CERTIFICATE OF ACKNOWLEDGMENT & SUPPORT

Canada's Right to Try Act

I, _____, Member of Parliament for the constituency of

_____, in the Province of _____,

Canada, hereby certify and acknowledge that I have reviewed the herein enclosed materials, including the draft Right to Try Act (the "Act"), and that I support, in principle, the Act becoming a Federal law in the Dominion of Canada.

Signed this ____ day of _____, 201__.

_____

[signature]

Right to Try Act

Preamble

Whereas the process of approval for life-saving treatments to terminally ill patients in Canada often takes many years;

And whereas patients who have a terminal illness do not have the luxury of waiting until a life-saving treatment receives final approval for its use;

And whereas patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing all available potential life-saving treatments;

And whereas the use of a potential life-saving treatment is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician;

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

Title

1. This Act shall be known as the Right to Try Act.

Definitions

2. In this Act:

a. "approving physician" means a licensed physician, certified as a specialist by the Royal College of Physicians and Surgeons of Canada, whose practice includes the treatment and care of the eligible patient's terminal illness;

b. "eligible patient" means a person who meets all of the following:

i. has a terminal illness;

ii. has considered all other treatment options currently approved by Health Canada;

iii. has received a prescription or recommendation from an approving physician for a potential life-saving treatment;

iv. has given informed consent by any means appropriate to their condition or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given informed consent on the patient's behalf in accordance with any laws of the respective jurisdictions governing substitute decisions; and

v. has documentation from a physician that the person has met the requirements of this subsection;

c. “informed consent” is given when an eligible patient confirms their understanding of all of the following:

i. a general explanation of the currently approved products and treatments, if any, for the terminal illness from which the eligible patient suffers;

ii. a description of the specific proposed potential life-saving treatment that the eligible patient is seeking to use;

iii. a general description of the best and worst potential outcomes of using the potential life-saving treatment and any known risks and side-effects associated with such treatment. If applicable, the description shall include the possibility that new, unanticipated, different, or worse symptoms may result and that death could be hastened by the administration of the proposed potential life-saving treatment;

iv. any costs for which the eligible patient may be responsible.

d. “person” includes a corporation;

e. “potential life-saving treatment” means a drug, biological product, device or process, or any combination of the foregoing, which, in the reasonable professional opinion of an approving physician in their absolute discretion, has the potential or possibility, whether or not remote, to:

i. treat or cure an eligible patient's terminal illness or assist in the alleviation of the symptoms associated with the terminal illness;

ii. extend or prolong an eligible patient’s life;

iii. stop, delay or reverse the progression of the terminal illness and its symptoms;

iv. improve an eligible patient’s quality of life; or

v. advance the research in the treatment of, or the alleviation of the symptoms associated with, the terminal illness;

f. “provider of a potential life-saving treatment” means:

i. a research facility, hospital or other medical institution engaged in investigating a treatment or cure of a terminal illness;

ii. a person who manufactures, imports or distributes a drug, biological product, or device which could be used in the treatment of a terminal illness; or

iii. any;

A. physician, nurse, pharmacist or other regulated health provider; or

B. other person as prescribed by the regulations

who is involved, either directly or indirectly, in the administration, dispensing, prescribing or delivery of the potential life-saving treatment; and

g. "terminal illness" means an irremediable and incurable disease for which there is no life-saving treatment. For greater certainty, the natural death of a patient suffering from a terminal illness must be reasonably foreseeable.

Provision of Potential Life-Saving Treatment

3. A provider of a potential life-saving treatment may make available or administer a potential life-saving treatment to eligible patients under this Act. This Act does not require that a provider of a potential life-saving treatment make available its potential life-saving treatment to an eligible patient.

4. A provider of a potential life-saving treatment shall have the discretion to devise the conditions, processes and parameters of the administration and delivery of the potential life-saving treatment to an eligible patient. Such conditions, processes and parameters shall include, but not be limited to, the determination of the proper dosing and method of delivery of the potential life-saving treatment, the performance of any necessary tests or examinations and the proper monitoring of the eligible patient's health. A provider of a potential life-saving treatment may administer and deliver a potential life-saving treatment to one or more eligible patients, in accordance with this Act, in the form of an experimental trial to evaluate the safety, tolerability, efficacy and therapeutic benefit of a potential life-saving treatment.

5. A provider of a potential life-saving treatment may:

a. provide a potential life-saving treatment to an eligible patient without receiving compensation; or

b. require an eligible patient to pay the costs of or associated with the manufacture, administration or delivery of the potential life-saving treatment.

This section does not require a health care insurer to provide coverage for the cost of any potential life-saving treatment. A health care insurer may provide coverage for a potential life-saving treatment.

No Liability

*[**ntd** - provinces may have to amend legislation regulating the practice of medicine to ensure that professional licences won't be revoked when acting in accordance with this Law]*

6. Except in the case of gross negligence or willful misconduct, any provider of a potential-life saving treatment to an eligible patient with a terminal illness in accordance with this Act shall not be:

a. liable in any civil action; or

b. held criminally responsible pursuant to any law or regulation

for any loss, damage, injury or death arising out of, relating to, or resulting from advice given or recommendations made to an eligible patient, the design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration or use of the potential life-saving treatment or for the safety or effectiveness thereof.

*[**ntd** - provinces may have to amend legislation regulating the practice of medicine to address exemption from malpractice claims and provincial offences when acting in accordance with this Law]*

Filing of Information

7. A provider of a potential life-saving treatment must, in accordance with the regulations, provide the information described in section 4 respecting the administration, delivery and use of a potential life-saving treatment, together with such other information required by those regulations, to the recipient designated in those regulations.

Approval for General Use

8. A potential life-saving treatment of a terminal illness may be approved for general use in Canada, subject to and in accordance with any conditions prescribed by the regulations.

Conflict

9. In the event of a conflict between this Act and any other law enacted by the Parliament of Canada, including, but not limited to, the Food and Drug Act, R.S. c. F-27, the Canada Health Act, 1984 c. 6 and the Criminal Code, R.S. C-34, the provisions of this Act shall prevail.

Regulations

10. The Minister of Health must make regulations:

a. prescribing additional persons as providers of potential life-saving treatment for the purposes of subparagraph 2(d)(iii)(B) and the conditions under which they may provide treatment; and

b. respecting the filing of information by a provider of a potential life-saving treatment pursuant to section 7; and

c. prescribing the conditions under which a potential life-saving treatment may be approved for general use in Canada pursuant to section 8.

Offence and Punishment

11. Any provider of a potential life-saving treatment who knowingly fails to comply with this Act or the regulations,

a. is guilty of an indictable offence and liable to a term of imprisonment of not more than two years;

b. is guilty of an offence punishable on summary conviction; or

c. is liable to pay a fine which shall not exceed * * * dollars ($* * *).

*[**ntd -** to determine amount of fine]*

Adaptive Canuck ALS Foundation

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28 October 2016

Attention: The Government of Canada
House of Commons
Ottawa, Ontario
K1A 0A6 Canada

Re: Right to Try Act

As young people diagnosed with Amyotrophic Lateral Sclerosis ("ALS"), we are writing this on behalf of other Canadians who have also fallen victim to this and other horrendous diseases. We have had numerous discussions with other ALS patients, and, based on those conversations, have endeavoured to draft a document which we hope, after passing through the proper parliamentary channels, will soon become a law. A copy of the proposed law is enclosed with this letter. We who are afflicted with terminal illnesses are acutely aware that time is our enemy.

In this letter we hope to summarize the substance and purpose of the proposed Right to Try legislation. As the writers of this letter have been diagnosed with ALS, the Right to Try Act will be analyzed primarily using this disease as a point of reference.

The Right to Die and the Right to Try

In 2015 the Supreme Court of Canada ruled that an existing law which banned the assisted suicide of terminally ill patients (predicated on the Rodriguez v British Colombia (AG) decision) was unconstitutional and violated Section 7 of the Canadian Charter of Rights and Freedoms. Voluntary euthanasia was to be made available to "a competent adult person who (1) clearly consents to the termination of life and (2) has a grievous and irremediable medical condition (including an illness, disease or disability) that causes enduring suffering that is intolerable to the individual in the circumstances of his or her condition." Justice Minister Jody Wilson-Raybould tabled a bill in April of 2016 to make an amendment to the Criminal Code of Canada allowing for medically assisted suicide. Bill C-14 was further amended after Carter v Canada (AG) to include "only patients suffering from and incurable illness whose natural death is 'reasonably foreseeable...'. On June 17th, 2016, Bill C-14 received royal assent, becoming law.

It is the intention of the Right to Try Act to offer terminally ill patients another option: the right to try unapproved, potential life-saving drugs and/or treatments before deciding whether to access the right afforded under Bill C-14.

There are some who might argue that a potential life-saving drug or treatment might be harmful and hasten the 'reasonably foreseeable' death of the terminally ill patient. But eligible patients (as defined in the Act) who have given informed consent should have the right to attempt to improve and or/extend the life that is left to them. We intend to work closely with approved physicians. We will rely on their guidance and advice, but the Act will protect and absolve them from liability (except in cases of gross negligence) for any risks or direct consequences to which the patient may be subjected.

Deficiencies of the Current System

Each year Health Canada receives many applications from universities, hospitals and pharmaceutical companies for permission to run clinical trials. This department uses the results of completed 'pre-clinical' studies to determine which trials should go forward. If approved, the investigators proceed, all the while governed by strict Canadian Regulations and adhering to the tenets of Good Clinical Practice. According to Health Canada's website, the entire process consists of: pre-clinical studies, clinical trials, regulatory product submission, submission review, market authorization decision, public access, and finally, surveillance, inspection and investigation. If the organization funding the research wishes to market the drug in Canada, it must apply for marketing approval, after which it is given a Notice of Compliance (NOC) and a Drug Identification Number (DIN). It is of course necessary to be cautious and vigilant when dealing with any new drug or treatment. But this entire process, from pre-trial to ultimate approval, usually takes years. Years that we, suffering under the tyranny of ALS, do not have.

It is our contention that the clinical trial system does not serve the needs of the terminally ill patient for whom there are no treatments or cures. Unfortunately, participation in most trials is limited to citizens of the country in which they are being run, and there are few trials taking place in Canada at any given time. Every trial requires a control group - a double blind random selection of participants who are given a placebo rather than the drug or treatment being investigated. Under ordinary circumstances the use of control groups to determine the efficacy and safety of any drug or treatment is a necessary part of the scientific process. For those suffering from ALS, for example, the use of a placebo group in drug trials is superfluous. Everyone in that group will decline and die. Another drawback of the trial system as it is currently structured is that even if the treatment does show a benefit to the participant, once the trial is over the treatment is in most cases no longer available to the participant as the drug continues on its way through the approval system.

The Right to Try Act, and section 4 in particular, would permit the provider of a potential life-saving treatment (as defined in the Act) to regard the historical population of ALS patients as the placebo group. Those ALS patients who live the 'normal' lifespan of a healthy person are anomalies: survival times vary between individuals, but ultimately they all die. Time is of the essence in treating those with ALS, so we are proposing 'Pilot' experimental trials (see section 4 of the Act) in which the placebo group is eliminated and where all participants are given varying doses of the treatment. At the end of the trial doctors and non-participating ALS patients could be apprised of the results and could, after being advised

of any possible adverse outcomes, then have access to the treatment if they so choose. It is important to remember that the Right to Try Act applies only to terminally-ill patients who represent a small portion of the country's population. It would have no application to, nor would it in any way interfere with, Health Canada's existing protocol governing clinical trials for non-fatal diseases.

It must be noted that presently Health Canada, through its Special Access Programme (SAP), "allows doctors to gain access to non-marketed drugs and medical devices that have not yet been approved for sale in Canada. Practitioners treating patients with serious or life-threatening conditions may request Special Access in cases where conventional therapies have failed, are unavailable or are unsuitable." However, this program allows access to drugs and devices only: there is no reference made to unusual regimens or the development of stem cell treatments, for example, which have shown promise when used in the fight against a variety of illnesses. The Right to Try Act hopes to streamline access to both drugs and treatment, be they established or unconventional. And as an added benefit to those participating, not only are they being given the opportunity to help themselves, but their willingness to try new and untested treatment could potentially benefit ALS sufferers the world over.

Benefits of the Proposed Legislation

The Right to Try Act will give ALS patients some modicum of control over their circumstances. It ensures that the approving physician will work with the supplier of any potential life-saving treatment as outlined in the Act. The physician can then convey this information to the patient and offer his or her advice as to the possible benefits and drawbacks of participation in a pilot experimental trial. It further requires that the costs of the treatment be made known to the patient from the outset, and that if the patient's consent to pursue the trial is given, it will be fully informed. Furthermore, the Act ensures that the physician will be protected from prosecution in the event of a poor outcome, unless gross negligence is involved.

Under the Act ALS sufferers will be given the opportunity to access 'off label' drugs, in other words, the patient will have the right to try conventional drugs that are usually prescribed for other medical conditions. There are approximately twenty-three states in the American Union that have passed Right to Try legislation. However, those state laws only permit access to drugs which have been through Phase One of the four phase trial system. The threshold under this Act is much more flexible when determining whether a treatment qualifies as a potential life-saving treatment and we believe this an important and necessary distinction. Furthermore, as suggested earlier, this Act would permit the use of a 'Pilot' experimental trial scenario, in which participants may be divided into several groups which are each given varying doses of the treatment or drug. This situation could adequately test the safety, tolerability and efficacy of the new drug or treatment all at once. If such a trial exhibits positive effects on a particular terminal illness, the Minister may consider authorizing them for General Use for other terminally ill patients.

Under the Act approving physicians will have a broader range of tools at their disposal. They will have the opportunity to fully examine a drug or treatment and to decide whether there is any possibility, no matter how remote, that it might be of assistance to their patient. The fact that there may be no guarantee that the procedure will improve or cure the terminally-ill patient is irrelevant: the patient should be

entitled, under a doctor's guidance, to decide whether he or she is willing to take on the risks associated with unapproved treatment. There is likely to be only one question in the mind of a terminally-ill patient in such circumstances. And that is "What have I got to lose?"

The Act will be subject to any filing requirements as determined by the Minister of Health but it also requires the Minister to make such regulations as are deemed necessary for the fulfillment of the provisions contained in it. This Act could pave the way for accelerated approval for the general use of drugs and treatments in any terminal disease, as long as the Minister's conditions (as prescribed by the regulations) are met. We cannot afford to forget that time is of the essence.

Close

We who suffer from ALS and other terminal illnesses are not suffering alone. Our spouses, our children, our parents, siblings and friends are suffering with us. Imagine watching, helpless, as everything is stolen from you, all the while knowing there is nothing and no one 'out there' to help you. In the case of ALS, it happens little by little: each day you are less able to walk, to talk, to eat, to breathe. Surely there cannot be anything more horrific than to be buried alive like this- your mind trapped in a body that is becoming a prison.

The proposed law gives Canada the opportunity to become a global leader in the research and treatment of terminal diseases. Please use all the intelligence, compassion and empathy you possess when considering this proposal. We have faith in you, as representatives of all Canadians, to use your good judgement in a way that will make us proud.

We invite you to visit www.righttotrycanada.com to read more about Canadians suffering with terminal illnesses.

It is our hope that these words will help to save us. Thank you for giving us the opportunity to 'speak'.

Yours very truly,

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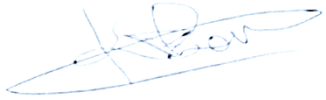

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