



MEMO

Date: October 22, 2021

To: External

From: Sick Cells

RE: Orphan Drug Tax Credit

Congress introduced the *Build Back Better Act* in September 2021. The Act included a surprise provision that would limit Orphan Drug Tax Credits (ODTC) to the first FDA-approved indication of a drug or therapy. The ODTC, which originally stipulated 50% cost reimbursement of rare disease clinical trial expenses, was cut in 2017 to reduce expense reimbursement to 25%. The proposed cut included in the *Build Back Better Act* aims to reduce tax credits available to for-profit industry, but would severely curtail drug development for rare diseases, ultimately harming the patient community. **As a national sickle cell disease (SCD) advocacy organization representing the patient voice, Sick Cells opposes the proposed cuts to the ODTC due to their potentially harmful impacts on the sickle cell disease patient population.**

1. **[Orphan Drug Tax Credit](#)**

- a. Approved in 1983 to provide incentives for rare disease (affecting <200,000 individuals) drug development

2. **2017 ODTC reimbursement cut**

- a. Reduced expense reimbursement for rare disease clinical trials from 50% to 25%
- b. Largely condemned by rare disease organizations across the U.S., including the [National Organization for Rare Diseases \(NORD\)](#), [American Society of Gene & Cell Therapy \(ASGCT\)](#), and the [Everylife Foundation for Rare Diseases](#)

3. **Sickle Cell Disease**

- a. A rare, genetic, life-shortening blood disorder that affects every organ in the body
- b. Affects 100,000+ individuals in the U.S.
- c. 4 FDA-approved therapies in the U.S.
- d. Hydroxyurea, the first FDA-approved therapy for SCD (1998), was originally developed as a therapy for leukemia by Bristol Myers Squibb

4. **[NORD Statement](#) on proposed ODTC cuts**

5. **[EveryLife Foundation statement](#) on proposed ODTC cuts**