

September 24, 2019

The Honorable Lindsey Graham
Chairman
U.S. Senate Committee on the Judiciary
Washington, DC 20510

The Honorable Dianne Feinstein
Ranking Member
U.S. Senate Committee on the Judiciary
Washington, DC 20510

Dear Chairman Graham and Ranking Member Feinstein:

As representatives of the 30 million Americans living with rare diseases, our organizations write to urge you to take steps to protect the lives of individuals with rare diseases and their caregivers who come to the United States to participate in clinical trials or receive life-saving care. The Department of Homeland Security's United States Citizenship and Immigration Services (USCIS) recently announced a policy shift that left these individuals facing deportation. Although USCIS apparently indicated to Congress that it intends to reverse this policy shift¹, this sequence of events has underscored a failure of policy to protect those rare disease patients that have come to the United States to participate in clinical trials.

Rare diseases are defined as diseases affecting fewer than 200,000 in the United States.² Even with all of the advances that the rare disease community has benefited from as a result of the landmark 1983 Orphan Drug Act, over 90 percent of the approximately 7,000 known rare diseases still do not have a treatment indicated specifically for the disease that has been approved by the Food and Drug Administration (FDA).³ Thus, there is still a great deal of research necessary to discover treatments and cures for these thousands of rare diseases. Many patients with rare diseases do not reside in the United States. Diagnosis and identification of rare disease patients can pose considerable challenges for entities in the United States seeking to conduct clinical trials on these small patient populations. It is in the collective interest of not only the rare disease community but of all Americans to ensure that if additional rare disease patients are needed for a trial, patients and their caregivers who are willing and able to come to the United States to participate do not face any barriers to doing so. Further, after having participated in the trial and advanced our collective scientific understanding of a disease, these individuals should be permitted to remain in the United States to continue receiving care without ever facing the threat of deportation if the treatment in question is not available in their country of origin.

Since the 1970s, USCIS has exercised prosecutorial discretion in the form of "deferred action" for individuals in exigent circumstances, including those with serious medical conditions and their caregivers. Under deferred action, individuals may remain in the United States without the threat of immediate deportation. Through granting of deferred action, these immigrants with rare diseases and their caregivers have been able to remain in the United States and access life-

¹Miriam Jordan, *Deportation Exemptions to Resume for Immigrants Needing Medical Treatment*, New York Times, September 19, 2019. <https://www.nytimes.com/2019/09/19/us/deferred-action-immigrants-deportation.html?searchResultPosition=1>

²21 C.F.R. § 316

³IQVIA. "Exclusivity, Pricing and Treated Populations." *Orphan Drugs in the United States*, December 18, 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf?_=1568137089860.

sustaining, if not life-saving, care. During this time, many of these individuals also have been permitted to gain employment or enroll in school and have been able to live full lives.⁴

On August 7, 2019, USCIS stopped adjudicating requests for deferred action, retroactively and without any notice, to all of those living in the United States under the auspices of this long-standing process. In so doing, USCIS essentially pulled out the rug from under vulnerable families and individuals across the country. At that time, USCIS stated that the granting of deferred action under these conditions would be handled only by Immigration and Customs Enforcement (ICE), despite the fact that ICE generally does not consider requests of this nature until after immigration removal proceedings.⁵

Testimony from USCIS at a September 11, 2019, hearing before the House Oversight and Reform Subcommittee on Civil Rights and Civil Liberties added further confusion to the situation.⁶ During the hearing, USCIS could not provide a date for resolution of the re-opened cases, clarity on the fate of future deferred action requests, or indication of a policy going forward. On September 19, USCIS apparently informed the House Oversight and Reform Committee that it would resume consideration of requests for deferrals. Although this is a positive development, the events over the last few weeks have illustrated the risks of leaving any Administration with the sole authority to adjudicate—or opt not to adjudicate—deferred action requests that dictate whether individuals with rare diseases having entered the United States to participate in a clinical trial may remain in the United States.

Sometimes, if unable to conduct international trials, researchers seeking to develop orphan therapies must seek out patients from across the world to participate in clinical trials in the United States. This participation in clinical trials advances research that can help improve or save the lives of Americans living with rare diseases. Having contributed to our overall knowledge of disease progression and etiology, we believe rare disease patients who have participated in a clinical trial should not be forced to rely solely on a B-2 or other visa to remain in the United States merely for the duration of the trial but should, instead, be able to count on a path toward legal residence if necessary to continue treatment.

Under the current system of relying on the discretion of the Administration to adjudicate deferred action requests, those with rare diseases who come to the United States to advance our science and participate in a clinical trial will continue to face uncertainty as to whether they can remain in the United States to receive treatment. We should not be endangering the lives of individuals with rare diseases that have been asked, and have agreed, to expose themselves to experimental therapies to help save the lives of those living with rare diseases.

⁴ Contreras, January. “Deferred Action: Recommendations to Improve Transparency and Consistency in the USCIS Process.” Citizenship and Immigration Services Ombudsman. U.S. Department of Homeland Security, July 11, 2011. <https://www.dhs.gov/xlibrary/assets/cisomb-combined-dar.pdf>.

⁵ “AILA - Featured Issue: USCIS’s Elimination of Non-Military Deferred Action at Local USCIS Offices.” American Immigration Lawyers Association, n.d. <https://www.aila.org/advo-media/issues/all/featured-issue-usciss-elimination-of-non-military>.

⁶ House Committee on Oversight and Reform, Subcommittee on Civil Rights and Civil Liberties. September 11, 2019 hearing: “The Administration’s Apparent Revocation of Medical Deferred Action for Critically Ill Children.” <https://oversight.house.gov/legislation/hearings/the-administration-s-apparent-revocation-of-medical-deferred-action-for>.

We urge you to consider legislation that would establish a pathway to legal immigration for those with rare diseases that have participated in a clinical trial in the United States and their caregivers. The recent actions by USCIS threatened the lives of rare disease patients who depend on care and treatments that, in many cases, can only be found in the United States. We urge Congress to take action to better protect the lives of those vulnerable people living with rare diseases, and their caregivers, who have participated in clinical trials. Our organizations stand ready to assist you in developing and advancing legislation that would attain these goals.

Sincerely,

A Cure In Sight
Adult Polyglucosan Body Disease Research Foundation
AKU Society of North America
American Behcet's Disease Association
Association for Creatine Deficiencies
Autoinflammatory Alliance
Cauda Equina Foundation, Inc.
Chloe's Fight Rare Disease Foundation
CMTC-OVM
Congenital Hyperinsulinism International
COPA Syndrome Foundation
Cure CMD
Cure HHT
Dreamsickle Kids Foundation
Familial Dysautonomia Foundation
Fat Disorders Resource Society
FOXG1 Research Foundation
Friedreich's Ataxia Research Alliance (FARA)
GRIN2B Foundation
International Pemphigus and Pemphigoid Foundation
Jansen's Foundation
Li-Fraumeni Syndrome Association
Lung Transplant Foundation
M-CM Network
Melanoma Research Foundation
MLD Foundation
Moebius Syndrome Foundation
National Ataxia Foundation
National Brain Tumor Society
National Niemann-Pick Disease Foundation, Inc.
National PKU News
National Tay-Sachs & Allied Diseases Association (NTSAD)
NBIA Disorders Association
National Organization for Rare Disorders
Phelan-McDermid Syndrome Foundation
Recurrent Respiratory Papillomatosis Foundation

Remember The Girls, Inc.
Rothmund-Thomson Syndrome Foundation
RYR-1 Foundation
SETBP1 Society
Snyder-Robinson Foundation
TargetCancer Foundation
Williams Syndrome Association
Worldwide Syringomyelia & Chiari Task Force