S.48

Introduced by Senators Shumlin, Mullin, Choate, Ashe, Ayer, Bartlett, Brock, Campbell, Carris, Cummings, Doyle, Flanagan, Giard, Hartwell, Illuzzi, Kitchel, Kittell, Lyons, MacDonald, Mazza, McCormack, Miller, Nitka, Racine, Scott, Sears, Snelling, Starr and White

Referred to Committee on

Date:

Subject: Health; prescription drugs; marketing; gift; ban; disclosure

Statement of purpose: This bill proposes to minimize the costs of marketing prescription drugs, medical devices, and biological products to health care professionals by eliminating most gifts and disclosing many of those allowed.

An act relating to marketing of prescribed products

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 4631(b) is amended to read:

(b) As used in this section:

* * *

(3) "Health care professional" shall have the same meaning as health care provider in section 9402 of this title.

* * *

Sec. 2. 18 V.S.A. § 4631a is added to read:

§ 4631a. GIFTS BY MARKETERS OF PRESCRIBED PRODUCTS

(a) As used in this section:

(1) "Approved clinical trial" means a clinical trial that has been approved by the U.S. Food and Drug Administration (FDA) or has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.

(2) "Bona fide clinical trial" means an approved clinical trial that constitutes "research" as that term is defined in 45 C.F.R. § 46.102 when the results of the research can be published freely by the investigator and reasonably can be considered to be of interest to scientists or medical health care professionals working in the particular field of inquiry.

(3) "Clinical trial" means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies, or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.

(4) "Gift" means a payment, food, entertainment, travel, honorarium, subscription, advance, service, product sample, or anything else of value provided to a health care professional.

(5) "Health care professional" means:

(A) a person who prescribes drugs or devices as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262 and who is licensed by this state to provide or is otherwise lawfully providing health care in this state; or

(B) a partnership or corporation made up of the persons described in subdivision (A) of this subdivision (5); or

(C) an officer, employee, agent, or contractor of a person described in subdivision (A) of this subdivision (5) who is acting in the course and scope of employment, agency, or contract related to or supportive of the provision of health care to individuals.

(6) "Labeler" means a person or entity that:

(A) receives prescribed products from a manufacturer or wholesaler;

(B) repackages the prescribed products for later resale; and

(C) has a labeler code from the federal Food and Drug Administration under section 207.20 of Title 21 of the Code of Federal Regulations.

(7) "Manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, processing, packaging, repacking, distributing, or labeling of prescribed products.

(8) "Marketing" shall include promotion, detailing, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, to market prescribed products to patients, or to evaluate the effectiveness of a professional pharmaceutical detailing task force. The term does not include the actions of a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(9) "Prescribed product" means a drug or device as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262.

(10) "Significant educational, scientific, or policy-making conference or seminar" means an educational, scientific, or policy-making conference or seminar that:

(A) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization; and

(B) offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

(b)(1) It is unlawful for any manufacturer or wholesale distributor of prescribed products, or any agent thereof, to offer or give any gift to a health care professional.

(2) The prohibition set forth in subdivision (1) of this subsection shall not apply to the following, of which subdivisions (A), (B), and (C) must be disclosed under section 4632 of this chapter:

(A) Payment to the sponsor of a significant educational, medical, scientific or policy-making conference or seminar, provided:

(i) the payment is not made directly to a health care professional;

(ii) funding is used solely for bona fide educational purposes; and

(iii) all activities are objective, free from industry influence, and do not promote specific products.

(B) Reasonable honoraria and payment of the reasonable expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:

(i) there is an explicit contract with specific deliverables which are restricted to scientific issues, not marketing efforts; and

(ii) the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) Compensation for the substantial professional or consulting services of a health care professional in connection with a bona fide clinical trial, provided there is an explicit contract with specific deliverables which are restricted to scientific issues, not marketing efforts.

(D) Samples of a prescribed product provided to a health care professional for free distribution to patients.

(E) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals.

(F) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(G) Prescription drug rebates and discounts.

(c) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorney's fees, and may impose on a manufacturer that violates this section a civil penalty of no more than $10,000.00 per violation. Each unlawful gift shall constitute a separate violation.

Sec. 3. 18 V.S.A. § 4632 is amended to read:

§ 4632. ~~PHARMACEUTICAL~~ DISCLOSURE OF GIFTS BY PRESCRIBED PRODUCT MARKETERS

(a)(1) Annually on or before ~~December~~ September 1 of each year, every ~~pharmaceutical manufacturing company~~ manufacturer shall disclose to the office of the attorney general the value, nature, ~~and~~ purpose, and recipient information of any gift~~, fee, payment, subsidy, or other economic benefit~~ not prohibited by section 4631a of this chapter and except as provided in subdivisions (b)(2)(D) through (G), inclusive, of that section, which is provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its ~~pharmaceutical~~ marketers, to:

(A) any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care professional, or any other person ~~in Vermont~~ authorized to prescribe, dispense, or purchase ~~prescription drugs~~ prescribed products in this state;

(B) any state-funded academic institution; or

(C) any nonprofit professional, educational, or patient organization representing health care professionals or consumers.

~~Disclosure shall include the name of the recipient. Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall 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 annually on the disclosures made under this section to the general assembly and the governor on or before April 1.~~

(2) Annually on ~~October~~ July 1, each ~~company subject to the provisions of this section~~ manufacturer also shall disclose to the office of the attorney general~~,~~ the name and address of the individual responsible for the company's compliance with the provisions of this section~~, or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section~~.

(3) ~~The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1, except that the office may disclose the information to the department of health and the office of Vermont health access for the purpose of informing and prioritizing the activities of the evidence-based education program in subchapter 2 of chapter 91 of Title 18. The department of health and the office of Vermont health access shall keep the information confidential. The disclosure form shall permit the company to identify any information that it claims is a trade secret as defined in subdivision 317(c)(9) of Title 1. In the event that the attorney general receives a request for any information designated as a trade secret, the attorney general shall promptly notify the company of such request.~~

~~Within 30 days after such notification, the company shall respond to the requester and the attorney general by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret. Any requester aggrieved by the company's response may apply to the superior court of Washington County for a declaration that the company's claim of trade secret is invalid. The attorney general shall not be made a party to the superior court proceeding. Prior to and during the pendency of the superior court proceeding, the attorney general shall keep confidential the information that has been claimed as trade secret information, except that the attorney general may provide the requested information to the court under seal.~~

~~(4) The following shall be exempt from disclosure:~~

~~(A) free samples of prescription drugs intended to be distributed to patients;~~

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

~~(C) any gift, fee, payment, subsidy or other economic benefit the value of which is less than $25.00;~~

~~(D) scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference of a national, regional, or specialty medical or other professional~~

~~association if the recipient of the scholarship or other support is selected by the association; and~~

~~(E) prescription drug rebates and discounts.~~

(A) Disclosure shall be made on a form and in a manner prescribed by the office of the attorney general and shall require manufacturers to report each gift expenditure, including:

(i) the value, nature, and purpose of each gift expenditure, according to specific categories identified by the office of the attorney general;

(ii) the name of the recipient;

(iii) the recipient's address;

(iv) the recipient's credentials;

(v) the recipient's institutional affiliation; and

(vi) the recipient's state board or DEA numbers.

(B) The office of the attorney general shall make all disclosed data publicly available and easily searchable on its website, except that the office may, by rule, identify certain disclosures that shall not be made available to the public.

(4) The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before April 1. The report shall include:

(A) Information on gifts required to be disclosed under this section, which shall be presented in both aggregate form and by selected types of health care professionals or individual health care professionals, as prioritized each year by the office, and analyzed to determine whether prescribing patterns by these health care professionals of prescribed products reimbursed by Medicaid or other state health care programs may reflect manufacturer influence.

(B) Information on violations and enforcement actions brought pursuant to this section and section 4631a of this title.

(b) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and ~~attorneys~~ attorney's fees, and to impose on a ~~pharmaceutical manufacturing company~~ manufacturer that fails to disclose as required by subsection (a) of this section a civil penalty of no more than $10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation.

~~(c) As used in this section:~~

~~(1) "Approved clinical trial" means a clinical trial that has been approved by the U.S. Food and Drug Administration (FDA) or has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or an equivalent set of standards of another federal agency.~~

~~(2) "Bona fide clinical trial" means an approved clinical trial that constitutes "research" as that term is defined in 45 C.F.R. § 46.102 when the results of the research can be published freely by the investigator and reasonably can be considered to be of interest to scientists or medical practitioners working in the particular field of inquiry.~~

~~(3) "Clinical trial" means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies, or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.~~

~~(4) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.~~

~~(5) "Pharmaceutical manufacturing company" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by~~

~~extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist licensed under chapter 36 of Title 26.~~

~~(6) "Unrestricted grant" means any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity.~~

~~(d) Disclosures of unrestricted grants for continuing medical education programs shall be limited to the value, nature, and purpose of the grant and the name of the grantee. It shall not include disclosure of the individual participants in such a program.~~

(c) The terms used in this section shall have the same meanings as they do in section 4631a of this title.

Sec. 4. 1 V.S.A. § 317(c) is amended to read:

(c) The following public records are exempt from public inspection and copying:

* * *

(9) trade secrets, including~~, but not limited to,~~ any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it, except that the disclosures required by section 4632 of Title 18 shall not be included in this subdivision;

Sec. 5. 18 V.S.A. § 4633(d) is amended to read:

* * *

(d) As used in this section:

(1) "Average wholesale price" or "AWP" means the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and listed in a nationally recognized drug pricing file.

(2) "Pharmaceutical manufacturing company" ~~is defined by subdivision 4632(c)(5) of this title~~ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription

drugs. The term does not include a wholesale drug distributor or pharmacist licensed under chapter 36 of Title 26.

(3) "Pharmaceutical marketer" ~~is defined by subdivision 4632(c)(4) of this title~~ means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.