIAL DISCLOSURES SHALL BE MADE ON OR
6 BEFORE JANUARY 1, 2010, FOR THE 12-MONTH PERIOD ENDING JUNE 30, 2009.

7 (III) ON OR BEFORE JUNE 1 OF EACH YEAR, THE SECRETARY
8 SHALL SUBMIT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE
9 STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY, A REPORT ON THE
10 DISCLOSURES MADE UNDER THIS SECTION.

11 (3) EACH MANUFACTURER SUBJECT TO THE PROVISIONS OF THIS
12 SECTION, ON OR BEFORE OCTOBER 1, 2009, AND ANNUALLY THEREAFTER,
13 SHALL DISCLOSE TO THE SECRETARY THE NAME AND ADDRESS OF THE
14 INDIVIDUAL RESPONSIBLE FOR THE MANUFACTURER'S COMPLIANCE WITH THE
15 PROVISIONS OF THIS SECTION.

16 (4) (I) THE SECRETARY SHALL KEEP CONFIDENTIAL ALL
17 TRADE SECRET INFORMATION.

18 (II) THE DISCLOSURE FORM PRESCRIBED BY THE
19 SECRETARY SHALL PERMIT THE COMPANY TO IDENTIFY ANY INFORMATION
20 THAT IS A TRADE SECRET.

21 (5) THE FOLLOWING SHALL BE EXEMPT FROM DISCLOSURE:

22 (I) THE PAYMENT OF REASONABLE COMPENSATION AND
23 REIMBURSEMENT OF EXPENSES IN CONNECTION WITH BONA FIDE CLINICAL
24 TRIALS;

25 (II) ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER
26 ECONOMIC BENEFIT THAT HAS A CASH VALUE OF \$25 OR LESS; AND

27 (III) SCHOLARSHIPS OR OTHER SUPPORT FOR MEDICAL
28 STUDENTS, RESIDENTS, AND FELLOWS TO ATTEND A SIGNIFICANT
29 EDUCATIONAL, SCIENTIFIC, OR POLICY-MAKING CONFERENCE OF A NATIONAL,
30 REGIONAL, OR SPECIALTY MEDICAL OR OTHER PROFESSIONAL ASSOCIATION IF
31 THE RECIPIENT OF THE SCHOLARSHIP OR OTHER SUPPORT IS SELECTED BY THE
32 ASSOCIATION.

1 (D) (1) THE ATTORNEY GENERAL OF MARYLAND MAY BRING AN
2 ACTION IN THE CIRCUIT COURT FOR INJUNCTIVE RELIEF, COSTS, AND
3 ATTORNEY'S FEES, AND TO IMPOSE ON A MANUFACTURER THAT FAILS TO
4 DISCLOSE AS REQUIRED BY SUBSECTIONS (B) AND (C) OF THIS SECTION, A CIVIL
5 PENALTY NOT EXCEEDING \$10,000 PER VIOLATION.

6 (2) EACH UNLAWFUL FAILURE TO DISCLOSE SHALL CONSTITUTE
7 A SEPARATE VIOLATION.

8 (E) THE SECRETARY SHALL ADOPT REGULATIONS TO CARRY OUT THIS
9 SECTION.

10 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
11 October 1, 2009.