HOUSE DOCKET, NO. 1171 FILED ON: 1/18/2017

HOUSE . . . . . No. 1129

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:
Nicholas A. Boldyga	*3rd Hampden*
Angelo L. D'Emilia	*8th Plymouth*
Donald F. Humason, Jr.	*Second Hampden and Hampshire*
James J. Lyons, Jr.	*18th Essex*
Kevin J. Kuros	*8th Worcester*
Shaunna L. O'Connell	*3rd Bristol*

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HOUSE . . . . . No. 1129

By Mr. Boldyga of Southwick, a petition (accompanied by bill, House, No. 1129) 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.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. *3270* OF 2015-2016.]

The Commonwealth of Massachusetts

In the One Hundred and Ninetieth General Court
(2017-2018)

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:

SECTION 1. Section 70E of chapter 111 of the General Laws, as appearing in the 2012 Official edition, is hereby amended by striking out, in line 99 the word “and”, the second time it appears.

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

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

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

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

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

"Eligible patient", an individual who has:

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

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

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

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

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

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

“Health care proxy”, a document delegating to an agent the authority to make health care decisions, executed in accordance with the requirements of chapter 201D.rment, that is not considered by a treandividual lacks the ability to meet essential requirements for physical health, safety or self-care, even with appropriate technological assistance.

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

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

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

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

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

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

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

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

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

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

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

manufacturer make available an investigational drug, biological product, or device to an eligible patient.

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

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

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

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

(f) A regulating board established pursuant to chapter 112 shall not revoke, fail to renew, suspend a license, or take any disciplinary action against a health care provider licensed by that

board based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

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

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

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