Your Name

First Line Address

Second Line Address

Town, State, ZIP

Date:

Dear Congressman_____/ Dear Senator _____,

I am writing to you today as one (or on behalf) of the 30,000 Americans living with ALS. I use the term living loosely since ALS is a rapidly progressing Neurodegenerative disease that takes a person's ability to walk, talk, breath and eventually leads to total paralysis and death within 2-4 years. There are no clinically meaningful treatments. Military Veterans have 2 times to risk of developing ALS.

The FDA has been working on an ALS Guidance Document since 2013. In 2018, the FDA issued a draft guidance that offered no innovation in the development of therapies for ALS. During the open public comment period, over 1400 comments were made all opposed to the draft guidance as issues. There have been at least 5 meetings between ALS advocates and the FDA discussing the document and asking for it to be released. It was promised to be completed by June and that deadline was missed again. In an Advocate meeting in June, Janet Woodcock, M.D. stated that the FDA was short-staffed and that is the reason they had not completed the document. Without this document, clinical trials for ALS will remain inhumane with placebo controls. Our first ask of you is to contact the FDA and demand the release of the ALS Therapy Guidance Document.

The second issue we will bring to your attention and ask for assistance is the FDA system that addresses Drug development. There is no system in place to address the urgent medical need of an always fatal disease like ALS. There is a promising therapy in development called NurOwn being developed by a small biopharma. It gained Fast track approval in 2014. It is

now in the middle of an archaic Phase 3 trial for 200 patients that is placebo-controlled. 100 patients are made to undergo a procedure called a bone marrow transplant, 7 lumbar punctures and 14 trips for the study to receive a placebo while dying for ALS. This is simply inhumane. This is the 4th trial for this therapy and it is showing promising results. We have asked the FDA to use accelerated approval to approve it immediately, we have asked for an interim analysis of the current phase 3 trial and they stated that BrainStorm has to ask for the analysis and take a penalty if it is not successful jeopardizing the whole trial, we have asked the FDA to consider the trial enrolled now with the number of patients currently enrolled to expedite the process. Thus far, all have been denied. We request you ask the FDA to waive the penalty for the interim analysis and/or complete enrollment in the trial with the number of patients enrolled now. We ask that you reach out to BrainStorm Cell Therapeutics to encourage them to go to the FDA to work together to expedite this promising therapy for those of us who do not have time to wait for this bureaucratic process.

We are asking you to help us with our unalienable rights of life that the FDA holds in its power to help us keep by a few actionable steps. We look forward to hearing back from you and finding ways to change the outcome of ALS.

Respectfully,

(enter your name)