



October 31, 2017

The Honorable Paul Ryan
Speaker
United States House of Representatives
H-232 The Capitol
Washington, DC 20515

The Honorable Kevin Brady
Chairman
Committee on Ways & Means
1102 Longworth House Building
Washington, DC 20515

Dear Speaker Ryan and Chairman Brady:

As members of the Council of State Bioscience Associations (CSBA), we write to urge you to maintain the Orphan Drug Tax Credit (ODTC), which supports research into these devastating conditions, in the reformed tax code. The CSBA is made up of state-based biotech organizations representing many of the companies developing treatments for a wide variety of rare diseases, ranging from rare pediatric cancers to deadly genetic disorders.

We support your efforts to reform America's corporate tax code to make the U.S. competitive on the global stage, including your drive to lower the corporate tax rate. However, paying for rate reduction by eliminating the ODTC would severely hamper our ability to bring life-saving treatments for rare and devastating diseases to patients. Thus, we strongly support preserving the ODTC in any tax reform legislation.

The ODTC was enacted in 1983 as part of the Orphan Drug Act (ODA) and was made permanent in 1997. Prior to the ODTC's enactment, the limited patient population of any given rare disease made it extremely difficult to finance the costly clinical trials necessary to find a treatment or cure. (The FDA defines a rare disease as any condition that impacts fewer than 200,000 Americans; an orphan drug is any treatment for a rare disease.) The FDA had approved fewer than 40 orphan drugs prior to 1983; since then, 477 orphan drugs have been granted FDA approval, resulting in treatments for 648 different indications. By reducing the costs of developing drugs for small patient populations, the ODTC allows companies to develop products that would otherwise not be commercially feasible.

A recent Ernst & Young study found that without the ODTC nearly 33% of the orphan drugs developed over the last 30 years would not be available to patients today. The same study showed that orphan drug research would decline significantly if the ODTC were to be repealed, to the tune of 33% fewer orphan drugs approved over the next ten years.

There are more than 7,000 rare diseases currently impacting nearly 30 million Americans. Only 305 have even one approved treatment option. The ODTC has contributed to the incredible progress the biopharmaceutical industry has made in the treatment of rare diseases since 1983, but we still have so much further to go to reduce the suffering of the millions of Americans still waiting for a cure. Repealing the ODTC would slow the development of orphan drugs, discourage investment in life-saving research, and ultimately harm patients.

The ODTC is critical to the development of treatments for rare diseases. In order to bring groundbreaking medicines to the 30 million Americans currently suffering from a rare disease for which there is no treatment option, the ODTC *must* be preserved in tax reform.

Sincerely,

Arizona Bioindustry Association
Bio Alabama
Bio Florida
Bio Forward, Inc. (WI)
Bio Kansas
Bio Nebraska
Bio New Jersey
Bio Ohio
Bio Utah
Biocom Life Science Association of California (Biocom)
Bioscience Association of Maine
Bioscience Association of North Dakota
Bioscience Association of West Virginia
California Life Sciences Association (CLSA)
Colorado BioScience Association
CURE, Connecticut Bioscience Innovation Network
Delaware BioScience Association
Georgia Bio
Illinois Biotechnology Innovation Organization
Indiana Health Industry Forum (IHIF)
Iowa Biotechnology Association
Kentucky Life Sciences Council
Life Sciences Pennsylvania
Life Science Tennessee
Life Science Washington
Massachusetts Biotechnology Council
Medical Alley Association (MN)
Michigan Biosciences Industry Association – MichBio
Mississippi Biotechnology Association
Missouri Biotechnology Association
Montana BioScience Alliance
NC Biosciences Organization, NC
Nevada Biotechnology & Health Science
New Mexico Biotechnology & Biomedical Association
The New Orleans BioInnovation Center (LA)
Oregon Bioscience Association
South Carolina Bio
South Dakota Biotech Association
Southern California Biomedical Council (SoCalBio)
Texas Healthcare and Bioscience Institute (THBI)
Vermont BioSciences Alliance
Virginia Bio