SENATE DOCKET, NO. 1461 FILED ON: 1/21/2011

SENATE . . . . . No. 1080

The Commonwealth of Massachusetts

PRESENTED BY:

Harriette L. Chandler

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:

An Act to create a genetic bill of rights.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Harriette L. Chandler	☐ *[District]* ☐
Ellen Story	*3rd Hampshire*
Cynthia S. Creem	☐ *[District]* ☐
Kay Khan	*11th Middlesex*
Sal N. DiDomenico	*Middlesex, Suffolk, and Essex*
Patricia D. Jehlen	☐ *[District]* ☐
Antonio F. D. Cabral	*13th Bristol*
Carolyn C. Dykema	*8th Middlesex*
Lori A. Ehrlich	*8th Essex*
Jay R. Kaufman	*15th Middlesex*
Denise Provost	*27th Middlesex*
Carl M. Sciortino, Jr.	*34th Middlesex*

Frank I. Smizik	*15th Norfolk*
Theodore C. Speliotis	*13th Essex*
Benjamin Swan	*11th Hampden*
Cleon H. Turner	*1st Barnstable*
Alice K. Wolf	*25th Middlesex*

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SENATE . . . . . No. 1080

By Ms. Chandler, petition (accompanied by bill, Senate, No. 1080) of Dykema, Khan, DiDomenico and other members of the General Court for legislation to create a genetic bill of rights [Joint Committee on Public Health].

The Commonwealth of Massachusetts

An Act to create a genetic bill of rights.

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 111 Section 70G of the General Laws, as appearing in the 2008 official edition, is hereby struck and replaced with the following: The Commonwealth recognizes that genetic information is a unique product of an individual's body, the unauthorized use of which interferes with both privacy rights and property interests of that individual. It is hereby declared that it shall be a goal of the Commonwealth to declare genetic information the exclusive property of the individual from whom the information is obtained. It is a further goal of the Commonwealth to maintain an individual's privacy by prohibiting the disclosure of said genetic information without the informed written consent of the person to whom the information pertains.

(a) For purposes of this section, the following words shall have the following meanings:

"Confidential research information", any results of a genetic test maintained pursuant to pharmacological or clinical research protocols which are subject to and conducted in accordance with the review and approval of an Institutional Review Board established pursuant to the provisions of 45 CFR 46 and 21 CFR 50 and 56 which protects the confidentiality of the individual who is the subject of the genetic test either by encryption, encoding or other means consistent with the requirements of said federal regulations, or where the identity of the individual is unknown or protected from disclosure by encrypting or encoding, or by other means consistent with the requirements of said federal regulations.

"Genetic information", any written or recorded individually identifiable result of a genetic test as defined by this section or explanation of such a result about a gene, gene product or inherited characteristic derived from the individual or a family member of the individual. For purposes of this section, the term genetic information shall not include any information about an identifiable person that is taken:

24 (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting
25 an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA,
26 chromosomes or proteins;

27 (2) as a blood sample solely for blood banking;

28 (3) as a newborn screening pursuant to section 110A;

29 (4) as information pertaining to the abuse of drugs or alcohol which is derived
30 from tests given for the exclusive purpose of determining the abuse of drugs or alcohol.

31 "Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or
32 proteins for the purpose of identifying genes, inherited, genetic mutations or acquired genetic
33 abnormalities, or the presence or absence of inherited or acquired characteristics in genetic
34 material. Genetic tests shall include those taken in the course of a physical medical exam or a
35 family history analysis. For the purposes of this section, the term genetic test shall not include
36 tests given for drugs, alcohol, cholesterol, or HIV.

37 "Informed written consent", a written consent form for the requested release of a
38 person's genetic information, or the release of genetic information, or for the release of medical
39 records containing such information. Such written consent form shall state the purpose for which
40 the information is being requested and shall be distinguished from written consent for the release
41 of any other medical information.

42 "Insurance Institution", any corporation, association, partnership, reciprocal exchange,
43 inter-insurer, insurance support organization as defined in chapter 175I, Lloyds insurer, so-
44 called, fraternal benefit society or other person engaged in the business of insurance, including
45 health maintenance organizations, medical service plans and hospital service plans, preferred
46 provider arrangements and savings bank life insurance, as defined in chapters 175, 176, 176A,
47 176B, 176C, 176G, 176I, and 178A.

48 "Person", any natural person, corporation, association, partnership or other legal entity.

49 "Prior written consent", a written consent form signed by the person who is the subject of
50 the test or, if that person lacks capacity to consent, signed by the person authorized to consent for
51 such person which form shall not be a general waiver or consent for genetic testing or a general
52 authorization for the release of medical records or medical information, which may be revoked
53 or amended at any time, and which shall include:—

54 (1) a statement of the purpose of the test;

55 (2) a statement that prior to signing the consent form, the consenting person
56 discussed with the medical practitioner ordering the test the reliability of positive or negative test

57 results and the level of certainty that a positive test result for that disease or condition serves as a
58 predictor of such disease;

59 (3) a statement that the consenting person was informed about the availability
60 and importance of genetic counseling and provided with written information identifying a
61 genetic counselor or medical geneticist from whom the consenting person might obtain such
62 counseling;

63 (4) a general description of each specific disease or condition tested for; and

64 (5) the person or persons to whom the test results may be disclosed;

65 (b) Genetic material shall be considered real property subject to one's individual
66 control and dominion in accord with generally held precepts of property law in the
67 Commonwealth. Individuals may make arrangement for appropriate storage, and maintenance of
68 genetic information and genetic material in keeping with the intent for which such information
69 and material may be stored for some future use as appropriate, as determined by the property
70 holder. In accordance with generally held precepts of property law in the Commonwealth, any
71 decedent may specifically authorize in writing for their surviving spouse or other family member
72 to use their genetic information or material as expressed under the terms and conditions of their
73 last will and testament. In the case where an entity collects genetic material or genetic
74 information with the possible future intent of resale, licensing, or transfer of this material for
75 collateral gain, the individual who provided the genetic material or information must be made
76 aware and compensated at a fair market value.; Prior to entering into a contract to share one's
77 personal health information, genetic material or genetic information, a person must be made
78 aware both orally and in writing that their donation is a commodity and is of some material
79 value.

80 (c) Hospital, dispensary, laboratory, hospital-affiliated registry, physician, insurance
81 institution, insurance support organization, or insurance representative, and commercial genetic
82 testing company, agency, or association reports and records pertaining to any genetic information
83 are the exclusive property rights of the person sampled or analyzed, shall not be public records,
84 and the contents thereof shall not be divulged by any person having charge of or access to the
85 same without informed written consent, except upon proper judicial order or to a person whose
86 official duties, in the opinion of the commissioner, entitle receipt of the information contained
87 therein, or as confidential research information for use in epidemiological or clinical research
88 conducted for the purpose of generating scientific knowledge about genes or learning about the
89 genetic basis of disease or for developing pharmaceutical and other treatments of disease.

90 The person sampled or analyzed shall be offered several options for storing any of their
91 remaining genetic material, donating said genetic material to another individual, discarding, or
92 donating for research. Disclosure of options for the storage of remaining genetic material must
93 be made at the time of attaining written consent for testing or use of genetic information. Any

94 entity handling and maintaining genetic information or genetic material are to follow the
95 documented guidelines for the disposal of Genetic Information as documented in the Centers for
96 Medicaid and Medicare Services Clinical Laboratory Improvement Amendments (CLIA
97 guidelines) or a similar subsequent regulation. Where subsequent regulations are silent on
98 questions of law addressed in the CLIA guidelines, the CLIA guidelines shall be legally
99 controlling.

100 A laboratory receiving a request to conduct a genetic test from a facility, as defined in
101 section 70E, or a physician or health care provider may conduct the requested test only when the
102 request is accompanied by a signed statement of the medical practitioner ordering the test
103 warranting that the appropriate prior written consent has been obtained from the patient except
104 where the test is conducted as confidential research information for use in epidemiological or
105 clinical research conducted for the purpose of generating scientific knowledge about genes or
106 learning about the genetic basis of disease or for developing pharmaceutical and other treatments
107 of disease. The signed request authorizes the laboratory to perform the test and disclose the
108 results to the medical practitioner.

109 (d) No facility, as defined in section 70E, and no physician or health care provider
110 shall: (1) test any person for genetic information without first obtaining the prior written consent;
111 (2) disclose the results of a genetic test to any person other than the subject thereof without first
112 obtaining the informed written consent except where the results disclosed will be used only as is
113 confidential research information for use in epidemiological or clinical research conducted for
114 the purpose of generating scientific knowledge about genes or learning about the genetic basis of
115 disease or for developing pharmaceutical and other treatments of disease; or identify the person
116 being tested to any other person without first obtaining informed written consent or upon proper
117 judicial order; (3) deny services to an individual solely on the basis of a genetic marker or
118 condition to which an individual's genetic information indicates he or she is predisposed.

119 (e) A laboratory receiving a request to conduct a genetic test from a facility, as
120 defined in section 70E, or a physician or health care provider or any entity which enters into a
121 contract with a third party for analysis of genetic information, genetic material or personal health
122 information, shall be responsible for safeguarding the confidentiality of said materials and data
123 which results thereof.

124 (f) Whoever violates any provisions of this section shall be deemed to have violated
125 section 2 of chapter 93A. Any person whose rights under this section have been violated,
126 interfered with, or attempted to be interfered with may institute and prosecute in his own name
127 and on his own behalf, or the attorney general, acting on behalf of the Commonwealth, may
128 institute a civil action for injunctive and other equitable relief. In addition to the actual damages
129 suffered by the person, a person violating this section shall be liable for damages in the amount
130 of $5,000 or, if the violation resulted in profit or monetary gain to the violator, $100,000.

131 (g) This section shall not apply to a law enforcement official in the execution of his
132 official duties; to a hospital, laboratory or physician carrying out tests upon proper judicial order;
133 or to law enforcement or health care personnel, or any other person, in the execution of their
134 official duties pursuant to chapter 22E.

135 SECTION 2. Chapter 175 Section 108I is hereby amended by striking in subsection (c)
136 the following language:

137 "If the applicant chooses to submit genetic information, then the insurer is authorized to
138 use that information to set the terms of a policy provided that such information is reliable
139 information relating to the insured's mortality or morbidity, based on sound actuarial principles,
140 or actual or reasonably anticipated experience."

141 SECTION 3. Chapter 175 Section 120E is hereby amended by striking in subsection (c)
142 the following language:

143 "If the applicant chooses to submit genetic information, then the insurer is authorized to
144 use that information to set the terms of a policy provided that such information is reliable
145 information relating to the insured's mortality or morbidity, based on sound actuarial principles,
146 or actual or reasonably anticipated experience."

147 SECTION 4. Chapter 175 the General Laws is hereby amended by adding the following
148 section:

149 Section 113X. For the purposes of this section the following words shall have the
150 following meanings:—

151 "Genetic information", a written recorded individually identifiable result of a genetic test
152 as defined in this section or explanation of such a result.

153 "Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or
154 proteins for the purpose of identifying the genes or genetic abnormalities, or the presence or
155 absence of inherited or acquired characteristics in genetic material. For the purpose of this
156 section, the term genetic test shall not include tests given for the exclusive purposes of
157 determining the abuse of drugs or alcohol.

158 No company, and no officer or agent thereof, and no insurance broker, shall cancel,
159 refuse to issue or renew, or in any way make or permit any distinction or discrimination in the
160 amount of payment of premiums or rates charged, in the length of coverage, or in any other of
161 the terms and conditions as authorized pursuant to section 113. Any violation of this section shall
162 constitute an unfair method of competition or unfair or deceptive act or practice in violation of
163 chapters 93A and 176D. The commissioner may promulgate rules and regulations pursuant to
164 this section.

165 SECTION 5. Chapter 93H Section 1 of the General Laws is hereby amended by inserting
166 after the words “general public” under the definition of “personal information”, the following:

167 (d) Genetic information as defined by Chapter 111 Section 70G(a).

168 SECTION 6. Chapter 151B Section 4 of the General Laws is hereby amended by adding
169 after the word “age” in section 14, the word “genetic information.”

170 SECTION 7. Chapter 265 Section 39 of the General Laws is hereby amended by adding
171 after the word “sexual orientation” in section (a), the word “genetic information.”

172 SECTION 8. Chapter 272 Section 98 of the General Laws is hereby amended by adding
173 after the word “sexual orientation” the words “genetic marker or handicap.”

174 SECTION 9. Chapter 118G is hereby amended by inserting after section 33 the following
175 section:--

176 Section 34. (a) As used in this section the following words shall, unless the context
177 clearly requires otherwise, have the following meanings:--

178 "Bona- fide clinical trial", any research project that prospectively assigns human
179 subjects to intervention and comparison groups to study the cause and effect relationship
180 between a medical intervention and health outcome, has received approval from an appropriate
181 Institutional Review Board, and has been registered at ClinicalTrials.gov prior to

182 "Marketing purpose", means any activity by a company making or selling prescribed
183 products, or such company's agent, intended to influence purchasing choices of its products,
184 including but not limited to:

185 (1) advertising, publicizing, promoting or sharing information about a product;

186 (2) identifying individuals to receive a message promoting use of a particular product,
187 including but not limited to an advertisement, brochure, or contact by a sales representative;

188 (3) planning the substance of a sales representative visit or communication or the
189 substance of an advertisement or other promotional message or document;

190 (4) evaluating or compensating sales representatives;

191 (5) identifying individuals to receive any form of gift, product sample, consultancy, or
192 any other item, service, compensation or employment of value;

193 “Genetic profiling,” any effort to attach an individual’s demographic information to their
194 genetic information or genetic material for marketing purposes.

195 (b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed
196 product information related to a regulated transaction that was the result of genetic profiling. A
197 record of a regulated transaction containing genetic information may be transferred to another
198 entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory
199 assurance that the recipient will safeguard the records from being disclosed or used in the
200 commonwealth for marketing purposes.

201 (c) Nothing in this section shall prohibit the collection use, transfer, or sale of
202 prescribed product information for marketing purposes if:-- (i) the data is aggregated; (ii) the
203 data does not contain identifying information; and (iii) the data cannot be used, directly or
204 indirectly, to obtain identifying information.

205 (d) Nothing in this section shall prohibit the collection, use, transfer, or sale of
206 prescribed product information for non- marketing purposes, including, but not limited to, patient
207 care, patient care management, utilization review, health care research, bona fide clinical trials,
208 product safety studies, transfer of information to the patient or patient's authorized
209 representative, and as required by law.

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

212 (g) Whoever violates any provision of this section shall be liable for damages in the
213 amount of $5,000, or if the violation resulted in profit or monetary gain to the violator, $100,000.

214 (h) A violation of this section shall also constitute an unfair or deceptive act or
215 practice in the conduct of trade in violation of Section 2 of Chapter 93A. Any person whose
216 rights under this section have been violated may institute and prosecute in his own name and on
217 his own behalf, or the attorney general, acting on behalf of the commonwealth, may institute a
218 civil action for injunctive and other equitable relief.

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

222 SECTION 10. Chapter 111E Section 9E is hereby amended by adding a section (17):

223 (17). Eligibility for and the medical benefits provided by MassHealth shall not be
224 determined solely on the basis of a genetic marker or condition.

225 SECTION 11. Chapter 4, Section 7, clause 26 (c) is herby amended by inserting after the
226 word, “information,” the following, “including genetic information.”

227 SECTION 12. Chapter 66A Section 1 is herby amended by inserting after the words,
228 "Personal data, any information concerning an individual," the following, "including genetic
229 information as defined in Chapter 111, Section 70G."

230 SECTION 13. Chapter 66A Section 2 (c) is herby amended after the words, "medical or
231 psychiatric data" by inserting the following, "excluding a genetic test or genetic information."

232 SECTION 14. Chapter 93 Section 50 is herby amended by adding the following
233 definition, "genetic information- any written or recorded individually identifiable result of a
234 genetic test as defined by Chapter 111, Section 70G."

235 SECTION 15. Chapter 93H Section 3 is herby amended by adding each time the words,
236 "personal information," appear the following, "including a person's genetic information."

237 SECTION 16. Chapter 266 Section 37E is herby amended by inserting after the words,
238 "social security number" the following words, "genetic information" as defined by Chapter 111
239 Section 70G.

240 SECTION 17. Chapter 152 is herby amended by adding a new section, "Section 14b."
241 and inserting the following:

242 Section 14b. For the purposes of this section the following words shall have the following
243 meanings:—

244 "Genetic information", a written recorded individually identifiable result of a genetic test
245 as defined in this section or explanation of such a result.

246 "Genetic test", a test of human DNA, RNA, mitochondrial DNA, chromosomes or
247 proteins for the purpose of identifying the genes or genetic abnormalities, or the presence or
248 absence of inherited or acquired characteristics in genetic material. For the purpose of this
249 section, the term genetic test shall not include tests given for the exclusive purposes of
250 determining the abuse of drugs or alcohol.

251 No company, and no officer or agent thereof, and no insurance broker, shall cancel,
252 refuse to issue or renew, or in any way make or permit any distinction or discrimination in the
253 amount of payment of premiums or rates charged, in the length of coverage, or in any other of
254 the terms and conditions of any individual policy of workers compensation insurance, authorized
255 pursuant to Chapter 152, based on genetic information as defined in this section. No company,
256 officer or agent thereof, and, no insurance broker shall require genetic tests or genetic
257 information as defined in this section, as a condition of the issuance or renewal of any such
258 individual or group policy of workers compensation authorized pursuant to Chapter 152. Any
259 violation of this section shall constitute an unfair method of competition or unfair or deceptive
260 act or practice in violation of chapters 93A and 176D. The commissioner may promulgate rules
261 and regulations pursuant to this section.

262 SECTION 18. If any provision of this act or its application to any person or
263 circumstance is held invalid, the remainder of the act or the application of the provision to other
264 persons or circumstances is not affected.

265 This bill protects Massachusetts residents' privacy, personal data, and First Amendment
266 rights in the context of government data collection. It prohibits law enforcement collection of
267 information about individuals' political and religious views, associations, or activities without
268 reasonable suspicion of criminal conduct. It also establishes practical standards to ensure that
269 government collection of our personal information is conducted in a secure, accountable manner,
270 and establishes necessary transparency and oversight structures.