

INVESTMENT IN RESEARCH SAVES LIVES AND MONEY

Celiac Disease

Celiac disease is a genetic autoimmune disease. When a celiac patient eats something that contains gluten, an immune response is triggered which damages the small intestine and prevents nutrients from properly being used by the body.¹ Gluten is a family of proteins found in wheat, barley, and rye, and all foods containing any of these three ingredients.² Celiac disease is inheritable and can affect men and women of all ages.¹ Undiagnosed patients with celiac disease may suffer from abdominal bloating, chronic diarrhea, fatigue, and delayed growth.³ Others with the condition may be asymptomatic. Celiac disease can further lead to infertility, low bone density, neurological disorders, and some cancers¹. There are no drug-based treatments for celiac disease. The only treatment is a 100% gluten-free diet, which can be difficult for patients.³

TODAY

1 out of every 133 Americans has celiac disease.¹

83% of Americans with celiac disease are undiagnosed or misdiagnosed.¹

Average of **6-10 years** for an American to be correctly diagnosed with celiac disease.¹

COST

2-4x more:

Celiac patients have 2-4 times larger health care costs compared to those without celiac disease⁴

\$7.4 million:

In 2014, the total hospitalization cost of celiac disease was \$7.4 million.⁵

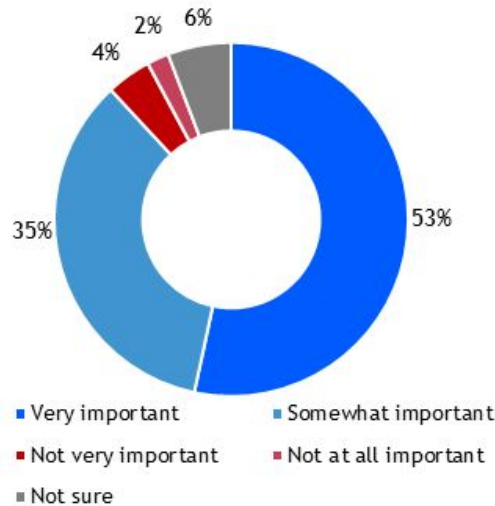
Research Delivers Solutions

There are no FDA-approved treatments for celiac disease. In May 2019, the first Phase 3 clinical trial began to test larazotide acetate as a therapy for celiac patients.⁶ Larazotide acetate regulates the connections where cells in the intestine touch one another.⁷ The trial is testing whether taking larazotide acetate before consuming gluten may keep these connections closed and prevent intestinal damage.

Prior to 2019, no biological models were available to study celiac disease. Without models to study a disease, it can be more difficult for researchers to find effective therapies and cures. In 2019, researchers developed a model of celiac disease by generating a 3-D model of the intestines from cells donated by celiac patients.⁸ In 2020, researchers developed another powerful biological model which mimics the gut inflammation caused by gluten in celiac patients.⁹

In 1997, researchers determined that the protein known as tissue transglutaminase triggers the dangerous autoimmune response in a celiac patient's gut.¹⁰ This discovery led to the creation of the celiac blood test known as the Tissue Transglutaminase Antibody (tTG-IgA) test.

How important is it for the President and Congress to assign a high priority to ensuring faster medical progress?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in January 2020

Celiac Disease

Then. Now. Imagine.

THEN

In 1887, Dr. Samuel Gee first presented the idea that the patient's diet was key to managing celiac disease.¹¹

NOW

While there is still no pharmaceutical treatment for celiac disease, there are at least 15 treatments currently being tested in clinical trials in the United States.¹²

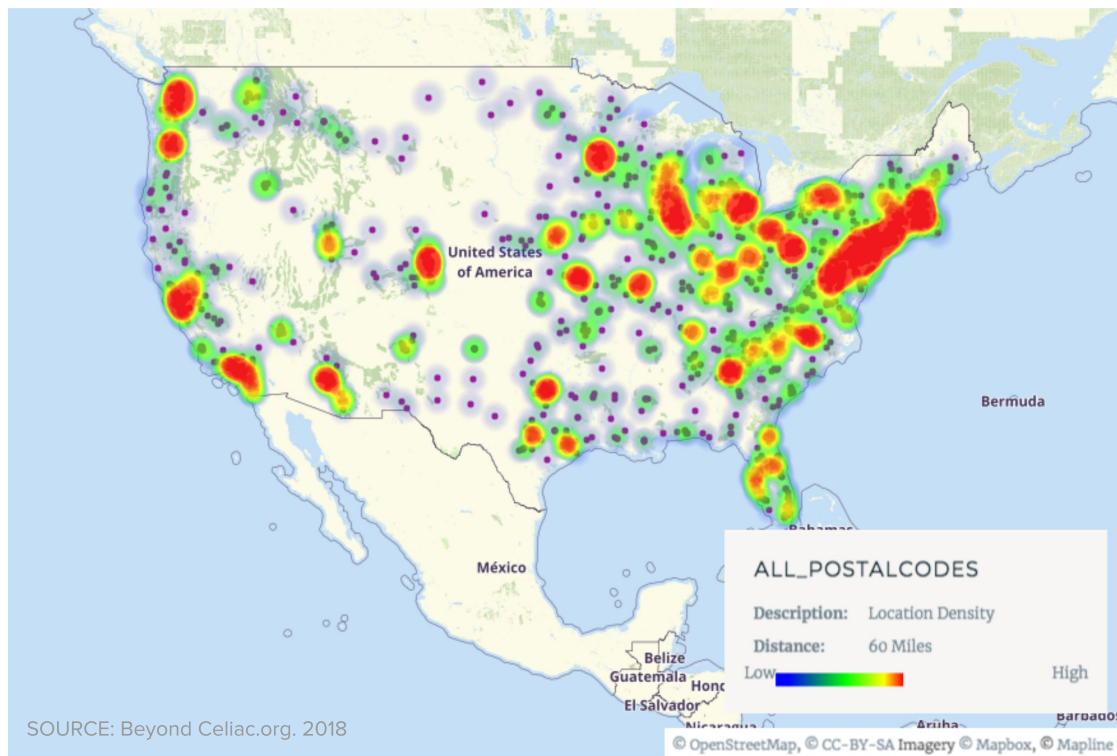
IMAGINE

A cure.

Spotlight

What is the difference between celiac disease, gluten sensitivity, and a wheat allergy? All three afflictions have similar symptoms but only celiac patients are at risk for long term damage to the gut.¹³ There is no test for gluten sensitivity and thus patients are diagnosed by process of food elimination.¹⁴ Patients with a wheat allergy are at risk of anaphylaxis, which can be a serious and life threatening symptom and patients are allergic to all proteins contained in wheat, not only gluten. Patients are tested for a wheat allergy using a traditional allergy scratch test, blood test, or elimination diet.¹⁵

Self-Reported Celiac Patients in the U.S.



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6. "Study to Evaluate the Efficacy and Safety of Larazotide Acetate for the Relief of CeD Symptoms" ClinicalTrials.gov. 2019.

7. "First Patient Dosed in First Ever Phase 3 Clinical Trial for Celiac Disease" Celiac Disease Foundation. 2019.

8. Freire et al. "Human gut derived-organoids provide model to study gluten response and effects of microbiota-derived molecules in celiac disease." Scientific Reports 2019;9:1-15

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11. Guandalini. "A Brief History of Celiac Disease" University of Chicago. 2007.

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13. "The Difference Between Celiac Disease, Gluten Intolerance, and Wheat Allergy" Closing the Gap. 2018.

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