RDDC
THE RARE DISEASE DIVERSITY COALITION

October 27, 2021

The Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker of the House
United States House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
United State House of Representatives
Washington, DC 20515

The Honorable Ron Wyden
Chairman
Senate Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Richard Neal
Chairman
House Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

The Honorable Michael Crapo
Ranking
Senate Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Kevin Brady
Ranking
House Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

Dear Majority Leader Schumer, Speaker Pelosi, Minority Leader McConnell, Minority Leader McCarthy, Chairman Wyden, Ranking Crapo, Chairman Neal, and Ranking Brady:

The purpose of this letter is to voice our strong opposition to the changes to the Orphan Drug Tax Credit (ODTC) proposed in Sec. 138141-- "Credit for Clinical Testing of Orphan Drugs Limited to First Use or Indication" -- of the House Ways and Means Committee-reported reconciliation bill and to urge you to remove this orphan drug tax credit limitation from the bill.

The undersigned are members of the Steering Committee of the Rare Disease Diversity Coalition (RDDC), a partnership involving rare disease and equity advocates, public health experts and industry leaders, launched last year to address the extraordinary challenges faced by rare disease patients of color. RDDC and its partners are committed to be a catalyst for progress for people of color with rare diseases, who are part of two struggles: as rare disease patients, they strive to be included (and not forgotten) in healthcare; and, as people of color, they fight daily for equity—against the reality of historic bias and its lingering disparate social, economic, and health effects. RDDC seeks to identify and advocate for evidenced-based solutions to alleviate the disproportionate burden of rare diseases on these communities.

Our patient communities look to specialists, diagnostics, and emerging, innovative therapies that target specific disease mechanisms for renewed hope that treatment options, and even a cure, might be on the horizon to address the life-limiting and life-threatening conditions they face. People of color in our patient communities often face additional hurdles due to the impact of the social determinants of health, socioeconomic status, cultural barriers, and the lingering impact of historic racism in this country. The genesis of many inequities in our healthcare stem from a precursor disparity in research and availability of new treatments.

Currently, treatments are available for less than 5% of the known rare diseases. One reason for the lack of rare disease therapies is high risk of development and low return on investment. Where therapies do exist, they can be difficult to access due to delays in diagnosis, reimbursement policies and restrictive labeling. Since rare diseases only affect a small portion of the population, developing treatments to address them is not always commercially viable. Recognizing this problem, Congress passed the Orphan Drug Act (ODA) in 1983 to incentivize the development of drugs for rare diseases by granting biopharmaceutical innovators tax credits, among other incentives, to lower the cost of developing therapies for rare diseases.

The ODA has been widely seen as a success. Since it was passed, the number of orphan drugs entering the market has jumped significantly. The ODA also has led to greater availability of therapies for children with rare diseases – due to incentives to develop novel therapies as well as continued incentives to repurpose research toward additional indications to address unmet medical needs of other rare diseases. It is crucial to our patient communities that Congress continue to incent innovators to repurpose biomedical research and develop therapies to address unmet medical needs beyond an original/1st indication. For this reason, Sec. 138141 of the House Ways and Means Committee-reported reconciliation bill would be a step backwards – re-building a barrier to rare disease research that Congress removed in the ODA. With the number of rare diseases in the thousands and relatively few treatments, Congress should continue to encourage and not limit research incentives to address the lingering unmet medical needs of rare diseases.

Given the enormous unmet need, and the interest expressed by the Administration and Congressional leaders in addressing health equity, we are very concerned that rare diseases have been targeted for the second time in four years by a provision that would ultimately impact rare families of color. As members of the Rare Disease Diversity Coalition Steering Committee, we strongly urge you to exercise your power to preserve the ODTC in its current form – and to remove Section 138141 -- as the Build Back Better reconciliation package is negotiated and finalized. This will continue to incent research and development of life changing therapies to address unmet medical needs in our patient communities.

Sincerely,

The following are members of the Rare Disease Diversity Coalition Steering Committee:

National Hispanic Medical Association

EveryLife Foundation for Rare Diseases
Black Women's Health Imperative
Global Genes
Global Foundation for Peroxisomal Disorders
Asian & Pacific Islander American Health Forum
National Black Nurses Association
American Muslim Health Professionals
The Balm in Gilead, Inc.
Health Equity Collaborative
Hispanic Institute
Sickle Cell Disease Association of America, Inc.
MANA, A National Latina Organization
Association of Black Cardiologists
Sickle Cell Disease Association of America, Inc.
Alexion Pharmaceuticals
Travere Therapeutics

CC: Rare Disease Congressional Caucus Co-Chairs Senators Roger Wicker (MS) and Amy Klobuchar (MN) and Representatives G. K. Butterfield (NC) and Gus Bilirakis (FL).