

## Who We Are

Celiac disease is one of the world's most prevalent genetic autoimmune diseases, affecting an estimated three million Americans, 70-80% of whom are undiagnosed. Celiac disease, which causes the body to attack its own small intestine, can lead to many other devastating health conditions, including cancer, and results in extraordinary economic and productivity costs to both the public and private sectors from employee and student absenteeism, as well as repeated, inconclusive visits to healthcare providers. The Celiac Disease Foundation seeks to advance government support for biomedical research to develop diagnostic tools, life-improving treatments, and a cure for celiac disease, and to raise public awareness of this serious disease.

## What We Accomplish

Since our founding in 1990, the Celiac Disease Foundation has played a key role in providing funding to those conducting research related to improving diagnostic tools, treatments, and a cure, and helped to achieve federal recognition of celiac disease.

- Convened and hosted the 1997 Serology Workshop leading to the development of the celiac disease (tTG-IgA) blood test.
- Served on the 2004 NIH Consensus Development Conference on Celiac Disease Planning Committee.
- Convened the American Celiac Disease Alliance (ACDA) to lobby the FDA for the Gluten-Free Labeling Rule.
- Developed the nation's largest celiac disease registry, iCureCeliac<sup>®</sup>, a Patient-Centered Outcomes Research Institute (PCORI) Patient-Powered Research Network.
- Provided testimony to House Appropriations Subcommittee and worked to secure FY2020, FY2021, and FY2022 report language directing NIH to study celiac disease.
- Provided testimony to the 2020 NIH Autoimmune Diseases Coordinating Committee on the need for focused research on celiac disease as proof of concept for treating other autoimmune diseases and invited to join as a member.
- Presented the patient view at the 2021 NIH Accelerating Progress in Celiac Disease workshop.

## What We Ask

### Increase Celiac Disease Congressional Caucus membership

In 2021, Congresswoman Betty McCollum launched the Congressional Celiac Disease Caucus. The bipartisan Caucus was launched to support federal funding of celiac disease research and to advance legislation that will ease the suffering of celiac disease patients. The Caucus will help Members of Congress raise awareness of celiac disease, both in their districts and in Washington, D.C., as well as amplify the voice of the celiac patient community.

### Secure funding for the National Institutes of Health (NIH) for the study of celiac disease

Until recently, celiac disease has not been a focus of research funding by the NIH. In 2021, NIH issued a Notice of Special Interest for celiac disease. For FY2022, NIH has been directed to devote sufficient, focused research to the study of celiac disease and to establish a Research Condition, Disease Categorization (RCDC) for celiac disease. NIAID has been directed to better coordinate existing research amongst the Institutes and Centers, and to focus new research efforts toward causation, diagnosis, management, treatment, and, ultimately, a cure for celiac disease. Additional resources for NIH are needed to support these efforts.

## What is Celiac Disease?

- Celiac disease is a multi-system genetic autoimmune disorder affecting 1-2% of people worldwide.
- For people with celiac disease, eating gluten (a protein found in wheat, rye, and barley) causes the immune system to create antibodies that attack the small intestine. Villi, small finger-like projections that line the small intestine, atrophy and eventually flatten, causing them to lose the ability to absorb nutrients.

## Celiac Disease by the Numbers

- 3 million+ Americans have celiac disease. Most studies show that less than 40% of all people with celiac disease are diagnosed.
- The prevalence of celiac disease has increased 4 or 5 fold since 1950 for unknown reasons.
- On average, it takes 4 years to be correctly diagnosed.
- There is no medication or cure for celiac disease—the only treatment is a lifelong, strict gluten-free diet.
- Studies show that 30-50% of people on a gluten-free diet continue to experience symptoms and have intestinal damage, revealing the ineffectiveness of the gluten-free diet as a treatment.
- iCureCeliac<sup>®</sup> patient registry participants report missing 23 days of work/school annually due to celiac-related illness, with 74% having been accidentally exposed to gluten within the past 30 days.
  - 96% reported “always” or “often” maintaining a strict gluten-free diet, but only 41% reported low symptom burden.
  - 93% said they want a treatment other than a gluten-free diet.

### Increased Mortality Risk Associated with Celiac Disease

- 6x increased risk of death from non-Hodgkin’s lymphoma
- 3.1x increased risk of death from liver disease
- 2.6x increased risk of death by pneumonia
- 4x increased risk of small bowel cancer

### Refractory Celiac Disease (RCD)

- 1 in 200 patients have RCD I or II, meaning they don’t respond to a strict gluten-free diet.
- RCD-II patients have a 50% increased risk of developing enteropathy-associated T cell lymphoma (EATL).
- The average survival time for patients with RCD-II is 3-10 years post-diagnosis.

## The Only Treatment: The Gluten-Free Diet

- As little as 50 mg/day of gluten triggers symptoms - a normal diet contains > 10 g/day of gluten.
  - 10 mg/day is considered “safe” for people with celiac - this is the equivalent of 1/8 teaspoon of flour.
- Gluten is virtually impossible to avoid, as it is in 80% of foodstuff.
- Gluten-free substitutes contain more fat and sugar, and fewer nutrients. This may increase risk of heart attack due to a reduced consumption of whole grains.