Statement of the National Organization for Rare Disorders (NORD)
Hearing on "The Administration's Apparent Revocation of Medical Deferred Action for Critically Ill Children"
U.S. House of Representatives
Committee on Oversight and Reform
Subcommittee on Civil Rights and Civil Liberties

The National Organization for Rare Disorders (NORD) applauds the House Committee on Oversight and Reform's Subcommittee on Civil Rights and Civil Liberties for holding this important hearing on "The Administration's Apparent Revocation of Medical Deferred Action for Critically Ill Children." This is an issue of great concern for many in the rare disease community. NORD is deeply troubled by the recent actions of this Administration that jeopardize the lives of immigrants with rare diseases receiving the care they need in the United States.

Founded in 1983, NORD is the leading independent nonprofit organization representing the 25 to 30 million Americans with rare diseases. NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

Since the 1970s, the United States Citizenship and Immigration Services (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-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.[1]

Rare diseases are defined in statute 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 Orphan Drug Act, over 90% 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 those in the United States seeking to conduct clinical trials

[1] 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.
[2] 21 C.F.R. § 316
[3] IQVIA. "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.

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, once identified, rare disease patients and their caregivers who are willing and able to come to the United States 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.

Yet on August 7, 2019, USCIS abruptly decided to stop adjudicating requests for deferred action, retroactively and without any notice, to all of those immigrants 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. On September 2, 2019, USCIS announced that it would re-open cases for deferred action that were pending on August 7, 2019. While NORD hopes that this change reflects an overall rethinking of this misguided step to end USCIS' role in affirmatively adjudicating deferred action requests before patients and their families have been placed into removal proceedings, there has been no indication that this is the case, particularly for those cases that were not pending on August 7, 2019. The vast majority of those impacted by this sudden change in policy are now living with uncertainty as to whether they can remain in the United States, further exacerbating the stress of living with a rare disease.[4]

As a part of its decision, USCIS has stated that the granting of deferred action under these conditions will now be handled only by Immigration and Customs Enforcement (ICE). Yet ICE has stated that it does not have, and will not gain, the capacity to handle these requests prior to removal proceedings.[5] Rather, ICE generally does not consider requests of this nature until after immigration removal proceedings.[6]

NORD urges USCIS to immediately reinstate adjudication of affirmative deferred action requests so that the lives of immigrants with rare diseases who are receiving needed medical care in the United States are not critically endangered by uncertainty and a lack of treatment. But that is not enough. Deferred action is temporary in nature and does not provide a path to citizenship. It is merely a tool used to allow flexibility in law enforcement. Thus, this sudden policy shift by the Administration has highlighted a greater problem beyond the scope of the kind of deferred action at issue here.

Foreigners with rare diseases who are willing to participate in clinical trials for orphan drugs and advance research that can help improve or save the lives of Americans ought to be provided with opportunities for legal residence themselves. Having contributed to our overall knowledge of disease progression and etiology, NORD believes immigrants who have participated in a clinical trial for an orphan drug should not be forced to rely solely on a visa to

[4] "USCIS Re-Opens Previously Pending Deferral Requests." USCIS, September 2, 2019. https://www.uscis.gov/news/alerts/uscis-re-opens-previously-pending-deferral-requests.
[5] Dooling, Shannon. "Feds Can't Agree On Which Agency - If Any - Handles Medical Deportation Deferrals." Feds Can't Agree On Which Agency - If Any - Handles Medical Deportation Deferrals | WBUR News. WBUR, August 28, 2019. https://www.wbur.org/news/2019/08/28/ice-uscis-immigrants-medical-deferred-action.
[6] "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.

remain in the United States for the duration of the trial but should, instead, be able to count on a path toward legal residence. NORD urges this Committee to work with other congressional committees to establish, in legislation, a pathway to legal immigration that permits those with rare diseases that have participated in a clinical trial for an orphan drug in the United States and their caregivers to remain legally and permanently in the United States. Further, Congress should consider additional pathways for individuals with rare diseases seeking life-saving care in the United States that cannot be obtained in their country of origin.

The actions of the Administration have injected dangerous uncertainty and 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.

NORD stands ready to assist this Subcommittee, the full Committee, and other members of Congress, in addressing this problem.