

**HOUSE . . . . . No. 3270**

**The Commonwealth of Massachusetts**

PRESENTED BY:

***Nicholas A. Boldyga***

*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 providing a right to try.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Nicholas A. Boldyga</i>	<i>3rd Hampden</i>
<i>Leonard Mirra</i>	<i>2nd Essex</i>
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>
<i>Kate D. Campanale</i>	<i>17th Worcester</i>
<i>Leah Cole</i>	<i>12th Essex</i>
<i>Viriato M. deMacedo</i>	<i>Plymouth and Barnstable</i>
<i>Angelo L. D'Emilia</i>	<i>8th Plymouth</i>
<i>Shawn Dooley</i>	<i>9th Norfolk</i>
<i>Peter J. Durant</i>	<i>6th Worcester</i>
<i>Ryan C. Fattman</i>	<i>Worcester and Norfolk</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>
<i>Michael J. Finn</i>	<i>6th Hampden</i>
<i>Paul K. Frost</i>	<i>7th Worcester</i>
<i>Susan Williams Gifford</i>	<i>2nd Plymouth</i>
<i>Sheila C. Harrington</i>	<i>1st Middlesex</i>
<i>Paul R. Heroux</i>	<i>2nd Bristol</i>
<i>Bradford R. Hill</i>	<i>4th Essex</i>
<i>Steven S. Howitt</i>	<i>4th Bristol</i>

<i>Donald F. Humason, Jr.</i>	<i>Second Hampden and Hampshire</i>
<i>Randy Hunt</i>	<i>5th Barnstable</i>
<i>Bradley H. Jones, Jr.</i>	<i>20th Middlesex</i>
<i>Kevin J. Kuros</i>	<i>8th Worcester</i>
<i>Marc T. Lombardo</i>	<i>22nd Middlesex</i>
<i>Paul W. Mark</i>	<i>2nd Berkshire</i>
<i>Joseph D. McKenna</i>	<i>18th Worcester</i>
<i>David K. Muradian, Jr.</i>	<i>9th Worcester</i>
<i>Shaunna L. O'Connell</i>	<i>3rd Bristol</i>
<i>Keiko M. Orrall</i>	<i>12th Bristol</i>
<i>Elizabeth A. Poirier</i>	<i>14th Bristol</i>
<i>Angelo J. Puppolo, Jr.</i>	<i>12th Hampden</i>
<i>John W. Scibak</i>	<i>2nd Hampshire</i>
<i>Todd M. Smola</i>	<i>1st Hampden</i>
<i>Bruce E. Tarr</i>	<i>First Essex and Middlesex</i>
<i>John C. Velis</i>	<i>4th Hampden</i>
<i>David T. Vieira</i>	<i>3rd Barnstable</i>
<i>Chris Walsh</i>	<i>6th Middlesex</i>
<i>Susannah M. Whipps Lee</i>	<i>2nd Franklin</i>

**HOUSE . . . . . No. 3270**

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By Mr. Boldyga of Southwick, a petition (accompanied by bill, House, No. 3270) of Nicholas A. Boldyga and others for legislation to authorize terminally ill patients to consent to treatment by investigational drugs, biological products or devices. Public Health.

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**The Commonwealth of Massachusetts**

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

An Act providing a right to try.

*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. Section 70E of chapter 111 of the General Laws, as appearing in the 2012  
2 Official edition, is hereby amended by striking out, in line 99 the word “and”, the second time it  
3 appears.

4 SECTION 2. Said section 70E of said chapter 111, as so appearing, is hereby further  
5 amended by inserting after the word, “request”, in line 104, the following words:- ; and

6 (p) to access, provided the patient is eligible, an investigational drug, biological product,  
7 or device in accordance with the provisions of section 9 of chapter 111N.

8 SECTION 3. Chapter 111N of the General Laws is hereby amended by inserting after  
9 section 8, as so appearing, the following section:-

10 Section 9. (a) As used in this section, the following words shall, unless the context clearly  
11 requires otherwise, have the following meanings:-

12           “Authorized representative”, (i) an agent to whom authority to make health care decisions  
13 on behalf of a person is delegated under a health care proxy; or (ii) a guardian appointed  
14 pursuant to part 3 of article V of the Massachusetts Uniform Probate Code to act on behalf of a  
15 person who is incapacitated; provided, however, a guardian appointed pursuant to said part 3 of  
16 said article V shall not be considered an authorized representative if an agent has been granted  
17 authority to make health care decisions on behalf of the incapacitated person under a valid health  
18 care proxy.

19           "Eligible patient", an individual who has:

20           (i) a terminal illness, attested to by the patient's treating physician;

21           (ii) considered all other treatment options currently approved by the United States Food  
22 and Drug Administration.

23           (iii) received a recommendation from his or her physician for an investigational drug,  
24 biological product, or device.

25           (iv) given written, informed consent for the use of the investigational drug, biological  
26 product, or device; and

27           (v) documentation from his or her physician that he or she meets the requirements  
28 provided in this definition.

29           “Health care proxy”, a document delegating to an agent the authority to make health care  
30 decisions, executed in accordance with the requirements of chapter 201D.

31           “Health care proxy”, a document delegating to an agent the authority to make health care  
32 decisions, executed in accordance with the requirements of chapter 201D. rment, that is not

33 considered by a treandividual lacks the ability to meet essential requirements for physical health,  
34 safety or self-care, even with appropriate technological assistance.

35 "Investigational drug, biological product, or device", a drug, biological product, or device  
36 that has successfully completed phase 1 of a clinical trial but has not yet been approved for  
37 general use by the United States Food and Drug Administration and remains under investigation  
38 in a United States Food and Drug Administration-approved clinical trial.

39 "Terminal illness", a progressive disease or medical or surgical condition that entails  
40 significant functional impairment, that is not considered by a treating physician to be reversible  
41 even with administration of current United States Food and Drug Administration-approved and  
42 available treatments, and that, without life-sustaining procedures, will soon result in death.

43 "Written, informed consent", a written document that is signed by the patient, the  
44 authorized person of a patient who is an incapacitated person or the parent or guardian of a  
45 patient who is a minor and attested to by such patient's physician and a witness and that, at a  
46 minimum, includes all of the following:

47 (i) An explanation of the currently approved products and treatments for the disease or  
48 condition from which the patient suffers.

49 (ii) An attestation that the patient concurs with his or her physician in believing that all  
50 currently approved and conventionally recognized treatments are unlikely to prolong the patient's  
51 life.

52 (iii) Clear identification of the specific proposed investigational drug, biological product,  
53 or device that the patient is seeking to use.

54 (iv) A description of the potentially best and worst outcomes of using the investigational  
55 drug, biological product, or device and a realistic description of the most likely outcome. The  
56 description shall include the possibility that new, unanticipated, different, or worse symptoms  
57 might result and that death could be hastened by the proposed treatment. The description shall be  
58 based on the physician's knowledge of the proposed treatment in conjunction with an awareness  
59 of the patient's condition.

60 (v) A statement that the patient's health plan or third party administrator and provider are  
61 not obligated to pay for any care or treatments consequent to the use of the investigational drug,  
62 biological product, or device, unless they are specifically required to do so by law or contract.

63 (vi) A statement that the patient's eligibility for hospice care may be withdrawn if the  
64 patient begins curative treatment with the investigational drug, biological product, or device and  
65 that care may be reinstated if this treatment ends and the patient meets hospice eligibility  
66 requirements.

67 (vii) A statement that the patient understands that he or she is liable for all expenses  
68 consequent to the use of the investigational drug, biological product, or device and that this  
69 liability extends to the patient's estate, unless a contract between the patient and the manufacturer  
70 of the drug, biological product, or device states otherwise.

71 (b) A manufacturer of an investigational drug, biological product, or device may make  
72 available and an eligible patient may request the use of a manufacturer's investigational drug,  
73 biological product, or device pursuant to this section. This section shall not require that a  
74 manufacturer make available an investigational drug, biological product, or device to an eligible  
75 patient.

76 A manufacturer may provide an investigational drug, biological product, or device to an  
77 eligible patient without receiving compensation or may require an eligible patient to pay the  
78 costs of, or the costs associated with, the manufacture of the investigational drug, biological  
79 product, or device;

80 (c) This section shall not expand insurance coverage requirements under chapter 32A,  
81 118E, 175, 176A, 176B or 176G or any other general or special law; provided, however, that the  
82 group insurance commission under chapter 32A, the division of medical assistance under chapter  
83 118E, an insurance company under chapter 175, a non-profit hospital service corporation under  
84 chapter 176A, a medical service corporation under 176B or a health maintenance organization  
85 under chapter 176G may provide or authorize coverage for the cost of an investigational drug,  
86 biological product, or device, or the cost of services related to the use of an investigational drug,  
87 biological product, or device pursuant to this section.

88 (d) This section shall not require a health care facility, as defined in section 9C of chapter  
89 112, to provide new or additional services, unless approved by such facility.

90 (e) If a patient dies while being treated by an investigational drug, biological product, or  
91 device, the patient's heirs or estate shall not be liable for any outstanding debt related to the  
92 treatment or lack of insurance due to the treatment.

93 (f) A regulating board established pursuant to chapter 112 shall not revoke, fail to renew,  
94 suspend a license, or take any disciplinary action against a health care provider licensed by that  
95 board based solely on the health care provider's recommendations to an eligible patient regarding  
96 access to or treatment with an investigational drug, biological product, or device.

97 (g) A health care provider's recommendation that a patient have access to an  
98 investigational drug, biological product, or device shall not affect medicare certification for that  
99 health care provider or the health care facility, as defined in section 9C of chapter 112, that the  
100 provider serves.

101 (h) This section shall not create a private cause of action against a manufacturer of an  
102 investigational drug, biological product, or device or against any other person or entity involved  
103 in the care of an eligible patient using the investigational drug, biological product, or device for  
104 any harm done to the eligible patient resulting from the investigational drug, biological product,  
105 or device, if the manufacturer or other person or entity is complying in good faith with the terms  
106 of this section and has exercised reasonable care.

107 (i) This section shall not affect any mandatory health care coverage for participation in  
108 clinical trials pursuant to chapters chapter 32A, 118E, 175, 176A, 176B, 176G or any other  
109 general or special law.