

**SENATE . . . . . No. 17**

**The Commonwealth of Massachusetts**

PRESENTED BY:

**Montigny, Mark (SEN)**

*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 passage of the accompanying bill:

**An Act Relative to Data Mining**

PETITION OF:

| NAME:                | DISTRICT/ADDRESS:                 |
|----------------------|-----------------------------------|
| Montigny, Mark (SEN) | Second Bristol and Plymouth       |
| Robert M. Koczera    | 11th Bristol                      |
| Barbara A. L'Italien | 18th Essex                        |
| Martha M. Walz       | 8th Suffolk                       |
| Stephen Kulik        | 1st Franklin                      |
| Denise Provost       | 27th Middlesex                    |
| Elizabeth A. Malia   | 11th Suffolk                      |
| John W. Scibak       | 2nd Hampshire                     |
| Frank I. Smizik      | 15th Norfolk                      |
| Gale D. Candaras     | First Hampden and Hampshire       |
| Peter v. Kocot       | 1st Hampshire                     |
| Ellen Story          | 3rd Hampshire                     |
| Bill Bowles          | 2nd Bristol                       |
| Patricia D. Jehlen   | Second Middlesex                  |
| John F. Quinn        | 9th Bristol                       |
| Bruce E. Tarr        | First Essex and Middlesex         |
| Benjamin B. Downing  | Berkshire, Hampshire and Franklin |
| David B. Sullivan    | 6th Bristol                       |
| Jennifer M. Callahan | 18th Worcester                    |

|                     |                              |
|---------------------|------------------------------|
| Karen E. Spilka     | Second Middlesex and Norfolk |
| Susan C. Fargo      | Third Middlesex              |
| Alice Hanlon Peisch | 14th Norfolk                 |
| Stephen R. Canessa  | 12th Bristol                 |
| Antonio F.D. Cabral | 13th Bristol                 |

# The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

## AN ACT RELATIVE TO DATA MINING.

*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 118G is hereby amended by inserting after section 33 the following  
2 section:—

3           Section 34. It is the intent of the legislature to safeguard the confidentiality of prescribing  
4 information, protect the integrity of the doctor-patient relationship, maintain the integrity and  
5 public trust in the medical profession, combat vexatious and harassing sales practices, restrain  
6 undue influence exerted by pharmaceutical industry marketing representatives over prescribing  
7 decisions and further the state interest in improving the quality and lowering the cost of health  
8 care. The legislature intends to regulate the monitoring of prescribing practices only for  
9 commercial marketing purposes by companies selling prescribed products. The intent is not to  
10 regulate monitoring for other uses, such as quality control, research unrelated to marketing, or  
11 use by governments or other entities not in the business of selling health care products.

12           (a) As used in this section the following words shall, unless the context clearly requires  
13 otherwise, have the following meanings:—

14 “Bona-fide clinical trial”, any research project that prospectively assigns human subjects to  
15 intervention and comparison groups to study the cause and effect relationship between a medical  
16 intervention and health outcome, has received approval from an appropriate Institutional Review  
17 Board, and has been registered at ClinicalTrials.gov prior to commencement.

18 “Identifying information”, information that can be used to directly or indirectly identify the  
19 patient or the prescriber, including, but not limited to, a person’s name, address, telephone  
20 number, facsimile number, electronic mail address, photograph or likeness, account, credit card,  
21 medical record, social security number, Drug Enforcement Agency (DEA) number, National  
22 Provider Identifier (NPI) or any other unique number, characteristic, code or information which  
23 is likely to lead to the identification of the patient or prescriber.

24 “Marketing purpose”, means any activity by a company making or selling prescribed  
25 products, or such company’s agent, intended to influence prescribing or purchasing  
26 choices of its products, including but not limited to:

- 27 (1) advertising, publicizing, promoting or sharing information about a product;
- 28 (2) identifying individuals to receive a message promoting use of a particular product,  
29 including but not limited to an advertisement, brochure, or contact by a sales  
30 representative;
- 31 (3) planning the substance of a sales representative visit or communication or the  
32 substance of an advertisement or other promotional message or document;
- 33 (4) evaluating or compensating sales representatives;
- 34 (5) identifying individuals to receive any form of gift, product sample, consultancy,  
35 or any other item, service, compensation or employment of value;
- 36 (6) advertising or promoting prescribed products directly to patients.

37 “Person”, any business, individual, corporation, union, association, firm, partnership, committee,  
38 or other organization or group of persons.

39 “Pharmacy”, a facility under the direction or supervision of a registered pharmacist which is  
40 authorized to dispense controlled substances, including but not limited to retail drug business as  
41 defined in Section 1 of Chapter 94C.

42 “Prescriber”, a person who is licensed, registered or otherwise authorized to prescribe and  
43 administer drugs in the course of professional practice.

44 “Prescribed product”, includes a biological product as defined in section 251 of the Public Health  
45 Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal  
46 Food, Drug and Cosmetic Act, 21 U.S.C. §321.

47 “Regulated transaction”, a prescription for a drug that is written by a prescriber within the  
48 commonwealth or that is dispensed within the commonwealth. The commonwealth does not  
49 regulate activities that take place wholly outside of the commonwealth.

50 (b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed product  
51 information related to a regulated transaction that has identifying  
52 information. A record of a regulated transaction containing individual identifying information  
53 may be transferred to another entity, including to another branch or subsidiary of the same firm,  
54 only if it carries satisfactory assurance that the recipient will safeguard the records from being  
55 disclosed or used in the commonwealth for marketing purposes

56 (c) Nothing in this section shall prohibit the collection use, transfer, or sale of prescribed product  
57 information for marketing purposes if:-- (i) the data is aggregated; (ii) the data does not contain

58 identifying information; and (iii) the data cannot be used, directly or indirectly, to obtain  
59 identifying information.

60 (d) Nothing in this section shall prohibit the collection, use, transfer, or sale of prescribed  
61 product information for non-marketing purposes, including, but not limited to, pharmacy  
62 reimbursement, prescription drug formulary or prior authorization compliance, patient care,  
63 patient care management, utilization review, health care research, bona fide clinical trials,  
64 product safety studies, transfer of prescription records that may occur when a pharmacy's  
65 ownership is changed or transferred, transfer of information to the patient or patient's authorized  
66 representative, and as required by law.

67 (e) Nothing in this section shall be interpreted to regulate conduct that takes place  
68 wholly outside of the commonwealth.

69 (f) Nothing in this section shall be interpreted to regulate the content, time, place or  
70 manner of any discussion between a prescriber and their patient, or a prescriber and any  
71 person representing a prescription drug manufacturer.

72 (g) Whoever violates any provision of this section shall be punished by imprisonment for not  
73 more than two and one half years in a house of correction, or by a fine of not less than twenty  
74 thousand dollars, or by both such fine and imprisonment. Whoever violates any provision of this  
75 section after one or more prior convictions of a violation of this section shall be punished by  
76 imprisonment in the state prison for not more than 10 years, or by a fine of not more than thirty  
77 thousand dollars or by both such fine and imprisonment.

78 (h) A violation of this section shall also constitute an unfair or deceptive act or practice in the  
79 conduct of trade in violation of Section 2 of Chapter 93A. Any person whose rights under this

80 section have been violated may institute and prosecute in his own name and on his own behalf,  
81 or the attorney general, acting on behalf of the commonwealth, may institute a civil action for  
82 injunctive and other equitable relief.

83 (i) If any provision of this act or its application to any person or circumstance is held  
84 invalid, the remainder of the act or the application of the provision to other  
85 persons or circumstances is not affected.

86 SECTION 2. This act shall take effect upon passage.