

SENATE No. 1304

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to restore integrity in the marketing of pharmaceutical products and medical devices.

PETITION OF:

NAME:

Mark C. Montigny

DISTRICT/ADDRESS:

Second Bristol and Plymouth

SENATE No. 1304

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 1304) of Mark C. Montigny for legislation to restore integrity in the marketing of pharmaceutical products and medical devices. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. 1233 OF 2017-2018.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

An Act to restore integrity in the marketing of pharmaceutical products and medical devices.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 111N of the General Laws is hereby amended by striking sections
2 1 through 7 in their entirety and inserting in place thereof the following:

3 Section 1. As used in this chapter, the following words shall have the following
4 meanings:-

5 "Department", the department of public health.

6 "Education program", a medical school, teaching hospital, or teaching health center
7 licensed to operate in the commonwealth.

8 "Gift", a payment, entertainment, meals, travel, honorarium, subscription, advance,
9 services or anything of value, unless consideration of equal or greater value is received and there

10 is an explicit contract with specific deliverables which are not related to marketing and are
11 restricted to medical or scientific issues. "Gift" shall not include anything of value received by
12 inheritance, a gift received from a member of the health care practitioner's immediate family or
13 from a relative within the third degree of consanguinity of the health care practitioner or of the
14 health care practitioner's spouse or from the spouse of any such relative, or prescription drugs
15 provided to a health care practitioner solely and exclusively for use by the health care
16 practitioner's patients.

17 "Health care practitioner" or "practitioner," a person who prescribes prescription drugs
18 for any person and is licensed to provide health care or a partnership or corporation made up of
19 those persons or an officer, employee, agent or contractor of that person acting in the course and
20 scope of employment, agency or contract related to or supportive of the provision of health care
21 to individuals.

22 "Immediate family", a spouse and any dependent children residing in the reporting
23 person's household.

24 "Medical device", an instrument, apparatus, implement, machine, contrivance, implant, in
25 vitro reagent, or other similar or related article, including any component, part, or accessory,
26 which is: (1) recognized in the official National Formulary, or the United States Pharmacopeia,
27 or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or
28 in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3)
29 intended to affect the structure or any function of the body of man or other animals, and which
30 does not achieve its primary intended purposes through chemical action within or on the body of

31 man or other animals and which is not dependent upon being metabolized for the achievement of
32 its primary intended purposes.

33 "Person", a business, individual, corporation, union, association, firm, partnership,
34 committee, or other organization or group of persons.

35 "Pharmaceutical or medical device manufacturer agent", a pharmaceutical or medical
36 device marketer or any other person who for compensation or reward does any act to promote,
37 oppose or influence the prescribing of a particular prescription drug, medical device, or category
38 of prescription drugs or medical devices. The term shall not include a licensed pharmacist,
39 licensed physician or any other licensed health care practitioner with authority to prescribe
40 prescription drugs who is acting within the ordinary scope of the practice for which he is
41 licensed.

42 "Pharmaceutical or medical device manufacturing company", any entity that participates
43 in a commonwealth health care program and which is engaged in the production, preparation,
44 propagation, compounding, conversion or processing of prescription drugs or medical devices
45 either directly or indirectly by extraction from substances of natural origin, or independently by
46 means of chemical synthesis or by a combination of extraction and chemical synthesis, or any
47 entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription
48 drugs. The term does not include a wholesale drug distributor licensed under section 36A of
49 chapter 112 or a retail pharmacist registered under section 37 of chapter 112.

50 "Pharmaceutical or medical device marketer", a person who, while employed by or under
51 contract to represent a pharmaceutical or, medical device manufacturing company that
52 participates in a commonwealth health care program, engages in detailing, promotional activities

53 or other marketing of prescription drugs, or medical devices in the commonwealth to any
54 physician, hospital, nursing home, pharmacist, health benefit plan administrator, any other health
55 care practitioner or any other person authorized to prescribe, dispense, or purchase prescription
56 drugs. The term does not include a wholesale drug distributor licensed under section 36A of
57 chapter 112, a representative of such a distributor who promotes or otherwise markets the
58 services of the wholesale drug distributor in connection with a prescription drug, or a retail
59 pharmacist registered under section 38 of chapter 112 if such person is not engaging in such
60 practices under contract with a manufacturing company.

61 “Physician”, a person licensed to practice medicine by the board of medicine under
62 section 2 of chapter 112 who prescribes prescription drugs for any person, or the physician’s
63 employees or agents.

64 “Prescription drugs”, any and all drugs upon which the manufacturer or distributor has
65 placed or is required by federal law and regulations to place the following or a comparable
66 warning: “Caution federal law prohibits dispensing without prescription.”

67 Section 2. No pharmaceutical or medical device manufacturer agent shall knowingly and
68 willfully offer or give to a health care practitioner, a member of a health care practitioner’s
69 immediate family, a health care practitioner’s employee or agent, a health care facility, an
70 employee or agent of a health care facility, an education program, or an employee or agent of an
71 education program a gift of any value.

72 Nothing in the section shall prohibit the provision, distribution, dissemination, or receipt
73 of peer reviewed academic, scientific or clinical information. Nothing in this section shall
74 prohibit the purchase of advertising in peer reviewed academic, scientific or clinical journals.

75 Section 3. (a)(1) By July first of each year, every pharmaceutical or medical device
76 manufacturing company shall disclose to the department the value, nature, purpose, and recipient
77 of any fee, payment, subsidy, or other economic benefit not prohibited in section 2, which is
78 provided by the company, directly or through its agents, to any physician, hospital, nursing
79 home, pharmacist, health benefit plan administrator, education program, health care practitioner
80 or any other person in this commonwealth authorized to prescribe, dispense, or purchase
81 prescription drugs or medical devices. Required disclosures under this section shall include, but
82 are not limited to, any payments made for board memberships, research, or consulting services.
83 For each expenditure, the company must also identify the recipient and the recipient's address,
84 credentials, institutional affiliation, and state board or DEA numbers.

85 (2) Each company subject to the provisions of this section also shall disclose to the
86 department the name and address of the individual responsible for the company's compliance
87 with the provisions of this section, or if this information has been previously reported, any
88 changes to the name or address of the individual responsible for the company's compliance with
89 the provisions of this section.

90 (3) Information disclosed pursuant to this section shall be accompanied by payment of a
91 fee, to be set by the department, to pay the costs of administering these provisions.

92 (b)(1) Information submitted to the department of public health pursuant to this section
93 shall be a public record except to the extent that it includes information that is protected by state
94 or federal law as a trade secret.

95 (2) Notwithstanding any other provision of law, the identity of health care practitioners
96 and other recipients of gifts, payments and materials required to be reported in this chapter shall
97 not constitute confidential information or trade secrets protected under this section.

98 (3) The department shall make all disclosed data publicly available and easily searchable
99 on its website.

100 (c) The department shall report to the attorney general any payment, entertainment,
101 meals, travel, honorarium, subscription, advance, services or anything of value provided in
102 violation of this chapter, including anything of value provided when consideration of equal or
103 greater value was not received or anything of value provided that was not subject to an explicit
104 contract with specific deliverables which were restricted to medical or scientific issues.

105 Section 4. The department, in consultation with the board of registration of pharmacy,
106 and board of registration of medicine, shall promulgate regulations requiring the licensing of all
107 pharmaceutical and medical device manufacturer agents. As a prerequisite to such licensing,
108 pharmaceutical and medical device manufacturer agents shall complete such training as may be
109 deemed appropriate by the department. As a prerequisite to the renewal of such license,
110 pharmaceutical and medical device manufacturer agents shall complete continuing education as
111 may be deemed appropriate by the department. The fee for such license shall be determined by
112 the department, in conjunction with the board of registration in pharmacy and the board of
113 registration in medicine at a rate sufficient to provide the administration and enforcement of this
114 chapter. Revenue generated from this fee shall be divided in equal shares, 75 per cent to the
115 department of public health and 25% to the office of attorney general, line item 0810-0000, for
116 the administration of this chapter.

117 Section 5. This chapter shall be enforced by the attorney general, the district attorney
118 with jurisdiction over a violation, or the department. A person who violates this chapter shall be
119 punished by a fine of not less than \$10,000 for each transaction, occurrence or event that violates
120 this chapter.