

**Proposed Substitute
Bill No. 6709**

LCO No. 4605

AN ACT CONCERNING THE RIGHT TO TRY EXPERIMENTAL DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2015*) (a) For purposes of this
2 section and sections 2 to 5, inclusive, of this act:

3 (1) "Investigational drug, biological product or device" means a
4 drug, biological product or device that has successfully completed
5 phase one of a clinical trial but has not yet been approved for general
6 use by the federal Food and Drug Administration and remains under
7 investigation in a clinical trial approved by the federal Food and Drug
8 Administration.

9 (2) "Patient" means a person who has a terminal illness, verified by
10 the patient's treating physician, and is not being treated as an inpatient
11 in a hospital licensed under chapter 368v of the general statutes.

12 (3) "Treating physician" means a physician licensed under chapter
13 370 of the general statutes who has primary responsibility for the
14 medical care of the patient and treatment of the patient's terminal
15 illness.

16 (4) "Terminal illness" means a medical condition that a patient's
17 treating physician anticipates, with reasonable medical judgment, will

18 result in a patient's death or a state of permanent unconsciousness
19 from which recovery is unlikely within a period of one year.

20 (b) A patient is eligible to receive treatment with an investigational
21 drug, biological product or device if the patient has (1) considered all
22 other treatment options currently approved by the federal Food and
23 Drug Administration, (2) been unable to participate in a clinical trial
24 for the terminal illness not more than one hundred miles from the
25 patient's home address, or not been accepted to a clinical trial not more
26 than one week after completion of the clinical trial application process,
27 (3) received a recommendation from his or her treating physician for
28 an investigational drug, biological product or device, (4) given written,
29 informed consent for the use of the investigational drug, biological
30 product or device, as provided in subsection (c) of this section, or, if
31 the patient is a minor or lacks the mental capacity to provide informed
32 consent, a parent or legal guardian has given such written, informed
33 consent on the patient's behalf, and (5) written documentation from his
34 or her treating physician stating that the patient meets the
35 requirements of this subsection.

36 (c) A patient gives written informed consent when the patient, or if
37 the patient is a minor the patient's parent or legal guardian, signs a
38 written document, verified by the patient's treating physician and a
39 witness that at a minimum: (1) Explains the currently approved
40 products and treatments for the terminal illness from which the patient
41 suffers, (2) verifies the fact that the patient concurs with his or her
42 treating physician in believing that all currently approved and
43 conventionally recognized treatments are unlikely to prolong the
44 patient's life, (3) clearly identifies the specific proposed investigational
45 drug, biological product or device with which the patient is seeking to
46 be treated, (4) describes the potentially best and worst outcomes of
47 using the investigational drug, biological product or device with a
48 realistic description of the most likely outcome, including the
49 possibility that new, unanticipated, different or worse symptoms
50 might result and that death could be hastened by the proposed
51 treatment based on the treating physician's knowledge of the proposed

52 treatment in conjunction with an awareness of the patient's condition,
53 (5) makes clear that the patient's health insurer, treating physician or
54 other health care provider is not obligated to pay for any care or
55 treatments resulting from the use of the investigational drug,
56 biological product or device, (6) makes clear that the patient's
57 eligibility for hospice care may be withdrawn if the patient begins
58 treatment with an investigational drug, biological product or device,
59 but that hospice care may be reinstated if such treatment ends and the
60 patient meets hospice eligibility requirements, (7) makes clear that in-
61 home health care may be denied if such treatment begins, and (8)
62 states that the patient understands that the patient is liable for all
63 expenses resulting from the use of the investigational drug, biological
64 product or device and that this liability extends to the patient's estate,
65 unless a contract between the patient and the manufacturer of the
66 drug, biological product or device states otherwise.

67 Sec. 2. (NEW) (*Effective October 1, 2015*) A manufacturer of an
68 investigational drug, biological product or device may make available
69 the manufacturer's investigational drug, biological product or device
70 to a patient, who is eligible under subsection (b) of section 1 of this act,
71 and may (1) provide the investigational drug, biological product or
72 device to such patient without receiving compensation, or (2) require
73 such patient to pay the costs of, or associated with, the manufacture of
74 the investigational drug, biological product or device.

75 Sec. 3. (NEW) (*Effective October 1, 2015*) (a) A health insurer may
76 provide coverage for the cost of an investigational drug, biological
77 product or device made available to a patient, who is eligible under
78 subsection (b) of section 1 of this act, pursuant to section 2 of this act.

79 (b) A health insurer may deny coverage to such patient from the
80 time such patient begins treatment with the investigational drug,
81 biological product or device for a period not to exceed six months from
82 the date such patient ceases treatment with the investigational drug,
83 biological product or device, except coverage may not be denied for a
84 preexisting condition or for coverage for benefits that commenced

85 prior to the date such patient begins such treatment.

86 (c) Nothing in this section shall affect the provisions of sections 38a-
87 504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the
88 general statutes concerning insurance coverage for certain costs
89 associated with clinical trials. Treatment with an investigational drug,
90 biological product or device pursuant to sections 1 to 5, inclusive, of
91 this act is not considered a clinical trial for purposes of said sections.

92 Sec. 4. (NEW) (*Effective October 1, 2015*) (a) Notwithstanding the
93 provisions of chapter 370 of the general statutes, the Department of
94 Public Health or the Connecticut Medical Examining Board shall not
95 revoke, fail to renew, suspend or take any disciplinary action against a
96 physician based solely on the physician's recommendation to a patient
97 regarding access to, or treatment with, an investigational drug,
98 biological product or device, provided such recommendation is
99 consistent with medical standards of care.

100 (b) No official, employee or agent of the state shall prevent, or
101 attempt to prevent, a patient who is eligible under subsection (b) of
102 section 1 of this act from accessing an investigational drug, biological
103 product or device.

104 Sec. 5. (NEW) (*Effective October 1, 2015*) Nothing in sections 1 to 4,
105 inclusive, of this act shall create a private cause of action against a
106 manufacturer of an investigational drug, biological product or device
107 or against the patient's treating physician or any other person or entity
108 involved in the care of a patient being treated with an investigational
109 drug, biological product or device for any harm done to such patient
110 resulting from the investigational drug, biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2015</i>	New section
Sec. 2	<i>October 1, 2015</i>	New section
Sec. 3	<i>October 1, 2015</i>	New section

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Sec. 4	<i>October 1, 2015</i>	New section
Sec. 5	<i>October 1, 2015</i>	New section