# Timeline of FDA's Creation of ALS Guidance

February 25, 2013: FDA hosts a one-day meeting on ALS drug development: *Considerations Regarding Food and Drug Administration Review of Amyotrophic Lateral Sclerosis*; its first public meeting on the topic.

May 2015: The National ALS Association (ALSA) announced it would spend $500,000 raised from the Ice Bucket Challenge in order to submit draft guidance to FDA in the first quarter of 2016.

May 2016: ALSA finishes its first draft of its ALS guidance and requests public comment, committing to getting the finalized guidance released.

September 20, 2016: People with ALS (pALS) and caregivers for people with ALS (cALS) Advisory Council (PCAC) sends a letter to Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), about the ALS FDA draft guidance.

August 2017: The community-led ALS guidance document is completed and submitted to the FDA.

February 15, 2018: The FDA publishes its draft guidance, *Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment.*

March 19, 2018: ALS Patient and Caregiver Advisory Committee (PCAC) met with FDA leaders with recommendations for draft guidance.

April 2018: 1,475 comments are submitted to the public docket regarding FDA's draft guidance. Most, if not all, of these comments are opposed to the document.

May 19, 2018: ALS pALS/cALS meets with Dr. Billy Dunn, the Director of the Division of Neurology Products in CDER's Office of New Drugs.

July 4, 2018: Cory Burell, a person with ALS who is now deceased, creates an ALS community survey which includes 615 participants. The feedback was sent to be included in the July 12th ALSA-FDA workshop, but was not presented.

September 2018: ALSA sends its recommendations to FDA to revise its document to reflect ALS advocates' call to action.

November 2018: Members of the U.S. House of Representatives send a letter to the FDA urging the agency to reply to pALS about revisions to its draft guidance document.

February 11, 2019: pALS & cALS meet with 14 FDA leaders to discuss the plight of ALS patients. The agency agrees to communicate its revisions of its guidance document within two months.

April 2019: Congressman Jason Crow (D-CO) sent a letter to the FDA voicing concerns about the agency's delay in issuing its guidance and requesting a timeline for release.

May 24, 2019: Senators James Inhofe (R-OK) and Ron Johnson (R-WI) send a letter to the FDA voicing concerns about the agency's delay in issuing its guidance and requesting a timeline for release.

June 12, 2019: ALS advocates protest FDA over its failure to provide information on its updated guidance.

July 2019: Brian Wallach, co-founder and CEO of I AM ALS and a person living with ALS, and Dan Tate, a person living with ALS, deliver two community-developed petitions to FDA to request the agency release its guidance.

September 23, 2019: The finalized FDA ALS Guidance Document: *Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment* is published.

September 26, 2019: I AM ALS Clinical Trials team meet with FDA leaders, including FDA Commissioner, Dr. Sharpless to review finalized guidance and request support of person living with ALS (pALS) in future IND meetings.