

HOUSE BILL NO. 563

INTRODUCED BY DOWELL, ELLIOTT, CLARK, WANZENRIED, JENT, WHEAT, JACOBSON, ROBERTS,
RASER, JUNEAU, WILSON, JOPEK, TESTER, GROESBECK, CAMPBELL

BY REQUEST OF THE GOVERNOR

A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING PHARMACEUTICAL MANUFACTURING COMPANIES
TO DISCLOSE CERTAIN MARKETING ACTIVITIES TO THE OFFICE OF THE ATTORNEY GENERAL;
PROVIDING EXCEPTIONS; PROVIDING FOR ENFORCEMENT; AND PROVIDING DEFINITIONS."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. Section 1. Pharmaceutical manufacturing company disclosure -- enforcement

-- definitions. (1) On or before January 1 of each year, each pharmaceutical manufacturing company shall disclose to the office of the attorney general the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or other individual authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure must include the name of the recipient. Disclosure must be made on a form and in a manner prescribed by rule by the office of the attorney general and must require pharmaceutical manufacturing companies to report the value, nature, and purpose of all gift expenditures according to specific categories. The office of the attorney general shall report on the disclosures made under this section to the legislature and the governor on or before March 1 of each year.

(2) In October of each year, a pharmaceutical manufacturing company that is subject to this section shall also disclose to the office of the attorney general the name and address of the individual responsible for the company's compliance with this section.

(3) The following are exempt from disclosure under this section:

(a) free samples of prescription drugs, SUPPLIES, AND EDUCATIONAL MATERIALS intended to be distributed to patients;

(b) the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials;



- 1 (c) a gift, fee, payment, subsidy, or other economic benefit with a value of less than \$25;
- 2 (d) scholarships or other support for medical students, residents, and fellows to attend a significant
3 educational, scientific, or policymaking conference of a national, regional, or specialty medical or other
4 professional association if the recipients of the scholarships or other support are selected by the association;
- 5 (e) unrestricted grants for continuing medical education programs; or
- 6 (f) prescription drug rebates and discounts.
- 7 (4) The attorney general may bring an action in the district court of the first judicial district, Lewis and
8 Clark County, for injunctive relief, costs, and attorney fees and to impose on a pharmaceutical manufacturing
9 company that fails to make the disclosure required by subsection (1) a civil penalty of no more than ~~\$10,000~~
10 \$2,000 for each violation. Each unlawful failure to make the disclosure is a separate violation.
- 11 (5) As used in this section, the following definitions apply:
- 12 (a) "Approved clinical trial" means a clinical trial that has been approved by the U.S. food and drug
13 administration or that has been approved by an institutional review board, as constituted pursuant to the
14 regulations of the food and drug administration and the U.S. department of health and human services, after
15 reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 CFR, part
16 50, 45 CFR, part 46, or an equivalent set of standards of another federal agency.
- 17 (b) "Bona fide clinical trial" means an approved clinical trial that constitutes research, as that term is
18 defined in 45 CFR, 46.102, when the results of the research can be published freely by the investigator and can
19 reasonably be considered to be of interest to scientists or medical practitioners working in the particular field of
20 inquiry.
- 21 (c) "Clinical trial" means a study assessing the safety or efficacy of drugs administered alone or in
22 combination with other drugs or other therapies or assessing the relative safety or efficacy of drugs in
23 comparison with other drugs or other therapies.
- 24 (d) (i) "Pharmaceutical marketer" means a person who, while employed by or under contract to
25 represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities,
26 or other marketing of prescription drugs in this state to a physician, hospital, nursing home, pharmacist, health
27 benefit plan administrator, or other individual authorized to prescribe, dispense, or purchase prescription drugs.
- 28 (ii) The term does not include a wholesale drug distributor or the distributor's representative who
29 promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription
30 drug.

1 (e) (i) "Pharmaceutical manufacturing company" means an entity that is engaged in the production,
2 preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or
3 indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by
4 a combination of extraction and chemical synthesis, or an entity engaged in the packaging, repackaging,
5 labeling, relabeling, or distribution of prescription drugs.

6 (ii) The term does not include a wholesale drug distributor or pharmacist licensed under Title 37.

7 (f) "Unrestricted grant" means a gift, payment, subsidy, or other economic benefit to an educational
8 institution, professional association, health care facility, or governmental entity that does not impose restrictions
9 on the use of the grant, such as favorable treatment of a certain product or an ability of the pharmaceutical
10 marketer to control or influence the planning, content, or execution of the educational activity.

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12 **NEW SECTION. Section 2. Codification instruction.** [Section 1] is intended to be codified as an
13 integral part of Title 44, chapter 4, and the provisions of Title 44, chapter 4, apply to [section 1].

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