



November 2nd, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dockets Management, FDA-2023-P-3942
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA Citizen Petition to Label Gluten as a Major Food Allergen
FDA Docket Number: FDA-2023-P-3942 (“Citizen Petition”)

Dear Secretary Becerra and Commissioner Califf:

The National Celiac Association (“NCA”) is a 501(c)3 nonprofit organization dedicated to educating and advocating for individuals with celiac disease and gluten-related conditions, their families, and communities throughout the nation. NCA provides the resources and programs to help people not only manage a gluten-free diet but to thrive as healthy individuals of all ages.

The National Celiac Association is submitting these comments in support of Celiac Journey’s FDA Citizen Petition to require the labeling of Gluten on all food packages in the United States, like Gluten is required to be declared on food labels in 87 other countries worldwide.¹

On June 14, 2022, the NCA voiced serious concerns in comments on the proposed FDA draft guidance: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff

¹ <https://www.regulations.gov/document/FDA-2023-P-3942-0001>

and Stakeholders. As we said, what was being proposed is very dangerous for people who medically require the Gluten Free diet, which is the only treatment option for Celiac Disease. We strongly urge you to consider our request to move no further with that guidance document and to pursue scientifically valid ways of protecting people with celiac disease and Gluten-related conditions instead of proposing actions such as this. FDA should be willing to receive citizen petitions regarding foods that cause any immune-mediated adverse reaction under FALCPA standards. Additionally, FDA should not limit its review of citizen petitions to only foods causing IgE-mediated reactions.² That is why the National Celiac Association is now lending its full support to FDA Citizen Petition to Label Gluten as a Major Food Allergen, FDA Docket Number: FDA-2023-P-3942.

My Background

As a father of a son with Celiac Disease, I recognize the importance of consistent labeling on packaged food items and the positive impact that this will have on our community. With more than 85 countries considering Gluten a Major Food Allergen, I feel that the timing is right for this same designation to be considered in the U.S. for the protection and well-being of consumers affected by Celiac and Gluten sensitivities.

When my son was diagnosed with Celiac Disease at the age of 12 in September 2013, it was a life-changing moment for our family. Obviously, he had to make significant changes to his everyday routines, but his diagnosis also affected me both personally and professionally. I immediately wanted to become involved and bring awareness to this disease that the majority of people, myself included, did not know about or understand. I joined the Gluten Intolerance Group staff in 2014 and started to build valuable relationships with individuals, product manufacturers, and medical professionals to support community outreach programs. One of these programs was Generation GF, designed to empower kids, teens, and young adults to be their own celiac disease advocates. In 2020, I joined the team at Beyond Celiac and worked with pharmaceutical companies in an effort to promote clinical trials and advance research toward finding a cure.

Throughout my time with these organizations, I was lucky enough to meet so many people from different walks of life who all had stories of their own unique celiac journeys. In listening and learning about them, my focus became less centered on my own son and more about the community as a whole, and during my two years away from direct involvement, there was a consistent internal voice telling me that I could do more. I wanted to come back and create a positive impact. I wanted to say “hello” again to all of the wonderful people that I have met who support others when and where they can. I wanted to do more to help this community. The National Celiac Association is providing me with that opportunity.

Food is Medicine – Label Gluten to Protect Celials

From speaking with people suffering every day, the National Celiac Association can attest that Celiac Disease is a very serious autoimmune disease and should be considered as significant as IgE-mediated responses.

Gluten is a toxin to those diagnosed with Celiac Disease or Non-Celiac Gluten Sensitivity and when exposed to Gluten, some people DO have immediate and serious reactions. Others have to

² FDA-2021-N-0553-0822, Tracking Number l4e-cf9x-ka7n
<https://www.regulations.gov/comment/FDA-2021-N-0553-0822>

deal with feeling chronically ill from any number of 200+ symptoms and being unable to live a healthy life because they are so sick.

Celiac Disease can affect all body systems, and some people have been so ill at the time of diagnosis that they have been hospitalized and on death's door. A single exposure to Gluten when this sick can land them back in the hospital.

Science tells us that it can take 1-3 years to recover after initial diagnosis but ONLY if there is adherence to a STRICT Gluten-Free diet.

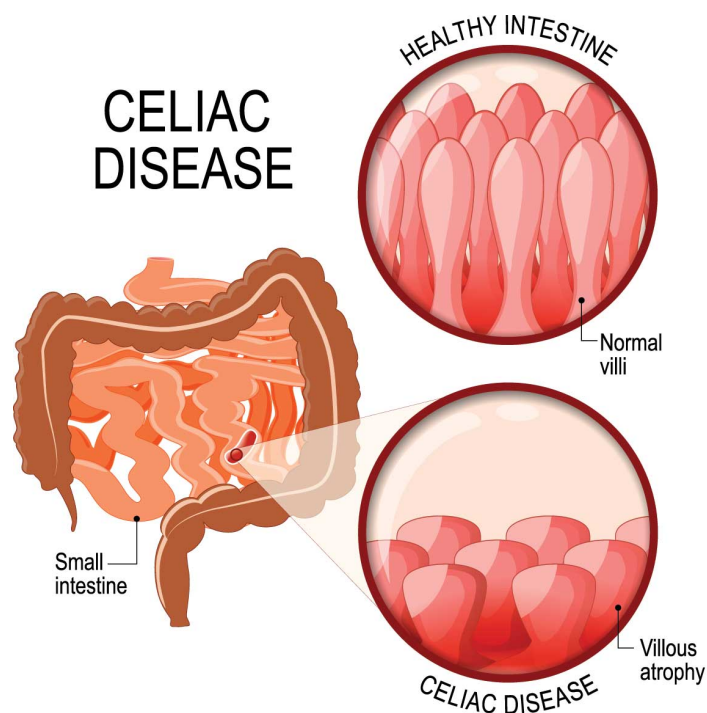
I agree with the FDA that people with Celiac Disease “face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.”³

However, research has shown that 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month, and “many with celiac disease pay over 40% more in annual healthcare costs.”⁴

While I remain hopeful that there will be some pharmacological treatments available in the future for Celiac Disease, the fact is that the only available treatment is a strict Gluten Free diet for life. That is why we need the FDA to require the labeling of Gluten.

To better understand the serious adverse health reactions that Gluten ingestion can cause, it is instructive to visualize villous atrophy that occurs in Celiacs.

Visualizing Villous Atrophy: Gluten Triggered Auto-Immune Cascade in Celiacs Damages the Small Intestine



³ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁴ <https://twitter.com/abast/status/1551780196243603457> and <https://www.beyondceliac.org/>

According to the NIH's "Notice of Special Interest (NOSI): Accelerating Progress in Celiac Disease Research" that was published on November 23, 2021, there are more than 3 million Americans who have Celiac Disease.

"Celiac disease is an autoimmune disease that occurs in genetically susceptible individuals who develop an immune response to ingested gluten. This disease affects greater than 1% of the US population, and incidence appears to have been increasing over the last several decades. The only known treatment is life-long strict avoidance of all forms of wheat, rye, and barley. Although a gluten-free diet is an effective treatment in many individuals, recent research has revealed that up to 50% of individuals following a gluten-free diet are inadvertently exposed to gluten, and a substantial minority develop persistent or recurrent symptoms.

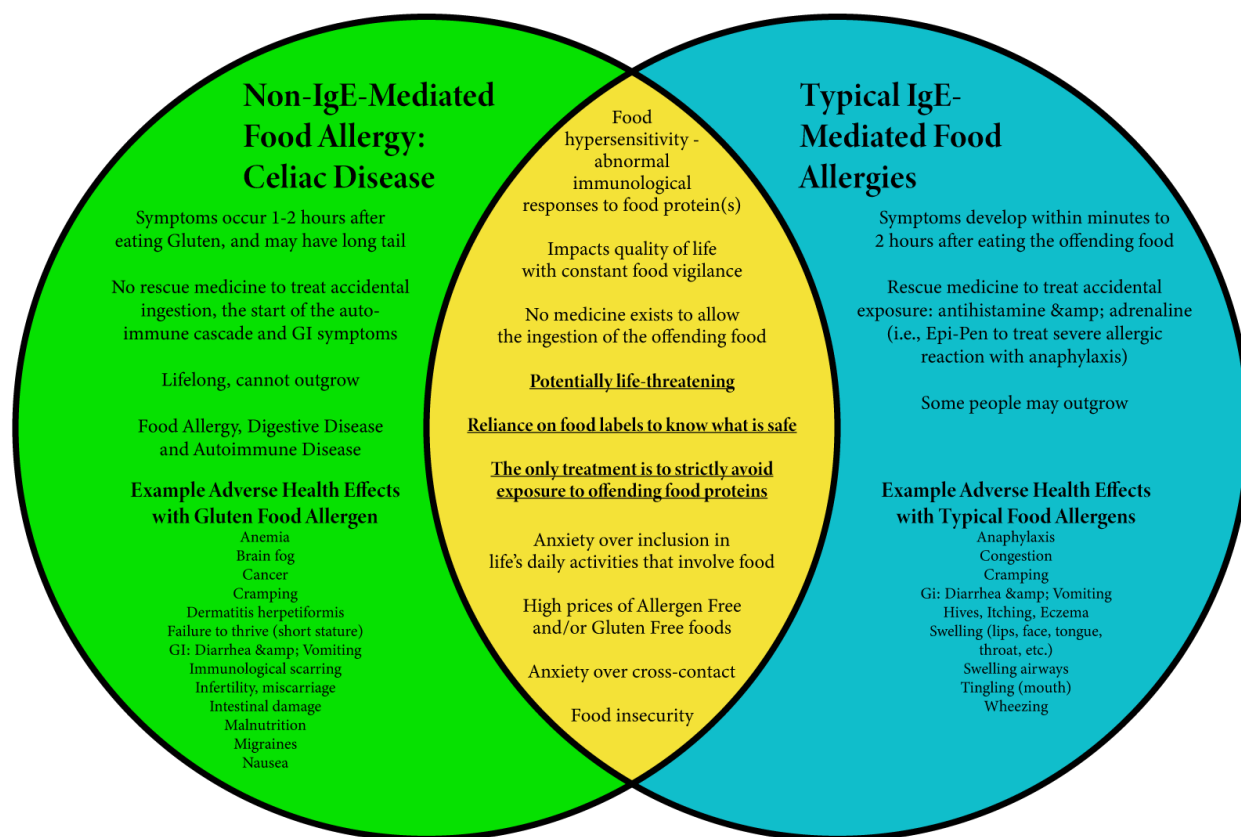
Clinical manifestations are multifaceted and include gastrointestinal (ranging from severe malabsorption to subclinical damage of the gastrointestinal tract) as well as extraintestinal (e.g., skin) expressions of disease. Additional manifestations may vary from subclinical damage of the gastrointestinal tract to refractory celiac disease that is non-responsive to a gluten-free diet. Although rare, celiac disease is associated with increased risk of gastrointestinal tract cancers and lymphomas."⁵

For someone with Celiac Disease, eating, sleeping, thinking, learning and working are major life activities that can be impacted on a daily basis through the ingestion of Gluten, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary. Celiacs are also at a greater risk of being diagnosed with additional auto-immune disorders.

The Venn diagram below illustrates the key near-peer similarities between food allergies that are Non-IgE-Mediated Mechanisms with Celiac Disease (Gluten) and typical IgE-Mediated Mechanisms: potentially life-threatening, the only treatment is to strictly avoid the food allergen(s), and consumers' reliance on food labels to know what is safe to eat.

The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms

⁵ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>



Labeling Gluten as a Major Food Allergen is congruent with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry including:

- 1999 Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives “Evaluation of Certain Food Additives and Contaminants: Fifty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. 2000. WHO Technical Report Series 896. World Health Organization, Geneva (“1999 FAO-WHO Expert Consultation”; also referred to as the “1999 Codex criteria”).⁶
- 2021 Food and Agriculture Organization of the United Nations/World Health Organization Expert Consultation on Risk Assessment of Food Allergens, which included the FDA’s Dr. Lauren Jackson, Chair, and the FDA’s Dr. Stefano Luccioli (“2021 FAO/WHO Expert Consultation”). The 2021 FAO/WHO Expert Consultation found, “[b]ased on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”⁷

According to research cited in the FAO and WHO 2022 Risk Assessment of Food Allergens, Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report, Food Safety and Quality Series No. 14, Rome,

⁶ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf

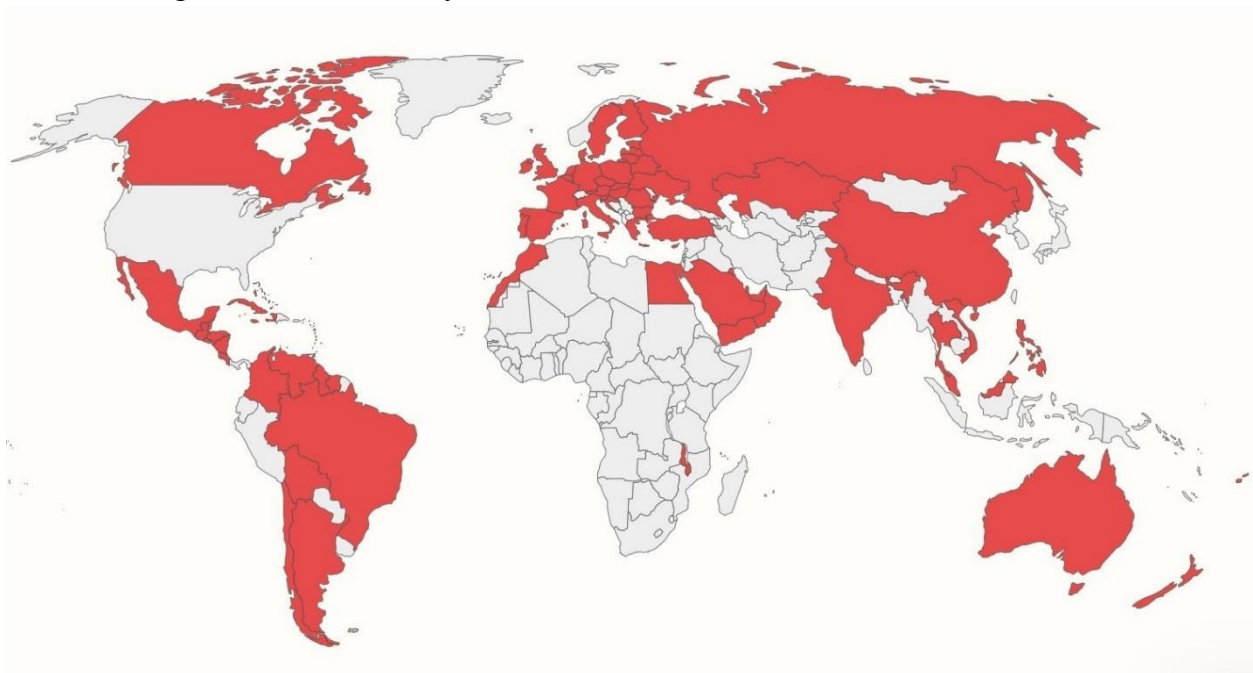
⁷ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

“It might be considered that oats should be on a regional priority allergen list because oats are generally contaminated, and often at significant levels, with gluten containing cereals. In Canada, taking into consideration lot-to-lot variability, approximately 88 percent of commercial oats samples (n = 133) were reported to be contaminated above the Codex-recommended gluten-free level (20 ppm), gluten concentration ranging from 21 to 3800 mg/kg of oats (Koerner et al., 2011). If oats are not on a priority allergen list, the possible presence of (contaminated) oats as an ingredient remains, and several products may cause reactions in consumers with coeliac disease. For this reason, oats are included in Canadian legislation.”⁸

Requested Action

Today, Wheat is required to be labeled in the U.S., but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. This Citizen Petition is requesting a long-overdue reckoning by the FDA to better protect more than 3.3 million Americans with Celiac by labeling Gluten (Wheat, Barley, Rye and Oats) as a Major Food Allergen on all packaged foods. Under its existing authority in the Food Allergen Labeling and Consumer Protection Act in statute at 21 U.S.C. § 343(x), we request that the FDA issue a rule to: 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA’s list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens” to address both labeling and cross contact issues related to food manufacturing practices.

The global implementation of the 1999 Codex Criteria and the 2021 FAO-WHO Expert Consultation can be seen in how 87 countries worldwide require that Gluten be labeled on all packaged foods, according to the map and chart produced by the Food Allergy Research and Resource Program at the University of Nebraska-Lincoln.⁹



⁸ <https://www.fao.org/3/cb9070en/cb9070en.pdf> , and <https://www.tandfonline.com/doi/pdf/10.1080/19440049.2011.579626?>

⁹ <https://farrp.unl.edu/IRChart>

Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE-Mediated mechanisms such as Celiac Disease. Additionally, those with a Non-IgE-Mediated food allergy to Gluten cannot outgrow their food allergy – Celiac is lifelong (until such time as a cure may be developed).

While U.S. consumers' reactions to a top 9 Major Food Allergens and Gluten vary, their consumer habits are the same -- they avoid purchasing foods that contain the allergen(s) that cause a potentially life-threatening immunological adverse reaction.

However, the key difference from a consumer protection standpoint is that under the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA"), the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is permissive. Just because something is Wheat free does not mean its Gluten Free. In other words, whereas sufferers of the current top 9 Major Food Allergens in the U.S. rely on what ingredients are expressly included in required labeling disclosures of packaged foods, the Celiac community cannot rely on manufacturers to declare Gluten on food labels.

I agree with the comments from Dr. Virginia Stallings, a board-certified nutrition pediatrician, Professor of Pediatrics and Director of the Nutrition Center at the Children's Hospital of Philadelphia. Dr. Stallings was also the Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies which published the seminal work: "Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy." As it pertains to Gluten, Dr. Stallings opined:

"While a Non-IgE-Mediated food allergy does not trigger anaphylaxis and is not immediately life-threatening, people with Celiac Disease face potentially life-threatening and severe adverse health effects that can arise through gluten ingestion including by way of example and not limited to: anemia, cancer, heart disease, immunological scarring, intestinal damage and malnutrition... A gluten free diet is not all that is needed to treat Celiac Disease; rather a gluten free diet is all that has ever been historically available to treat Celiac Disease. Additionally, with respect to labeling food products in the United States, the voluntary gluten free labeling scheme does not sufficiently protect consumers who are on medically required and very restrictive gluten free diets. My strong recommendation is that gluten be labeled on all packaged foods in the United States, in accordance with the 2021 FAO/WHO Expert Consultation, just like it is in more than 85 countries around the world."¹⁰

¹⁰ https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

I am respectfully requesting that the FDA change the voluntary labeling rule to a mandatory labeling rule to keep 3.3 million Americans with Celiac safer. I would be pleased to answer any questions that you may have. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Rich', with a long horizontal flourish extending to the right.

Christopher Rich
CEO and Executive Director

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