SENATE DOCKET, NO. 777 FILED ON: 1/15/2015

SENATE . . . . . No. 1186

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:	DISTRICT/ADDRESS:
Mark C. Montigny	*Second Bristol and Plymouth*

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SENATE . . . . . No. 1186

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 1186) 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. *1052* OF 2013-2014.]

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

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:

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

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

"Gift", a payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value, unless consideration of equal or greater value is received and there is an explicit contract with specific deliverables which are not related to marketing and are restricted to medical or scientific issues. “Gift" shall not include anything of value received by inheritance, a gift received from a member of the health care practitioner’s immediate family or

10 from a relative within the third degree of consanguinity of the health care practitioner or of the
11 health care practitioner's spouse or from the spouse of any such relative, or prescription drugs
12 provided to a health care practitioner solely and exclusively for use by the health care
13 practitioner's patients.

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

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

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

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

32 “Pharmaceutical or medical device marketer”, a person who, while employed by or under
33 contract to represent a pharmaceutical or, medical device manufacturing company that
34 participates in a state health care program, engages in detailing, promotional activities or other
35 marketing of prescription drugs, or medical devices in this state to any physician, hospital,
36 nursing home, pharmacist, health benefit plan administrator, any other health care practitioner or
37 any other person authorized to prescribe, dispense, or purchase prescription drugs. The term
38 does not include a wholesale drug distributor licensed under section 36A of chapter 112, a
39 representative of such a distributor who promotes or otherwise markets the services of the
40 wholesale drug distributor in connection with a prescription drug, or a retail pharmacist
41 registered under section 37 of chapter 112 if such person is not engaging in such practices under
42 contract with a manufacturing company.

43 “Pharmaceutical or medical device manufacturing company”, any entity that participates
44 in a state health care program and which is engaged in the production, preparation, propagation,
45 compounding, conversion or processing of prescription drugs or medical devices either directly
46 or indirectly by extraction from substances of natural origin, or independently by means of
47 chemical synthesis or by a combination of extraction and chemical synthesis, or any entity
48 engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs.
49 The term does not include a wholesale drug distributor licensed under section 36A of chapter
50 112 or a retail pharmacist registered under section 37 of chapter 112.

51 “Pharmaceutical or medical device manufacturer agent”, a pharmaceutical or medical
52 device marketer or any other person who for compensation or reward does any act to promote,
53 oppose or influence the prescribing of a particular prescription drug, medical device, or category
54 of prescription drugs or medical devices. The term shall not include a licensed pharmacist,

55 licensed physician or any other licensed health care practitioner with authority to prescribe
56 prescription drugs who is acting within the ordinary scope of the practice for which he is
57 licensed.

58 "Physician", a person licensed to practice medicine by the board of medicine under
59 section 2 of chapter 112 who prescribes prescription drugs for any person, or the physician's
60 employees or agents.

61 "Prescription drugs", any and all drugs upon which the manufacturer or distributor has
62 placed or is required by federal law and regulations to place the following or a comparable
63 warning: "Caution federal law prohibits dispensing without prescription."

64 Section 2. No pharmaceutical or medical device manufacturer agent shall knowingly and
65 willfully offer or give to a health care practitioner, a member of a health care practitioner's
66 immediate family, a health care practitioner's employee or agent, a health care facility or
67 employee or agent of a health care facility, a gift of any value. Nothing in the section shall
68 prohibit the provision, distribution, dissemination, or receipt of peer reviewed academic,
69 scientific or clinical information. Nothing in this section shall prohibit the purchase of
70 advertising in peer reviewed academic, scientific or clinical journals.

71 Section 3.

72 (a)(1) By July first of each year, every pharmaceutical or medical device manufacturing
73 company shall disclose to the department of public health the value, nature, purpose, and
74 recipient of any fee, payment, subsidy, or other economic benefit not prohibited in Section 2,
75 which is provided by the company, directly or through its agents, to any physician, hospital,
76 nursing home, pharmacist, health benefit plan administrator, health care practitioner or any other

77 person in this state authorized to prescribe, dispense, or purchase prescription drugs or medical
78 devices in this state. For each expenditure, the company must also identify the recipient and the
79 recipient's address, credentials, institutional affiliation, and state board or DEA numbers.

80 (2) Each company subject to the provisions of this section also shall disclose to the
81 department of public health the name and address of the individual responsible for the company's
82 compliance with the provisions of this section, or if this information has been previously
83 reported, any changes to the name or address of the individual responsible for the company's
84 compliance with the provisions of this section.

85 (3) The report shall be accompanied by payment of a fee, to be set by the department of
86 public health, to pay the costs of administering these provisions.

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

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

93 (3) The department of public health shall make all disclosed data publicly available and
94 easily searchable on its website.

95 (c) The department of public health shall report to the attorney general any payment,
96 entertainment, meals, travel, honorarium, subscription, advance, services or anything of value
97 provided in violation of this chapter, including anything of value provided when consideration of

98 equal or greater value was not received or anything of value provided that was not subject to an
99 explicit contract with specific deliverables which were restricted to medical or scientific issues.

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

112 Section 5. This chapter shall be enforced by the attorney general, the department of
113 public health or by any district attorney of the commonwealth with jurisdiction. A person who
114 violates this chapter shall be punished by a fine of not more than $5,000 for each transaction,
115 occurrence or event that violates this chapter.