SENATE DOCKET, NO. 2305 FILED ON: 8/14/2017

SENATE . . . . . No. 2159

The Commonwealth of Massachusetts

PRESENTED BY:

Richard J. Ross

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 to improve patient access to cancer clinical trial programs.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	
Richard J. Ross	*Norfolk, Bristol and Middlesex*	
Carmine L. Gentile	*13th Middlesex*	*12/4/2017*
James B. Eldridge	*Middlesex and Worcester*	*12/5/2017*
Randy Hunt	*5th Barnstable*	*12/6/2017*

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SENATE . . . . . No. 2159

By Mr. Ross, a petition (accompanied by bill, Senate, No. 2159) (subject to Joint Rule 12) of Richard J. Ross, Carmine L. Gentile, James B. Eldridge and Randy Hunt for legislation to improve access to cancer clinical trial programs. Public Health.

The Commonwealth of Massachusetts

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

An Act to improve patient access to cancer clinical trial programs.

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 of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by adding the following section:-

Section 237. (a) The general court finds and declares that:

(1) A resident of the commonwealth will be diagnosed with cancer approximately every 14 minutes, and every 41 minutes a resident of the commonwealth will die of cancer. African American residents of the commonwealth, in particular, face higher rates of cancer incidence and mortality compared to other races and ethnicities. The commonwealth ranks 45th in the nation for cigarette smoking and 46th in the nation for obesity, two factors that lead to increased risk of cancer.

(2) The ability to translate medical findings from research to practice relies largely on having robust and diverse patient participation in cancer clinical trials. A low participation rate or a homogenous participant group prevents segments of the population from benefitting from

advances achieved through clinical research and creates uncertainties over the applicability of research findings.

(3) Diverse patient participation in a clinical trial depends, in part, on whether a participant can afford ancillary costs like transportation, childcare, or lodging during the course of his or her participation. A national study in 2015 found that patient households making less than $50,000 annually were almost 30 percent less likely to participate in clinical trials.

(4) This disparity threatens one of the most basic ethical underpinnings of clinical research, the requirements that the benefits of research be made available equitably among all eligible individuals.

(5) According to the National Cancer Institute, Cancer Clinical Trials Resource Guide, some of the barriers preventing individuals with cancer or at high risk of developing cancer from participating in clinical trials are direct and indirect financial and personal costs, including travel and child care expenses.

(6) While the United States Food and Drug Administration (FDA) has recently confirmed to Congress that reimbursement of direct patient incurred expenses is not inducement, many organizations, pharmaceutical companies, philanthropic individuals, charitable organizations, government entities, and others still operate under the understanding that such reimbursement could be considered inducement.

(7) It is the intent of the general court to enact legislation that would therefore further define and establish a clear difference between what is considered “inducement” for a patient to participate in a clinical trial and the reimbursement of expenses for participating in a cancer clinical trial.

(8) Therefore, new, additional, and further clarification of the FDA's confirmation is appropriate and important in order to improve cancer clinical trial participation, which is the primary intent of this legislation.

(b) As used in this section, the following words shall have the following meanings:

"Cancer clinical trials", research studies that test new cancer treatments on people, including but not limited to medications, chemotherapies, stem cell therapies, and other new treatments.

"Inducement", paying a person money, including a lump sum or salary payment, to participate in a cancer clinical trial.

"Patient subject", a person participating in a cancer clinical trial.

(c)(1) Inducement:

(i) All sponsors of cancer clinical trials shall inform potential enrollees at the time of the informed consent process that:

(A) Reimbursement for travel and ancillary costs is available to all enrollees based on financial need;

(B) Reimbursement of travel and ancillary costs is provided to eliminate financial barriers to enrollment in order to retain subjects in the clinical trial; and

(C) Family, friends, or chaperones that attend the cancer clinical trial treatments to support the patient are eligible for reimbursement of their travel and ancillary expenses.

(ii) Reimbursement of these travel and ancillary costs is not considered an inducement to participate in a cancer clinical trial. The reimbursement for travel and ancillary expenses is not considered coercive or exerting undue influence to participate in a trial. It is a means to create parity in clinical trial access and remove a barrier to participation for financially burdened patients.

(2) Government, industry, public and private foundations, corporations, and individuals may offer financial support to cover ancillary costs through their support of third party nonprofit corporations and public charities that seek to increase enrollment, retention, and minority participation in cancer clinical trials.

(3) Reimbursement programs to cover ancillary and travel expenses must be reviewed and approved by the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) in conjunction with their review of the proposed clinical trial. IRBs and IECs must consider whether the reimbursed patients are recruited fairly, informed adequately, and reimbursed. The nature of the ancillary support and general guidelines on financial eligibility must be disclosed in the informed consent process and the reimbursement process must conform to state and federal laws and guidance.

(d) This act shall take effect in 90 days.