Unofficial Copy 2003 Regular Session
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By: **Delegate Bromwell**
Introduced and read first time: January 29, 2003
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Pharmaceutical Manufacturing Companies - Reporting Requirements

FOR the purpose of requiring certain pharmaceutical manufacturing companies to submit to the Maryland Health Care Commission on a certain form certain information relating to the detailing, promotional, and marketing activities of certain pharmaceutical manufacturing companies; exempting certain pharmaceutical manufacturing companies from certain reporting requirements under certain circumstances; requiring the Commission to compile a certain report by a certain date for distribution to the Governor and the General Assembly; requiring the Commission to keep certain information concerning trade secrets confidential unless required to disclose by a certain court; requiring certain pharmaceutical manufacturing companies to identify certain information on a certain form; authorizing the Commission to impose certain fines for certain violations; defining certain terms; and generally relating to reporting requirements for pharmaceutical manufacturing companies.

BY adding to
Article - Health - General
Section 19-142 and 19-143 to be under the new part "Part IV. Pharmaceutical Marketing Data Collection"
Annotated Code of Maryland
(2000 Replacement Volume and 2002 Supplement)

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

Article - Health - General

PART IV. PHARMACEUTICAL MARKETING DATA COLLECTION.

19-142.

(A) IN THIS PART IV OF THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) (1) "APPROVED CLINICAL TRIAL" MEANS ANY RESEARCH THAT:

(I) IS APPROVED BY:

1. THE UNITED STATES FOOD AND DRUG ADMINISTRATION; OR

2. A DULY CONSTITUTED INTERNAL REVIEW BOARD THAT HAS REVIEWED AND EVALUATED THE CLINICAL TRIAL IN ACCORDANCE WITH:

A. THE HUMAN SUBJECT PROTECTION STANDARDS AS DESCRIBED IN 45 CFR PART 46; OR

B. THE FEDERAL FOOD AND DRUG ADMINISTRATION REGULATIONS GOVERNING THE PROTECTION OF HUMAN SUBJECTS AS DESCRIBED IN 21 CFR PART 50;

(II) INVOLVES HUMAN SUBJECTS; AND

(III) IS DESIGNED TO:

1. TEST THE SAFETY OR EFFICACY OF AN INTERVENTION TO DIAGNOSE, TREAT, OR PREVENT DISEASE; AND

2. EXPOSE RESEARCH SUBJECTS TO TREATMENTS THAT THEY WOULD NOT HAVE RECEIVED FROM THEIR OWN HEALTH CARE PROVIDER AS PART OF THEIR CLINICAL CARE.

(2) "APPROVED CLINICAL TRIAL" INCLUDES ANY RESEARCH DESCRIBED IN PARAGRAPH (1) OF THIS SUBSECTION THE RESULTS OF WHICH CAN BE:

(I) PUBLISHED BY THE INVESTIGATOR; AND

(II) CONSIDERED OF INTEREST TO SCIENTISTS OR MEDICAL PRACTITIONERS WORKING IN THE PARTICULAR FIELD OF INQUIRY.

(C) (1) "PHARMACEUTICAL MANUFACTURING COMPANY" MEANS ANY ENTITY THAT IS ENGAGED IN THE PRODUCTION, PREPARATION, PROPAGATION, COMPOUNDING, CONVERSION, OR PROCESSING OF PHARMACEUTICAL PRODUCTS:

(I) DIRECTLY OR INDIRECTLY BY EXTRACTION FROM SUBSTANCES OF NATURAL ORIGIN;

(II) INDEPENDENTLY BY MEANS OF CHEMICAL SYNTHESIS; OR

(III) BY A COMBINATION OF EXTRACTION AND CHEMICAL SYNTHESIS.

(2) "PHARMACEUTICAL MANUFACTURING COMPANY" INCLUDES ANY ENTITY ENGAGED IN THE PACKAGING, REPACKAGING, LABELING, RELABELING, OR DISTRIBUTION OF PHARMACEUTICAL PRODUCTS.

(3) "PHARMACEUTICAL MANUFACTURING COMPANY" DOES NOT INCLUDE A WHOLESALE DRUG DISTRIBUTOR OR PHARMACIST LICENSED UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.

(D) (1) "PHARMACEUTICAL MARKETER" MEANS A PERSON WHO, WHILE EMPLOYED BY OR UNDER CONTRACT TO REPRESENT A PHARMACEUTICAL MANUFACTURING COMPANY, ENGAGES IN PHARMACEUTICAL:

(I) DETAILING;

(II) PROMOTIONAL ACTIVITIES; OR

(III) MARKETING TO ANY PHYSICIAN, NURSE PRACTITIONER, PHARMACIST, HOSPITAL, NURSING HOME, OR OTHER PERSON AUTHORIZED TO PRESCRIBE, DISPENSE, OR PURCHASE FOR RESALE OR DISTRIBUTION ANY PHARMACEUTICAL PRODUCT.

(2) "PHARMACEUTICAL MARKETER" DOES NOT INCLUDE:

(I) A WHOLESALE DRUG DISTRIBUTOR; OR

(II) THE REPRESENTATIVE OF A WHOLESALE DRUG DISTRIBUTOR WHO PROMOTES OR MARKETS THE SERVICES OF THE WHOLESALE DRUG DISTRIBUTOR IN CONNECTION WITH A PHARMACEUTICAL PRODUCT.

(E) "PHARMACEUTICAL PRODUCT" MEANS A DRUG OR MEDICINE THAT MAY BE PRESCRIBED BY AN AUTHORIZED PRESCRIBER.

(F) "UNRESTRICTED GRANT" MEANS ANY GIFT, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT TO AN EDUCATIONAL INSTITUTION, PROFESSIONAL ASSOCIATION, HEALTH CARE FACILITY, OR GOVERNMENTAL ENTITY THAT DOES NOT IMPOSE ANY RESTRICTIONS ON THE USE OF THE GRANT.

19-143.

(A) (1) ON OR BEFORE JANUARY 1 OF EACH YEAR, EACH PHARMACEUTICAL MANUFACTURING COMPANY DOING BUSINESS IN THE STATE SHALL SUBMIT TO THE COMMISSION, ON THE FORM THE COMMISSION REQUIRES, A REPORT ON THE VALUE, NATURE, AND PURPOSE OF ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT PROVIDED BY A PHARMACEUTICAL MANUFACTURING COMPANY, DIRECTLY OR THROUGH ITS PHARMACEUTICAL MARKETERS, IN CONNECTION WITH:

(I) DETAILING;

(II) PROMOTIONAL ACTIVITIES; OR

(III) MARKETING TO ANY PHYSICIAN, NURSE PRACTITIONER, PHARMACIST, HOSPITAL, NURSING HOME, OR OTHER PERSON AUTHORIZED TO

PRESCRIBE, DISPENSE, OR PURCHASE FOR RESALE OR DISTRIBUTION ANY PHARMACEUTICAL PRODUCT.

(2) THE FOLLOWING ARE EXEMPT FROM THE REPORTING REQUIREMENTS UNDER PARAGRAPH (1) OF THIS SUBSECTION:

(I) FREE SAMPLES OF A PHARMACEUTICAL PRODUCT;

(II) THE PAYMENT OF REASONABLE COMPENSATION AND REIMBURSEMENT OF EXPENSES IN CONNECTION WITH CLINICAL TRIALS;

(III) ANY GIFT, FEE, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT OF VALUE THAT IS LESS THAN $25;

(IV) ANY SCHOLARSHIP OR OTHER SUPPORT FOR MEDICAL STUDENTS, RESIDENTS, OR FELLOWS TO ATTEND AN EDUCATIONAL, SCIENTIFIC, OR POLICYMAKING CONFERENCE; AND

(V) ANY UNRESTRICTED GRANTS FOR CONTINUING MEDICAL EDUCATION.

(B) ON OR BEFORE MARCH 1 OF EACH YEAR, THE COMMISSION SHALL COMPILE THE REPORTS REQUIRED UNDER SUBSECTION (A) OF THIS SECTION AND ISSUE AN ANNUAL PHARMACEUTICAL MARKETING REPORT TO THE GOVERNOR AND, SUBJECT TO § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY.

(C) (1) UNLESS DISCLOSURE IS REQUIRED BY A COURT OF COMPETENT JURISDICTION IN A LEGAL PROCEEDING, THE COMMISSION SHALL KEEP CONFIDENTIAL AND MAY NOT DISCLOSE ANY INFORMATION CONCERNING TRADE SECRETS RECEIVED UNDER SUBSECTION (A) OF THIS SECTION.

(2) A PHARMACEUTICAL MANUFACTURING COMPANY SUBJECT TO THE REPORTING REQUIREMENTS UNDER SUBSECTION (A) OF THIS SECTION SHALL IDENTIFY, ON THE FORM REQUIRED BY THE COMMISSION, ANY INFORMATION THAT IT CONSIDERS A TRADE SECRET.

(D) IF THE COMMISSION FINDS THAT A PHARMACEUTICAL MANUFACTURING COMPANY HAS VIOLATED THIS SECTION, THE COMMISSION MAY IMPOSE A FINE NOT EXCEEDING $10,000 FOR EACH VIOLATION.

SECTION 2. AND BE IT FURTHER ENACTED, That the initial reporting period for the report required under § 19-143(a)(1) of the Health - General Article as enacted by this Act shall be made on or before January 1, 2005 and shall cover the 12-month period ending June 30, 2004, and the initial report issued by the Maryland Health Care Commission under § 19-143(b) of the Health - General Article as enacted by this Act shall be made on or before March 1, 2005.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2003.