



September 15, 2020

The Honourable Adrian Dix, Minister of Health, British Columbia
hlth.minister@gov.bc.ca

Re: ALS Treatment Options, Care and Research in BC

Dear Minister Dix:

Earlier this year, 15 BC families dealing with ALS sent you two letters setting out in detail how the current treatment and care environment in BC is failing the families who receive this devastating diagnosis every year.

Since that time we have joined together with families across Canada and have formed ALS / SLA Action Canada, a new patient-led advocacy group. We invite you to visit our website (www.alsaction.org), where you can review our ALS Plan, and to follow us on Twitter (@ALSAction) and FaceBook.

ALS / SLA Action Canada

We formed ALS Action Canada because we saw a gap in patient-led advocacy in support of these goals:

- (1) ensuring immediate access to promising therapies, including AMX0035 and NurOwn, once approved in other countries;
- (2) ensuring immediate provincial health care plan coverage for these new ALS therapies;
- (3) bringing more, and better designed, clinical trials to Canada for ALS; and
- (4) increasing the funding of ALS research.

While we support, and are highly appreciative of, the programs and services offered by the ALS Society of BC and other ALS societies across Canada, these societies lack the resources to address all of the priorities of Canadian families dealing with ALS.

In furtherance of the goals noted above, we are also actively working at the federal level, including with Health Canada and the federal multi-party ALS Caucus, which has MP's from BC (e.g. Kerry-Lynne Findlay and Todd Doherty), to drive forward our ALS Plan.

Our Stories

We have also collected stories from more BC families devastated by ALS. See the attached (21 families in total). Most, but not all, of these people are members of our group.

As our stories reflect, we are BC's doctors, firefighters, lawyers, teachers, business owners, executives, managers, tradespeople and home-makers. We are also your neighbours and your friends. Given that ~150 BC families receive an ALS diagnosis every year, we know that these stories represent only the tip of the iceberg.

A Time of Unprecedented Hope

This is a time of unprecedented hope for people with ALS given that:

- there are over 160 drug companies worldwide working in the ALS space.
- there are 60+ ALS clinical trials going on worldwide including several in their final stages.
- in September 2020, Amylyx Pharmaceuticals announced that its drug, AMX0035, slowed the progression of ALS in a clinically meaningful and statistically significant way in a Phase 2 trial. See Jeff Derby's story below.
- the NurOwn Phase 3 trial by Brainstorm Cell Therapeutics will end in October 2020 and many trial participants, including a member of our group, believe it has slowed down, stopped or even reversed their ALS progression. See Ryoichi Hoysoya's story below.
- there has been a breakthrough therapy in the fight against genetic ALS. Chris Snow, the Assistant General Manager for the Calgary Flames, publically announced in December 2019 that he had been diagnosed with ALS in June 2019. Chris has a type of genetic ALS that affects 2 percent of ALS patients and that had already killed his father, two uncles and his 28 year-old cousin. The average life expectancy for this type of ALS is 6 to 18 months. Almost immediately after his diagnosis Chris enrolled in a Phase 3 clinical trial at Sunnybrook Health Sciences Centre in Toronto for those with his type of genetic ALS. Chris has since been able to participate in this same clinical trial out of Calgary. The therapy, tofersen by Biogen, is working in that Chris' ALS progression has essentially stopped since he has been in the trial.

- for the first time ever, innovative new ALS clinical trial formats have been initiated. For example, the HEALEY Trial has started to become operational at 54 sites in the US. The trial, following the oncology model, will test multiple therapies and is highly-patient-centric in its design. The trial administrators want to bring the trial and/or therapies to Canada and have commenced discussions with the Montreal Neurological Hospital (“MNH”) in this regard. The trial would be overseen by the MNH in Canada but could be expanded to other provinces including BC. ALS platform trials are also being initiated in the UK, Europe and Australia.

A Time of Unprecedented Mobilization and Advocacy in the US

This is also a time of unprecedented patient-led mobilization and advocacy concerning the need for ALS treatments. By way of example in January 2019, I AM ALS.org was launched by lawyer and former President Obama staffer and federal prosecutor, Brian Wallach who was diagnosed with ALS in 2017. Brian was profiled in People Magazine and on the Today Show and CNN, among other national media outlets, and now has 50,000 followers on Twitter. I AM ALS has received support from President Obama and the Obama Foundation, Joe Biden and the Chan–Zuckerberg Initiative. It has placed ads in Times Square and has been an instrumental player in most major ALS announcements and legislative developments over the last 12 months.

A Time of Unprecedented Political Leadership in the US

The patient-led mobilization and advocacy has led to unprecedented political and legislative action in the US. By way of example:

- A bi-partisan House of Representatives ALS Caucus was formed in June 2019 and now has over 130 members. A bi-partisan Senate ALS Caucus was formed in January 2020 and has 18 members. As a result, almost 30% of the members of Congress are part of an ALS caucus.
- In May 2020, a bipartisan bill (*Accelerating Access to Critical Therapies for ALS Act*) was introduced in the House of Representatives that will create an infrastructure to fund early access to promising therapies discovered through clinical trials for patients suffering from fast-progressing neurodegenerative and terminal diseases like ALS. Specifically, it will make \$75 million available in FY 2021 and 2022 for a pilot program to support expanded access programs. It will bring treatments for rapidly progressing neurodegenerative diseases to patients beyond the ongoing clinical trial and establish a Center of Excellence for Neurodegenerative Diseases at the FDA to accelerate the development and approval of therapies for neurodegenerative diseases.
- Also in May 2020 a bill (*Promising Pathway Act*) was introduced in the Senate that will speed up the regulatory processes for getting drugs showing benefits to the patients who need them. The bill requires the FDA to establish a rolling, real-time, priority review pathway to evaluate provisional approval applications for drugs intended to treat, prevent, or diagnose serious or life-threatening diseases or conditions, including those that pose a threat of epidemic or pandemic. Under this pathway, provisional approval would be granted by the FDA to drugs demonstrating substantial evidence of safety and relevant early evidence of positive therapeutic outcome(s).

After 100+ years and tens of thousands of deaths, we think it's time for this same commitment, urgency and compassion to be shown to Canadians living with ALS.

Our Requests

Against this backdrop, we reiterate our requests for improved treatment options, care and research in BC. Specifically, we request that:

1. The BC ALS Centre of Excellence ("COE"), initiated by the ALS Society of BC, be fully operational by March 31, 2021, such that people in BC with ALS no longer have to travel out of province / out of country to receive treatment and thus hope. The Ministry of Health's recent announcement that the COE would be developed over the next *five years* cannot be reconciled with the fact that ~150 new BC families are diagnosed with ALS each year and 80% of people diagnosed with ALS currently die within two to five years. It also cannot be reconciled with our stories below.

We specifically request that immediate and sufficient ongoing funding be provided to transform the ALS Clinic at the GF Strong Rehabilitation Centre into the COE envisioned by the ALS Society of BC, which includes having:

- a. the COE located at the Centre for Brain Health at UBC;
 - b. a full-time COE director / neurologist leading the COE;
 - c. clinical trials;
 - d. sufficient staff to ensure that people who receive a preliminary diagnosis of ALS can get an appointment at the COE within two weeks of that diagnosis; and
 - e. a website with robust information about treatment options and clinical trials.
2. Best efforts be used to bring the HEALEY ALS Platform Trial to the COE in 2021.
 3. BC expedite the approval of new ALS therapies for coverage under the provincial formulary. The recent announcement that BC would cover Radicava was welcome but the facts are:
 - a. this approval came 22 months after Health Canada approved Radicava's use in Canada;
 - b. BC was the third to last province to announce that it would cover the drug; and
 - c. BC waited four months after the cost negotiations with the drug manufacturer had concluded before approving it (in contrast, Quebec made

the announcement one week after the negotiations concluded).

- d. the eligibility criteria established for coverage will result in many British Columbians with ALS not having access to Radicava despite it being only one of two drugs currently available to treat ALS.

If AMX0035, NurOwn and other therapies are approved by Health Canada in 2020 or 2021, BC families simply cannot wait almost two years for these therapies to be approved for coverage in BC.

4. Provide consistent and sufficient funding to the ALS Society of BC to operate their patient service/quality of life programs, so that all money raised by the societies through community fundraising can be directed to research, therapy development and clinical trials.
5. Directly fund ALS research in a meaningful and ongoing way.

More generally, we ask that BC move from the back of the pack to the front of the pack and take on a leadership role in ALS care, treatment options and research by working with Health Canada, the federal ALS Caucus and Health Ministers in other provinces to give hope to the 1,000 families in Canada that are given this diagnosis every year.

Conclusion

As we stated in our previous letters, we, along with our families, friends and communities, no longer accept the status quo which has rendered us expendable for so many decades and which has seen ALS patients in BC receive substandard care for far too long. Our lives are as important as the lives afflicted by COVID-19 and cancer.

The ALS clock is constantly ticking. We look forward to the Government's commitment to our requests. We would also like to have a Zoom call with you at your earliest convenience so that you can hear directly from ALS patients. Given our previous correspondence we would kindly request a response by September 30, 2020.

Yours truly,

Deane Gorsline, Chair, ALS Action Canada
[email redacted]

Greg Gowe, North Vancouver
[email redacted]

Kerry Winkler, West Vancouver
[email redacted]

Rick Wilson, South Surrey
[email redacted]

cc: Andrew Wilkinson, Q.C. Leader of the Opposition
Norm Letnick, Opposition Health Critic
Sonia Furstenuau, Leader, Green Party of British Columbia

Our ALS Stories

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[SEE "CANADA'S ALS STORIES" ON OUR WEBSITE]

[www.alsaction.org]