

**HOUSE . . . . . No. 00621**

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The Commonwealth of Massachusetts

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PRESENTED BY:

*John W. Scibak*

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*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 providing for the establishment and operation of a cancer drug repository program.

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PETITION OF:

NAME:

*Anne M. Gobi*

DISTRICT/ADDRESS:

*5th Worcester*

# HOUSE . . . . . No. 00621

By Mr. John W Scibak of South Hadley, petition (accompanied by bill, House, No. 00621) of Anne M. Gobi that the Board of Registration in Pharmacy be authorized to provide for the establishment and operation of a cancer drug repository program. Joint Committee on Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION  
SEE  
□ HOUSE  
□ , NO. 2156 OF 2009-2010.]

## The Commonwealth of Massachusetts

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**In the Year Two Thousand Eleven**  
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An Act providing for the establishment and operation of a cancer drug repository program.

*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 111 of the General Laws, as appearing in the 2004 Official  
2 Edition, is hereby amended by adding the following section: Section 25J. Cancer drug  
3 repository program.

4 Section 1. Definitions. The following words as used in this chapter, unless a different meaning  
5 is required by the context or is specifically prescribed, shall have the following meanings:

6 “Board”, the Board of Registration in Pharmacy.

7 “Cancer drug”, a prescription drug that is used to treat any of the following:

- 8 Cancer or the side effects of cancer.
- 9 The side effects of a prescription drug used to treat cancer or its side effects.
- 10 “Commissioner”, the Commissioner of the Department of Public Health.
- 11 “Department”, the Department of Public Health.
- 12 “Dispense”, has the meaning given to that term in Section 1 of Chapter 94 C of the General  
13 Laws.
- 14 “Medical facility” means any of the following:
- 15 An entity licensed by the Commonwealth to provide clinically related health  
16 services, including any hospital or clinic, nursing home or long-term care  
17 nursing facility, or hospice, as defined in Section 71 of Chapter 111 of the  
18 General Laws.
- 19 A cancer treatment center where radiation therapy and chemotherapy are administered on an  
20 ambulatory basis.
- 21 An office where a physician licensed to practice medicine in the Commonwealth conducts the  
22 practice of medicine.
- 23 “Pharmacy”, any pharmacy licensed by the Commonwealth for transacting retail drug business  
24 in accordance with Section 38 of Chapter 112 of the General Laws.
- 25 “Program”, the Cancer Drug Repository Program established in Section 2.

26 “Supplies”, any supplies used in the administration of a cancer drug.

27 Section 2. Establishment. The Department and the Board of Registration in Pharmacy shall  
28 establish a cancer drug repository program for the purpose of authorizing and facilitating the  
29 donation of cancer drugs or supplies and their dispensation to residents of the Commonwealth  
30 who meet the eligibility standards established in the administrative regulations promulgated by  
31 the Department and the Board pursuant to Section 5 of this Act. Under the program, donations  
32 may be made on the premises of a medical facility or pharmacy that elects to participate in the  
33 program and meets the requirements specified in Section 3 of this Act as well as those  
34 promulgated by the Department in regulations.

35 Section 3. Requirements for participation by pharmacies and medical facilities. (a) Participation  
36 in the program shall be voluntary.

37 (b) To be eligible for participation in the cancer drug repository program, a pharmacy or medical  
38 facility must be licensed and in compliance with all applicable federal and state laws and  
39 administrative rules and regulations.

40 (c) A pharmacy or medical facility may fully participate in the cancer drug repository program  
41 by accepting, storing, and dispensing donated drugs and supplies, or may limit its participation to  
42 only accepting and storing donated drugs and supplies. If a pharmacy or medical facility chooses  
43 to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully  
44 participating cancer drug repository in accordance with Section 3.

45 (d) A pharmacy or medical facility may withdraw from participation in the cancer drug  
46 repository program at any time upon notification in writing to the commissioner.

47 Section 3. Donation of cancer drugs. Any person or entity, including but not limited to,  
48 a cancer drug manufacturer, or medical facility, may donate cancer drugs or supplies to the  
49 program or to a participating pharmacy or medical facility. Cancer drugs or supplies may not be  
50 donated to a specific cancer patient, and donated drugs or supplies may not be resold by the  
51 program or a participating pharmacy or medical facility.

52 Section 4. Acceptance and dispensation of cancer drugs. A cancer drug or supplies needed to  
53 administer a cancer drug may be accepted and dispensed under the program if all of the  
54 following requirements are met:

55 (a) The cancer drug or supplies to administer a cancer drug is in its original, unopened, sealed  
56 and tamper-evident unit-dose packaging or, if packaged in single-unit doses, the single-unit-dose  
57 packaging is unopened.

58 (b) The cancer drug bears an expiration date that is later than 6 months after the date that the  
59 drug was donated.

60 (c) The cancer drug or supplies needed to administer a cancer drug are not adulterated or  
61 misbranded, as determined by a pharmacist who must inspect the drug or supplies before it can  
62 be dispensed.

63 The drugs accepted under the program may be distributed to another participating physician's  
64 office, pharmacy, hospital or health clinic for dispensing.

65 Nothing in this section shall be construed as prohibiting a pharmacy or medical facility from  
66 accepting drugs that are not eligible to be dispensed under the drug repository program for the  
67 proper disposal of those drugs.

68 Section 5. Storage, distribution and fees. (a) A pharmacy or medical facility that accepts  
69 donated cancer drugs under the program shall comply with all applicable provisions of Federal  
70 and State law relating to the storage, distribution and dispensing of cancer drugs.

71 (b) The cancer drugs dispensed through the program shall only be dispensed pursuant to a  
72 prescription issued by a prescribing practitioner.

73 (c) A pharmacy or medical facility may charge a handling fee for distributing or dispensing  
74 cancer drugs under the program. The fee shall be established in regulations promulgated by the  
75 Board.

76 Section 6. Immunity. (a) Unless a pharmaceutical manufacturer exercises bad faith, the  
77 manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or  
78 property for matters related to the donation, acceptance, or dispensing of a cancer drug or supply  
79 manufactured by the manufacturer that is donated by any person under this Act, including  
80 liability for failure to transfer or communicate product or consumer information or the expiration  
81 date of the donated cancer drug or supply.

82 (b) Except as provided in Section 6(c), a pharmacy or medical facility participating in the  
83 program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner  
84 administering a drug or supply pursuant to the program, or the donor of a cancer drug or supply  
85 is immune from civil liability for an act or omission that causes injury to or the death of an  
86 individual to whom the cancer drug is dispensed and no disciplinary action shall be taken against  
87 a pharmacist or practitioner so long as the drug or supply is donated, accepted, distributed, and  
88 dispensed in accordance with the requirements of this section.

89 (c) The immunity or the prohibition of a finding of guilty of unprofessional conduct under  
90 Section 6(b) does not extend to the donation, acceptance, distribution, or dispensation of a cancer  
91 drug or supply by a person whose act or omission involved reckless, wanton, or intentional  
92 misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

93 SECTION 7. In consultation with the Department, the Board shall establish rules and  
94 regulations governing the drug repository program that establish all of the following:

95 Eligibility criteria for pharmacies and medical facilities to receive and dispense donated drugs  
96 under the program.

97 Standards and procedures for accepting, safely storing, and dispensing donated cancer drugs or  
98 supplies needed to administer cancer drugs.

99 Standards and procedures for inspecting donated cancer drugs or supplies needed to administer  
100 cancer drugs to determine whether the drugs or supplies are in their original, unopened sealed  
101 and tamper-evident unit-dose packaging or, if packaged in single-unit doses, the single-unit-dose  
102 packaging is unopened.

103 Standards and procedures for inspecting donated cancer drugs or supplies needed to administer  
104 cancer drugs to determine that the drugs or supplies are not adulterated or misbranded and are  
105 safe and suitable for dispensing;

106 Eligibility criteria for individuals to receive donated cancer drugs or supplies needed to  
107 administer cancer drugs. The standards shall include a method to determine priority of eligible  
108 patients under the program.

109 A means, such as an identification card, by which an individual who is eligible to receive  
110 donated cancer drugs or supplies needed to administer cancer drugs may demonstrate eligibility  
111 to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

112 A form that an individual receiving a drug from the repository must sign before receiving the  
113 drug to confirm that the individual understands the immunity provisions of the program;

114 A formula to determine the handling fee that pharmacies, hospitals, and nonprofit clinics may  
115 charge to drug recipients to cover restocking and dispensing costs;

116 A list of cancer drugs and supplies to administer cancer drugs, arranged either by category or by  
117 individual drug or supply, that the repository will accept for dispensing.

118 A list of cancer drugs and supplies to administer cancer drugs, arranged either by category or by  
119 individual drug or supply, that the repository will not accept for dispensing. The list must include  
120 a statement that specifies the reason that the drug or supplies are ineligible for donation.

121 Any other standards and procedures the Board considers appropriate.