
By: **Delegates Boutin, Amedori, Bromwell, Goldwater, Hogan, McComas,
Oaks, Smigiel, F. Turner, and Weldon**

Introduced and read first time: February 2, 2004

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Pharmaceuticals - Marketing - Disclosure and Registration**

3 FOR the purpose of requiring a pharmaceutical manufacturing company to make a
4 certain disclosure to the Board of Pharmacy (Board) of certain marketing
5 information on or before a certain date each year; requiring the Board and the
6 Office of the Attorney General (Office) to keep confidential certain information;
7 requiring the Board to provide the Office with complete access to certain
8 information; requiring the Office to make a certain annual report to the
9 Governor and the General Assembly; requiring a pharmaceutical manufacturing
10 company to disclose the name and address of certain pharmaceutical marketers
11 to the Board each year; requiring an individual to register with the Board before
12 practicing pharmaceutical marketing in the State; requiring the Board to collect
13 a certain registration fee to be valid for a certain term; requiring the Board to
14 pay certain registration fees to the Comptroller; requiring the Comptroller to
15 distribute certain fees to the State Board of Pharmacy Fund; requiring a
16 pharmaceutical marketer, upon registration with the Board, to certify adherence
17 to a certain code of ethics; authorizing the Office to bring a certain cause of
18 action for certain violations; requiring the Board, in consultation with the
19 Office, to develop certain regulations by a certain date; defining certain terms;
20 and generally relating to disclosure and registration requirements for
21 pharmaceutical manufacturing companies and pharmaceutical marketers.

22 BY adding to

23 Article - Health Occupations

24 Section 12-6B-01 through 12-6B-06, inclusive, to be under the new subtitle

25 "Subtitle 6B. Pharmaceutical Marketers and Pharmaceutical

26 Manufacturing Companies"

27 Annotated Code of Maryland

28 (2000 Replacement Volume and 2003 Supplement)

29 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

30 MARYLAND, That the Laws of Maryland read as follows:

1 **Article - Health Occupations**2 **SUBTITLE 6B. PHARMACEUTICAL MARKETERS AND PHARMACEUTICAL**
3 **MANUFACTURING COMPANIES.**

4 12-6B-01.

5 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
6 INDICATED.7 (B) (1) "PHARMACEUTICAL MARKETER" MEANS AN INDIVIDUAL WHO,
8 WHILE EMPLOYED BY OR UNDER CONTRACT TO REPRESENT A PHARMACEUTICAL
9 MANUFACTURING COMPANY, ENGAGES IN PHARMACEUTICAL DETAILING,
10 PROMOTIONAL ACTIVITIES, OR OTHER MARKETING OF PRESCRIPTION DRUGS IN
11 THIS STATE TO ANY:

12 (I) PHYSICIAN;

13 (II) HOSPITAL;

14 (III) NURSING HOME;

15 (IV) PHARMACIST;

16 (V) HEALTH BENEFIT PLAN ADMINISTRATOR; OR

17 (VI) INDIVIDUAL AUTHORIZED TO PRESCRIBE, DISPENSE, OR
18 PURCHASE PRESCRIPTION DRUGS.19 (2) "PHARMACEUTICAL MARKETER" DOES NOT INCLUDE A WHOLESALE
20 DRUG DISTRIBUTOR OR REPRESENTATIVE OF THE DISTRIBUTOR WHO PROMOTES OR
21 OTHERWISE MARKETS THE SERVICES OF THE WHOLESALE DRUG DISTRIBUTOR IN
22 CONNECTION WITH A PRESCRIPTION DRUG.23 (C) (1) "PHARMACEUTICAL MANUFACTURING COMPANY" MEANS ANY
24 ENTITY ENGAGED IN THE:25 (I) PRODUCTION, PREPARATION, PROPAGATION, COMPOUNDING,
26 CONVERSION, OR PROCESSING OF PRESCRIPTION DRUGS, EITHER DIRECTLY OR
27 INDIRECTLY BY EXTRACTION FROM SUBSTANCES OF NATURAL ORIGIN, OR
28 INDEPENDENTLY BY MEANS OF CHEMICAL SYNTHESIS, OR BY A COMBINATION OF
29 EXTRACTION AND CHEMICAL SYNTHESIS; OR30 (II) PACKAGING, REPACKAGING, LABELING, RELABELING, OR
31 DISTRIBUTION OF PRESCRIPTION DRUGS.32 (2) "PHARMACEUTICAL MANUFACTURING COMPANY" DOES NOT
33 INCLUDE A WHOLESALE DRUG DISTRIBUTOR OR PHARMACIST LICENSED UNDER
34 THIS TITLE.

1 12-6B-02.

2 (A) ON OR BEFORE JANUARY 1 OF EACH YEAR, EACH PHARMACEUTICAL
3 MANUFACTURING COMPANY SHALL DISCLOSE TO THE BOARD THE VALUE, NATURE,
4 AND PURPOSE OF ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC
5 BENEFIT PROVIDED IN CONNECTION WITH DETAILING, PROMOTIONAL, OR OTHER
6 MARKETING ACTIVITIES BY THE COMPANY, DIRECTLY OR THROUGH ITS
7 PHARMACEUTICAL MARKETERS, TO ANY:

8 (1) PHYSICIAN;

9 (2) HOSPITAL;

10 (3) NURSING HOME;

11 (4) PHARMACIST;

12 (5) HEALTH BENEFIT PLAN ADMINISTRATOR; OR

13 (6) INDIVIDUAL IN THE STATE AUTHORIZED TO PRESCRIBE, DISPENSE,
14 OR PURCHASE PRESCRIPTION DRUGS.

15 (B) (1) THE DISCLOSURE REQUIRED UNDER SUBSECTION (A) OF THIS
16 SECTION SHALL:

17 (I) BE MADE ON A FORM AND IN A MANNER PRESCRIBED BY THE
18 BOARD; AND

19 (II) PERMIT A PHARMACEUTICAL MANUFACTURING COMPANY TO
20 IDENTIFY ANY INFORMATION THAT IS A TRADE SECRET.

21 (2) THE BOARD AND THE OFFICE OF THE ATTORNEY GENERAL SHALL
22 KEEP CONFIDENTIAL ALL INFORMATION THAT IS IDENTIFIED ON THE DISCLOSURE
23 AS A TRADE SECRET.

24 (C) THE FOLLOWING INFORMATION SHALL BE EXEMPT FROM THE
25 DISCLOSURE REQUIRED UNDER SUBSECTION (A) OF THIS SECTION:

26 (1) FREE SAMPLES OF PRESCRIPTION DRUGS INTENDED FOR
27 DISTRIBUTION TO PATIENTS;

28 (2) THE PAYMENT OF REASONABLE COMPENSATION AND
29 REIMBURSEMENT OF EXPENSES IN CONNECTION WITH APPROVED CLINICAL TRIALS
30 CONDUCTED IN CONNECTION WITH A RESEARCH STUDY DESIGNED TO ANSWER
31 SPECIFIC QUESTIONS ABOUT VACCINES, NEW THERAPIES, OR NEW WAYS OF USING
32 UNKNOWN TREATMENTS;

33 (3) ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT
34 THAT HAS A VALUE OF LESS THAN \$25; AND

1 (4) SCHOLARSHIP OR OTHER SUPPORT FOR MEDICAL STUDENTS,
2 RESIDENTS, AND FELLOWS TO ATTEND A SIGNIFICANT EDUCATIONAL, SCIENTIFIC,
3 OR POLICY-MAKING CONFERENCE OF A NATIONAL, REGIONAL, OR SPECIALTY
4 MEDICAL OR OTHER PROFESSIONAL ASSOCIATION IF THE RECIPIENT OF THE
5 SCHOLARSHIP OR OTHER SUPPORT IS SELECTED BY THE PROFESSIONAL
6 ASSOCIATION.

7 (D) THE BOARD SHALL PROVIDE THE OFFICE OF THE ATTORNEY GENERAL
8 WITH COMPLETE ACCESS TO THE INFORMATION THAT IS REQUIRED TO BE
9 DISCLOSED UNDER THIS SECTION.

10 (E) ON OR BEFORE JULY 1 OF EACH YEAR, THE OFFICE OF THE ATTORNEY
11 GENERAL SHALL REPORT ON THE DISCLOSURES MADE UNDER THIS SECTION TO THE
12 GOVERNOR AND, SUBJECT TO § 2-1246 OF THE STATE GOVERNMENT ARTICLE, TO THE
13 GENERAL ASSEMBLY.

14 12-6B-03.

15 EACH PHARMACEUTICAL MANUFACTURING COMPANY SUBJECT TO THE
16 PROVISIONS OF THIS SUBTITLE SHALL DISCLOSE TO THE BOARD, ON OR BEFORE
17 JANUARY 1 OF EACH YEAR, THE NAME AND ADDRESS OF ANY PHARMACEUTICAL
18 MARKETER RESPONSIBLE FOR THE PHARMACEUTICAL MARKETING COMPANY'S
19 COMPLIANCE WITH THE PROVISIONS OF THIS SUBTITLE.

20 12-6B-04.

21 (A) AN INDIVIDUAL SHALL REGISTER WITH THE BOARD TO PRACTICE AS A
22 PHARMACEUTICAL MARKETER BEFORE THE INDIVIDUAL MAY PRACTICE AS A
23 PHARMACEUTICAL MARKETER IN THE STATE.

24 (B) (1) THE BOARD SHALL COLLECT A REGISTRATION FEE OF \$400.

25 (2) THE FEE COLLECTED BY THE BOARD SHALL BE VALID FOR A 2-YEAR
26 TERM.

27 (3) THE BOARD SHALL PAY ALL FEES COLLECTED UNDER THE
28 PROVISIONS OF THIS SECTION TO THE COMPTROLLER OF THE STATE.

29 (4) THE COMPTROLLER SHALL DISTRIBUTE THE FEES TO THE STATE
30 BOARD OF PHARMACY FUND ESTABLISHED UNDER § 12-206 OF THIS TITLE.

31 (C) UPON REGISTERING WITH THE BOARD, EACH PHARMACEUTICAL
32 MARKETER SHALL CERTIFY THAT THE PHARMACEUTICAL MARKETER WILL ADHERE
33 TO THE "PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA CODE ON
34 INTERACTIONS WITH HEALTHCARE PROFESSIONALS" AND ANY SUBSEQUENT
35 REVISION OF THAT CODE.

1 12-6B-05.

2 (A) IF A PHARMACEUTICAL MANUFACTURING COMPANY FAILS TO DISCLOSE
3 THE INFORMATION REQUIRED BY § 12-6B-02 OF THIS SUBTITLE, THE OFFICE OF THE
4 ATTORNEY GENERAL MAY:

5 (1) BRING AN ACTION FOR INJUNCTIVE RELIEF, INCLUDING COSTS AND
6 ATTORNEYS' FEES AGAINST THE COMPANY; AND

7 (2) IMPOSE A CIVIL PENALTY AGAINST THE COMPANY OF NOT MORE
8 THAN \$10,000 FOR EACH VIOLATION.

9 (B) EACH UNLAWFUL FAILURE TO DISCLOSE THE INFORMATION REQUIRED
10 BY § 12-6B-02 OF THIS SUBTITLE SHALL CONSTITUTE A SEPARATE VIOLATION.

11 12-6B-06.

12 BY DECEMBER 1, 2004, THE BOARD, IN CONSULTATION WITH THE OFFICE OF
13 THE ATTORNEY GENERAL, SHALL ADOPT REGULATIONS TO IMPLEMENT THE
14 PROVISIONS OF THIS SUBTITLE.

15 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
16 July 1, 2004.