Adaptive Canuck ALS Foundation

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11 October 2016

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

c/o Ms. Bernadette Jordan, M.P.
129 Aberdeen Road
Suite 106
Bridgewater, N.S.
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via e-mail: Bernadette.Jordan@parl.gc.ca

Dear Ms. Jordan:

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, potentially 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 potentially 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 potentially 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 a potentially life-saving 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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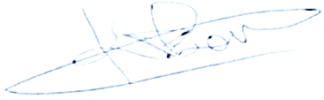

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Diagnosed with ALS in
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