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November 29, 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:

As a board certified nutrition pediatrician, the Jean A. Cortner Endowed Chair in the Division of Gastroenterology, Hepatology and Nutrition at Children's Hospital of Philadelphia ("CHOP") and Director in CHOP's Nutrition Center, I am writing to strongly recommend that the FDA grant Celiac Journey's FDA Citizen Petition to require the labeling of Gluten on all food packages in the United States,<sup>1</sup> just like Gluten is required to be declared on food labels in 87 other countries worldwide.

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<sup>1</sup> <https://www.regulations.gov/document/FDA-2023-P-3942-0001>  
Children's Hospital of Philadelphia

I also served as the report Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies: “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy” (“Finding a Path”).<sup>2</sup>

### **Citizen Petition - 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 FDA has the authority and responsibility to label Gluten.

### **My Meetings with the FDA and HHS on Labeling Gluten**

I appreciate the opportunity to have spoken at a series of meetings with the Bari family from Celiac Journey (including Jax Bari who is a patient at CHOP’s Center for Celiac Disease), FDA and HHS and to have shared my strong opinion that it is time for the FDA to issue rulemaking that would require the labeling of Gluten on all packaged foods in the U.S. To date, I attended these meetings:

- September 26, 2023 with Laura Carroll, Senior Advisor to the Chief of Staff in FDA Commissioner Robert M. Califf’s Office; Dr. Don Prater, Acting Center Director, the Center for Food Safety and Applied Nutrition (“CFSAN”); Dr. Claudine Kavanaugh, Director, Office of Nutrition and Food Labeling, CFSAN; Dr. Patricia Hansen, Deputy Director, Office of Nutrition and Food Labeling, CFSAN; Dr. Stefano Luccioli, Senior Physician, Office of Compliance, CFSAN; Emily Carey, Policy Analyst, Office of Executive Programs, CFSAN; Janesia Robbs, Public Engagement Staff, CFSAN; and Kari Barrett, Public Engagement Lead, CFSAN.
- April 17, 2023 with Senior Staff in the Immediate Office of HHS Secretary Xavier Becerra.<sup>3</sup>
- December 6, 2022 with senior FDA leadership including Dr. Susan Mayne, FDA’s Director, CFSAN; Dr. Claudine Kavanaugh, FDA’s Director, Office of Nutrition and Food Labeling (ONFL); Dr. Pat Hansen, FDA’s Deputy Director, Office of Nutrition and Food Labeling; Dr. Stefano Luccioli, and FDA’s Acting CFSAN Chief Medical Officer and Allergen Coordinator.<sup>4</sup>

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<sup>2</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>3</sup> <https://www.celiacjourney.com/hhsreadout>

<sup>4</sup> <https://www.celiacjourney.com/fda2>

I also appreciate the FDA reviewing my August 2, 2022 “Comments on ‘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 and Stakeholders- Draft Guidance’, FDA Docket Number: FDA-2021-N-0553.”<sup>5</sup>

### **NAS Food Allergy Committee Findings**

Our Food Allergy Committee’s work for the National Academy of Sciences found that “Food allergy, as opposed to a food intolerance, which does not have an immunologic component, arises from a specific immune response. Food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated”<sup>6</sup> (page 4) such as Celiac Disease. However, it should be noted that while there were certain references to Celiac Disease in the Food Allergy Committee’s Federally-funded report, Celiac Disease was not covered in our report because it was “beyond the scope of the statement of task.”<sup>7</sup>

### **Celiacs Face Adverse Health Effects from Gluten Ingestion Including Potentially Life-Threatening Illnesses**

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.”<sup>8</sup>

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.”<sup>9</sup>

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

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<sup>5</sup> FDA Comment ID: FDA-2021-N-0553-1169, FDA Tracking Number: 16g-mawc-nbs8, August 5, 2022.

[https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf)

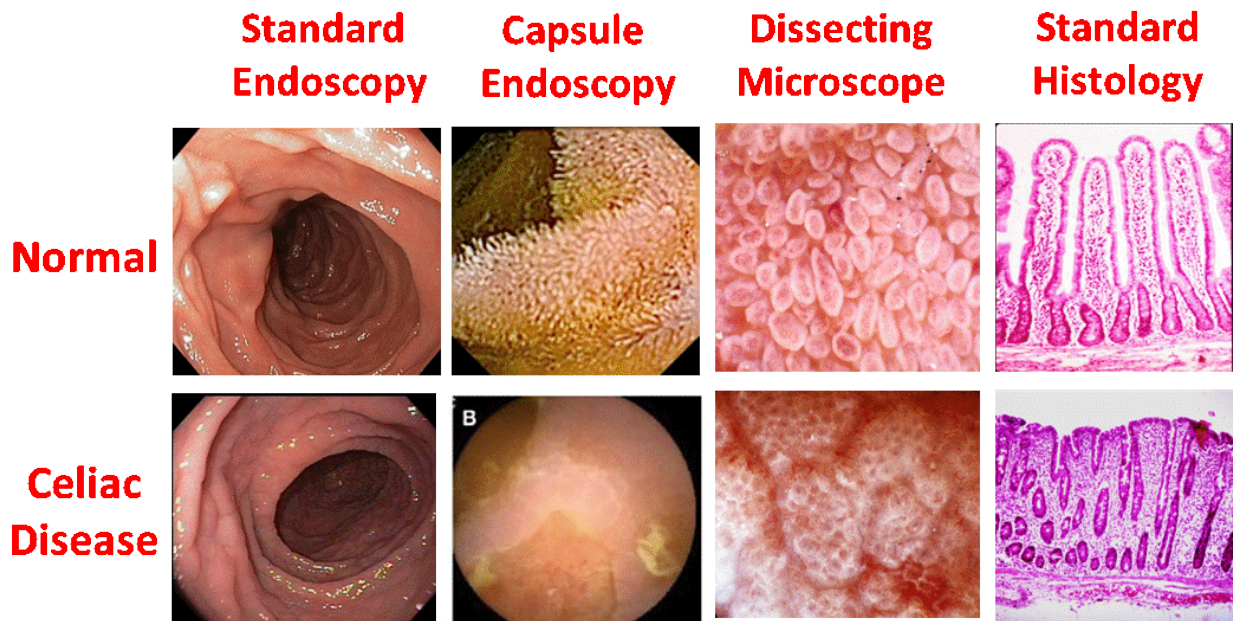
<sup>6</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>7</sup> Following are references to Celiac Disease in the Finding a Path report: “Other food-related diseases, such as celiac disease, or food intolerances, such as lactose intolerance, or toxicity of food additives, are not covered in this report because they were beyond the scope of the statement of task.” (page 26); “Non-IgE-mediated food allergy reactions (e.g., food protein induced enterocolitis) are less common and the mechanisms of the reactions are less well characterized. Celiac disease is a well-characterized, immune-mediated disease that has food as an exacerbating factor but will not be detailed in this report.” (page 41); and “BOX C-2 Study Exclusion Criteria - Studies seeking to prevent potential manifestations of food allergy (e.g., atopic eczema/dermatitis or asthma) but not including an explicit diagnosis of sensitization to food or food allergy or studies investigating celiac disease were excluded, as well as management guidance documents, narrative reviews, letters to the editor, commentaries, studies that used animal or in vitro models, ecological studies, and studies of transplant patients.” (page 448). [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>8</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

<sup>9</sup> <https://twitter.com/abast/status/1551780196243603457> and [https://www.beyondceliac.org/Children’s Hospital of Philadelphia](https://www.beyondceliac.org/Children’s%20Hospital%20of%20Philadelphia)

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



Source: Graphic provided by Ciaran Kelly, MD, Medical Director, Celiac Center, Beth Israel Deaconess Medical Center, Boston, Professor of Medicine & Co-founder, Celiac Research Program, Harvard Medical School.

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."<sup>10</sup>

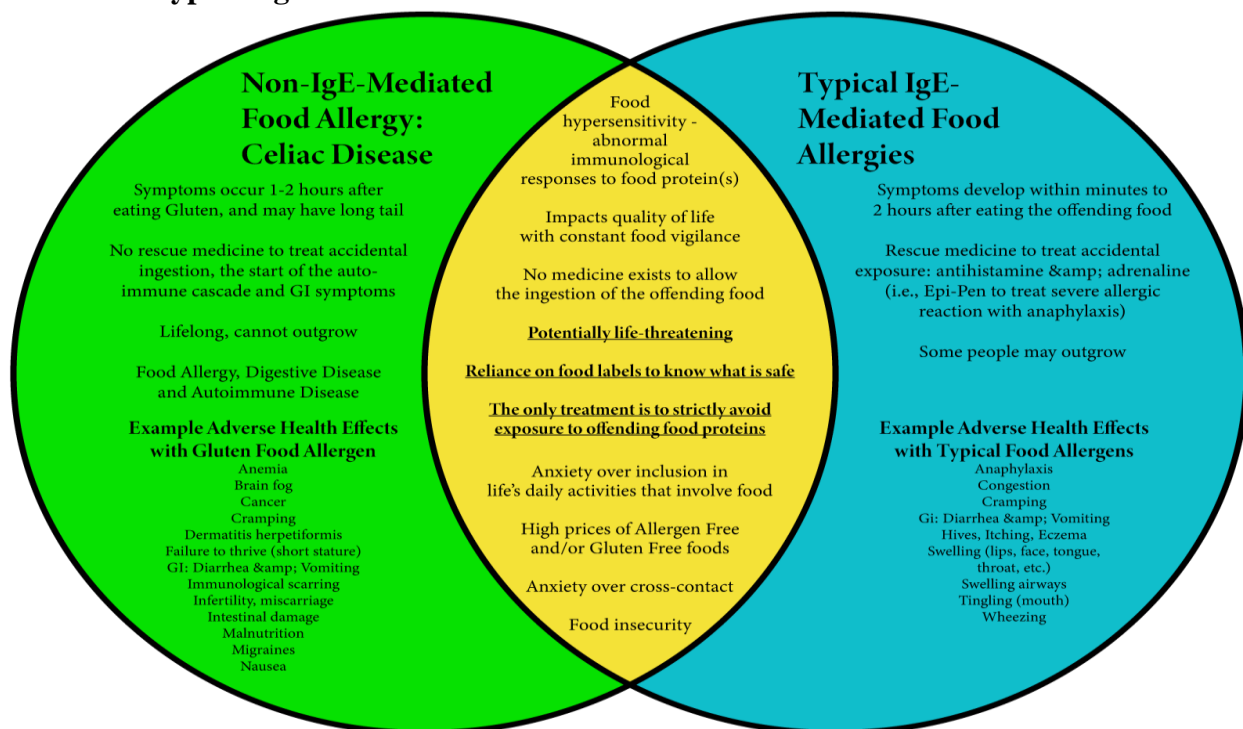
<sup>10</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>  
Children's Hospital of Philadelphia

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.

While a Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, Celiacs face potentially life-threatening and severe adverse health effects that can arise through Gluten ingestion including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.<sup>11 12</sup>

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



<sup>11</sup> <https://www.fda.gov/media/157637/download>

<sup>12</sup> <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ;  
 “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. Dig Dis Sci 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>  
 Children’s Hospital of Philadelphia

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”).<sup>13</sup>
- 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).”<sup>14</sup>

For example, the 1999 FAO/WHO Expert Consultation determined:

“The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products; Crustacea and products of these; Egg and egg products; Fish and fish products; Peanuts, soybeans, and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulfites in concentrations of 10 mg/kg or more.”<sup>15</sup>

As the Food Allergy Committee which I chaired found,

“The 1999 CAC [Codex Alimentarius Commission] priority list included milk, egg, fish, crustacean shellfish, peanut, soybean, tree nuts, cereal grain sources of gluten, and sulfites. Several of these items were added because the FAO [Food and Agriculture Organization of the United Nations] Technical Consultation also considered celiac disease, intolerances, and sensitivity reactions in addition to immunoglobulin E (IgE)-mediated food allergies in its deliberations. For example, gluten was included because of its association with celiac disease.” (page 284)<sup>16</sup>

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<sup>13</sup> [https://apps.who.int/iris/bitstream/handle/10665/42378/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf)

<sup>14</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>15</sup> [https://apps.who.int/iris/bitstream/handle/10665/42378/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf)

<sup>16</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

“In the United States, the priority list of allergenic foods was established by the Congress with the passage of the Food Allergen Labeling and Consumer Protection Act,<sup>6 7</sup> [‘For an analysis on Food Allergen Labeling and Consumer Protection Act see Derr (When Food Is Poison), 2006.’] (FALCPA) of 2004. The FALCPA list mirrored the 1999 CAC list except that the FALCPA list did not address celiac disease and therefore did not recognize cereal sources of gluten as major allergenic foods.” (page 286)<sup>17</sup>

The 2021 FAO/WHO Expert Consultation, which was chaired by the FDA’s Dr. Lauren Jackson, Chief, Process Engineering Branch, Division of Processing Science & Technology, Institute for Food Safety & Health, determined:

“Based 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).”<sup>18 19</sup>

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,

“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.”<sup>20</sup>

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.<sup>21</sup>

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<sup>17</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>18</sup> “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.”

<sup>19</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>20</sup> <https://www.fao.org/3/cb9070en/cb9070en.pdf> , and

<https://www.tandfonline.com/doi/pdf/10.1080/19440049.2011.579626?>

<sup>21</sup> According to the University of Nebraska-Lincoln, the following countries require that Gluten be labeled on packaged foods: Anguilla, Antigua and Barbados, Argentina, Australia, Austria, Children’s Hospital of Philadelphia







On February 6, 2018 (in response to the citizen petition filed by Ms. Davis on September 10, 2008), Douglas Stearn, Deputy Director, Center for Food Safety and Applied Nutrition, FDA, wrote to Ms. Davis,

“Your petition does not include adequate information to show that rye and barley are common causes of severe immunoglobulin E (IgE)-mediated allergies, such as wheat and other major food allergens under FALCPA. Rather, your petition focuses on the needs of people with celiac disease, which we have taken steps to address. Your citizen petition provides as a statement of grounds: ‘It has been shown that celiacs are not just sensitive to wheat, but are also sensitive to the gluten of rye and barley’ (Petition at page 1). We agree with this statement and note that information voluntarily provided on food labels concerning the absence of gluten-containing grains *may* provide additional label information that is helpful to consumers seeking to avoid barley and rye.”<sup>25</sup>

With respect to labeling food products in the United States, the current voluntary Gluten Free labeling scheme that has been in place since August 5, 2014 does not sufficiently protect consumers who are on medically required and very restrictive Gluten Free diets.

With respect to criteria that the FDA has historically used to evaluate the public health importance of requiring the labeling of Gluten, the FDA cannot scientifically, biologically, and equitably continue to utilize criteria requiring that Gluten is a common cause of severe IgE-Mediated food allergy. That is a false premise.

It is foundationally important to recognize that food allergies are both IgE-Mediated and Non-IgE-Mediated. The FDA under the FALCPA is required to recognize both. The FDA’s own experts in conjunction with the 2021 FAO/WHO Expert Consultation including the FDA’s Dr. Lauren Jackson and FDA’s Dr. Stefano Luccioli as well as American food allergy experts Dr. Joseph Baumert and Dr. Stephen Taylor did not adversely distinguish between IgE-Mediated and Non-IgE-Mediated food allergies in their systematic and thorough assessments which used all three criteria (prevalence, severity and potency) to determine the Risk Assessment of Food Allergens. The FDA must stop discriminating between IgE-Mediated and Non-IgE-Mediated food allergies with Celiac Disease when it comes to equitably evaluating the labeling of Gluten as a Major Food Allergen to protect 3.3 million American celiacs.

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).

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P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie Jane Davis. Available at <https://www.regulations.gov>, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0007, <https://www.regulations.gov/docket/FDA-2008-P-0509/document>, [https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2008-P-0509-0001/attachment_1.pdf)

<sup>25</sup> [https://downloads.regulations.gov/FDA-2008-P-0509-0008/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2008-P-0509-0008/attachment_1.pdf)

Children’s Hospital of Philadelphia

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. They rely on food labels to know what is safe to eat.

However, the key difference from a consumer protection standpoint is that under FALCPA, the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is voluntary. Just because something is Wheat free does not mean it's 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. This must change.

I believe that 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.

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.

Sincerely,

A handwritten signature in blue ink, reading "VA Stallings". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Virginia A. Stallings, MD

Professor of Pediatrics