Policy Objective: Reduce Diet-Related Disease by Labeling Gluten as a Major Food Allergen

The Evaluation of the Public Health Importance of Labeling Gluten as a Major Food Allergen Should Be Conducted Now Through the Lens of President Biden's Executive Order 13985 (1/20/21) and Executive Order 14091 on "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (2/16/23)

An Analysis of How Celiacs Belong to an Underserved Community of Persons with Disabilities Who Have Systematically Been Denied a Full Opportunity to Participate in Aspects of Economic, Social, and Civic Life

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April 17, 2023 (revised April 23, 2023)

WHITE HOUSE CONFERENCE ON HUNGER, NUTRITION, & HEALTH

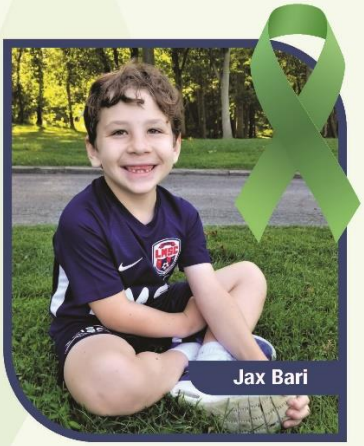
Policy Objective: Reduce Diet-Related Disease by Labeling Gluten

Labeling Gluten (Wheat, Barley, Rye and most Oats) as a Major Food Allergen on all packaged foods in the U.S. like it is in 85 countries around the world will better protect 3.3 Million Celiacs. Labeling Gluten is in alignment with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians, individuals and risk managers from academia, government and the food industry including:

- 2021 Food and Agriculture Organization of the United Nations/World Health Organization Expert Consultation on Risk Assessment of Food Allergens, chaired by the FDA's Dr. Lauren Jackson.
- 1,576 Comments submitted to the FDA on Labeling Gluten in Summer 2022 including 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, Beyond Celiac, National Celiac Association, Gluten Free Watchdog, University of Chicago Center for Celiac Disease, etc. (Docket: FDA-2021-N-0553)

Eating without fear is our hope. Food insecurity happens every day for Celiacs because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the high price of Gluten Free food, and Gluten is not required to be labeled on all packaged foods in the U.S.

Jax Bari, Age 9



Jax Bari

I admire your courage and the incredible work you've done to help the millions of Americans like you who live with Celiac disease.

President Joe Biden to **Jax Bari**

CELIAC DISEASE OVERVIEW

- Celiac Disease is a potentially life-threatening food allergy and auto-immune disease that impacts at least 3.3 million Americans, greater than 1.0% of the general population.
- Researchers are finding that Celiac Disease prevalence is doubling approximately every 15 years, making it a public health epidemic. Gluten ingestion for people with Celiac can cause anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.
- The only available treatment is strict adherence to a lifelong, Gluten Free diet. There is no rescue medication in the event of accidental ingestion and one cannot outgrow Celiac.

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I. Introduction

A. Policy Objective

We are grateful for the opportunity to share our lived experience and inform public policy with the objective of better protecting 3.3 million American Celiacs by labeling Gluten (Wheat, Barley, Rye and Oats[1]) as a Major Food Allergen, just like labeling Gluten is done in 85 other countries and in alignment with the conclusions of the 2021 Food and Agriculture Organization of the United Nations ("FAO")/World Health Organization ("WHO") Expert Consultation.[2]

[1] Gluten containing grains are Wheat, Barley, Rye and most Oats. Wheat is already codified as a Major Food Allergen in the US as per the Food Allergen Labeling and Consumer Protection Act of 2004. As such, the focus of these Comments is on adding Barley, Rye and Oats. While Oats are naturally Gluten Free, it is instructive to read the 1999 Codex Criteria (See FDA Ref. 25 in FDA Docket FDA-2021-N-0553) which stated, "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." Source: https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf . Also see 2021 FAO/WHO Expert Consultation as detailed herein (See FDA Ref. 45 in FDA Docket FDA-2021-N-0553). Source: http://www.fao.org/3/cb4653en/cb4653en.pdf

In addition, it is instructive to read the following from General Mills about Oats being cross contaminated with Gluten, "Oats themselves do not contain gluten. However, oats cultivated in North America, Europe and even other parts of the world are commonly contaminated by gluten containing foreign grains, including wheat, barley, rye and triticale. This contamination is commonly known to come from various sources, mainly from the rotation of small grain crops on the same land, with residual contaminating seeds germinating with a seeded oat crop. In addition, contamination from other grains which are harvested, transported, stored and merchandized in common with oats is a contributing factor. As a result, it is not uncommon to find from 0.5% to 5.0% of these other grains mixed with commercially marketed oats. Therefore, absent dedicating land, harvesting equipment, transporting vehicles, storage units, packaging and production facilities, and the like only for use in connection with oats, cross contamination is inevitable." Source: https://patents.google.com/patent/US9968937B2/en .

Further, it is instructive to understand the market position and expertise of General Mills in the food industry. According to General Mills' 2021 Annual Report, "We are a leading global manufacturer and marketer of branded consumer foods sold through retail stores. We also are a leading supplier of branded and unbranded food products to the North American foodservice and commercial baking industries. We are also a leading manufacturer and marketer in the wholesome natural pet food category. We manufacture our products in 13 countries and market them in more than 100 countries. In addition to our consolidated operations, we have 50 percent interests in two strategic joint ventures that manufacture and market food products sold in more than 120 countries worldwide." Source: https://s22.q4cdn.com/584207745/files/doc_financials/2021/ar/Final-GMI-2021-Annual-Report.pdf

[2] http://www.fao.org/3/cb4653en/cb4653en.pdf

B. Summary of Recent Meetings with the Biden-Harris Administration

To date, we have held various meetings as a follow up to the White House Conference on Hunger, Nutrition, and Health and on September 28, 2022[3] ("White House Conference") including Jax's capsule video,[4] Jax meeting President Joe Biden on October 20, 2022 and asking the President to help better protect Celiacs by labeling Gluten,[5] our meeting with staff from the White House Domestic Policy Council at the White House on November 10, 2022,[6] [7] and meetings with senior FDA leadership on December 6, 2022.[8]

C. Labeling Gluten as Major Food Allergen is a Public Health Problem Long Overdue for Robust Consumer Protection Action

We write to underscore our concern that the Food and Drug Administration ("FDA") is not sufficiently prioritizing a public health problem long overdue for robust action: reducing diet-related disease by requiring the labeling of Gluten as a Major Food Allergen on all packaged foods. We respectfully call on the President's leadership to address this critical consumer protection food safety issue with the urgency it requires.

D. Advancing Equity Must Be a Central Component of HHS & FDA Decision-Making to Protect Celiacs, An Underserved Community With a Chronic Disability

We are respectfully requesting that the evaluation of the labeling of Gluten should be conducted now through the lens of President Biden's Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" (January 20, 2021) and President Biden's Executive Order 14091 on "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government." (February 16, 2023):

> "Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity."[9]

According to the HHS Equity Action Plan, "**advancing equity must be a central component of the decision-making framework that all agency functions are routed through**."[10]

E. The FDA's 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 and Stakeholders, April 19, 2022" Represents a Biased and Unfair Decision-Making Framework

Based on detailed research, analysis and the Celiac community's lived experiences with a chronic disability (as per the Americans with Disabilities Act), we believe that advancing equity must be a central component of the decision-making framework that all FDA functions are routed through, including with "Evaluating the Public Health Importance of Food Allergens

[3] www.celiacjourney.com/takeaways
[4] https://whconfhungerhealth.capsule.video/v/ojdDpea388a6
[5] www.celiacjourney.com/biden2
[6] https://www.celiacjourney.com/whitehouse
[7] https://tinyurl.com/CeliacJourney
[8] https://www.celiacjourney.com/fda2
[9] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government
[10] https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf

Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance", Docket: FDA-2021-N-0553, April 19, 2022 ("FDA's Draft Guidance").[11]

However, with respect to the Celiac Disease community, which has been historically underserved and marginalized by the Federal government (i.e., underfunding medical research for Celiac Disease,[12] labeling Gluten only with a voluntary scheme,[13] disqualifying Celiacs from service in the military,[14] excluding Celiac Disease from the CDC's Index of Diseases & Conditions,[15] etc.), the FDA's Draft Guidance presented an inequitable evaluation framework.

In total, there were 1,903 public comments submitted to the FDA on the FDA's Draft Guidance,[16] and of those, 1,576 comments mentioned Celiac and/or Gluten as a food allergen (82.8% of all comments submitted).[17] There was a common theme among the 1,576 comments – label Gluten to better protect the Celiac community. While the comment period closed on August 16, 2022, the FDA has not provided any updates or responses.

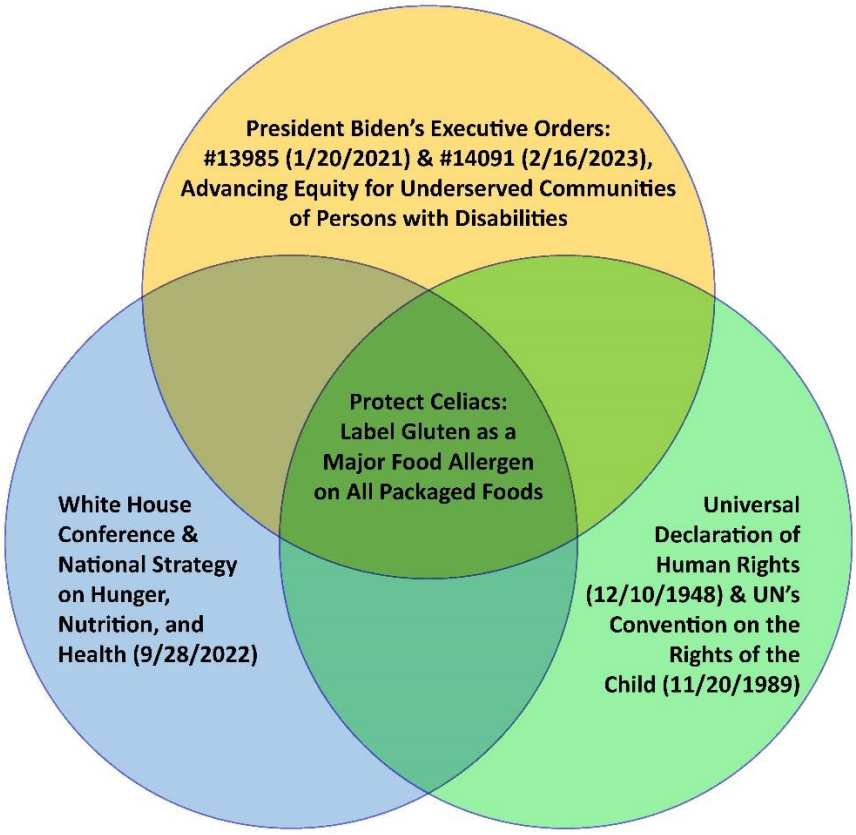
When we met with the FDA on December 6, 2022 and asked for an update including whether they were going to revise the FDA's Draft Guidance to include the evaluation of the public health importance of labeling Gluten as a Major Food Allergen, the FDA offered no comment and no timetable, other than to seemingly say because of the volume of responses they could not provide any timeframe to respond (we pointed out that almost 83% of the comments were about labeling Gluten). This is especially troublesome since according to the 2019 Congressional testimony of Marilyn Geller, CEO of the Celiac Disease Foundation, "Americans are dying because we haven't paid sufficient attention to this disease."[18] We just do not have the privilege of time to wait any longer. See section herein entitled, "FDA's Draft Guidance Illustrates Bias Against Celiac Disease."

This is also further discussed in greater detail in the section herein "President Biden's Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden's Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government." Unfortunately, the FDA's Draft Guidance, which was published in April 2022 is incongruent with HHS Equity Action Plan as also detailed herein.

[11] https://www.fda.gov/media/157637/download
[12] https://www.celiacjourney.com/briefing
[13] https://www.celiacjourney.com/falcpa
[14] U.S. Department of Defense, DoD Instruction 6130.03, Medical Standards for Appointment, Enlistment, or Induction into the Military Services, Section 5.12.c.(3), May 6, 2018, https://www.esd.whs.mil/DD/ ; and https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003_vol1.PDF?ver=7fhqacc0jGX_R9_1iexudA%3d%3d
[15] https://www.cdc.gov/az/f.html
[16] https://www.regulations.gov/docket/FDA-2021-N-0553/comments
[17] https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac
[18] https://www.youtube.com/live/KGRHg-840KE?feature=share&t=11485 , and https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42

F. The labeling of Gluten as a Major Food Allergen Sits at the Intersection of President Biden's Executive Orders on Advancing Equity for Underserved Communities, the White House Conference and National Strategy on Hunger, Health, Nutrition and Human Rights

The labeling of Gluten as a Major Food Allergen sits at the intersection of President Biden's Executive Orders 13985 and 14901 on advancing equity for underserved communities for persons with disabilities such as 3.3 million American Celiacs (see Section IV herein); the White House Conference and National Strategy on Hunger, Health, Nutrition, the Universal Declaration of Human Rights -- the Right to Feed Oneself in Dignity (see Section IV.G. herein); and the UN's Convention on the Rights of the Child (see Section IV.H. herein).



G. Cost Estimates for Declaring Gluten as a Major Food Allergen

Labeling Sesame as the 9th Major Food Allergen is instructive in terms of the cost for labeling Gluten as a Major Food Allergen. See the section herein, "Cost Estimates with Naming Gluten as a Major Food Allergen."

H. HHS Secretary Xavier Becerra Has Existing Statutory Authority to Label Gluten Now

According to the Food & Drug Law Journal and the former Chief Counsel to the FDA, we believe that the Secretary of HHS has existing statutory authority as codified by the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA") to label Gluten as a Major Food Allergen. This is discussed in greater detail in the section herein "HHS Secretary Xavier Becerra Has Existing Statutory Authority to Label Gluten Now."

I. Our Guiding Path

In Judaism, the process of Teshuva implies both reflection on the past and the initiation of different action in the future. In order to improve the lives of 3.3 million American Celiacs, including our son Jax, we view our work and policy objective through the lens of Teshuva.

II. Celiac Disease

A. Overview

Celiac Disease is an immune-mediated food allergy,[19] auto-immune disease[20] and digestive disease[21] that is triggered by eating Gluten. Accordingly, Celiac does not fit into a nice little box or category. We 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."[22]

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 3.3 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**."[23] (emphasis added)

Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat the 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). As Jax told President Biden, insulin is to Diabetics as Gluten Free food is to Celiacs.

B. Our Lived Experience

As President Joe Biden said at the White House Conference on Hunger, Health, and Nutrition,

> "[I]f a parent cannot feed a child, there's nothing else that matters for that parent. **If you look at your child and you can't feed your child, what the hell else matters?** I really mean it."[24] (emphasis added)

Unfortunately, that has been our lived the experience and that of many people with Celiac Disease as well as parents and caretakers of children with Celiac, including when Jax has gotten "glutened" and violently ill as he recently was on April 1, 2023 in Denver, Colorado (see photo

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[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf (pages 5, 11-12); and https://www.fda.gov/media/157637/download (page 10)
[20] https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#
[21] https://www.niddk.nih.gov/health-information/digestive-diseases
[22] https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says
[23] https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html
[24] https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/#

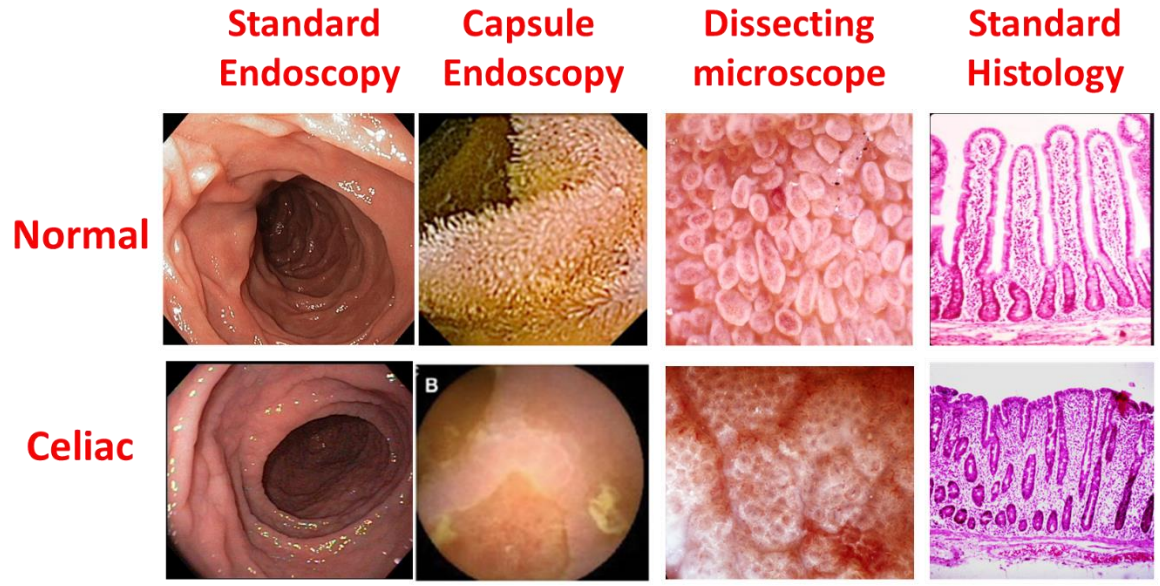
on the cover of this Memo of Jax Bari incapacitated for hours on a bathroom floor).[25] Eating out of the house is very challenging for Celiacs, and this impacts their quality of life on a daily basis. As such, this represents an example of how Celiacs have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. One key way to help mitigate accidental glutenings is to require that Gluten be labeled as a Major Food Allergen.

As reported by World News Tonight with David Muir, Jax was featured on the America Strong segment and told David that, "Eating without fear is our hope. Food insecurity happens every day for Celiacs because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the high price of Gluten Free food, the limited availability of Gluten Free food, and moreover Gluten is not required to be labeled on packaged foods in the US like it is in Canada and Europe."[26]

To that end, we have been working on getting Gluten labeled as a Major Food Allergen for a number of years since Jax was diagnosed with Celiac right before he started Kindergarten in August 2018. Diagnosis was done through repeated serology tests and an endoscopy at Children's Hospital of Philadelphia ("CHOP"). At age 5, the endoscopy revealed Marsh 3 level (significant) damage to his small intestine which caused anemia and failure to thrive by inhibiting him from absorbing proper nutrients for growth and development.

Jax's intestine took years to heal, although he is still anemic, even after 4 years of being on a strict Gluten Free diet. However, every time Jax accidentally gets Glutened (even just a crumb of Gluten is enough), he gets violently ill (like food poisoning) and the auto-immune cascade repeats and attacks his small intestine.

Visualizing Villous Atrophy: Gluten Triggered Auto-Immune Cascade in Celiacs Damages the Small Intestine[27]



[25] https://www.instagram.com/p/CqnYV7lrRR4/
[26] www.celiacjourney.com/abcnews
[27] Graphic provided by Ciaran Kelly, MD, Medical Director, Celiac Center, BIDMC, Boston, Professor of Medicine & Co-founder, Celiac Research Program, Harvard Medical School, Used with Permission.

Jax's story has helped put a face to people who are involuntarily Gluten Free due to Celiac Disease and their deeply personal struggles which many say they quietly face in the shadows. We have met so many amazing Celiac families which have had their health and quality of life impacted by adverse reactions to Gluten, as well as the food insecurity and anxiety that goes hand in hand with maintaining a strict Gluten Free diet, regardless of their socioeconomic status. However, it should be noted that families with low incomes, who have at least one member with Celiac Disease, are disproportionately impacted to an even greater extent in terms of food insecurity.

We are not lobbyists or lawyers; we are parents trying to protect the Celiac community including about 730,000 children like Jax. While it is a labor of love, it is also an exhausting full-time job in addition to our day jobs. It should not be this hard to protect our children and that's why we are respectfully asking for help from President Biden and Secretary Becerra!

C. Every Bite, Every Day! – There is No Break Ever from Celiac Disease!

There are no days off from Celiac! There is no cheating on the Gluten Free diet. The lifetime treatment burden of the Gluten Free diet is perceived by patients to be second only to end-stage renal disease, and by caregivers, comparable to caring for a patient with cancer. People with Celiac report a higher negative impact on their quality of life (treatment burden) than do people with Type 2 diabetes, congestive heart failure, hypertension, and inflammatory bowel disease.[28] Diagnosed patients report that they miss, on average, 23 days of work and school annually, resulting in excess utilization of our healthcare resources.[29]

We can attest to the treatment burden including the continuous concern over intestinal healing, proper nutrition, cross contact, and inclusion of our son in life's numerous daily activities that involve food at home, at school and away from home in daily life. Leslie is Jax's "advance team," and it is non-stop. Given that stress can trigger and/or exacerbate migraine attacks, our experience indicates that there is a connection between Leslie's diagnosis with chronic migraines in Summer 2018 and Jax's diagnosis with Celiac at that same time.[30] Since July 2018, Leslie has had on average about 12 debilitating headache days per month.

We worry nonstop about how the accidental ingestion of Gluten could trigger Jax developing another autoimmune disease at some point since there is a significant association between Celiac

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[28] "Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions," PMC, National Library of Medicine, National Institutes of Health, Shah, S., Akbari, M., Vanga, R., Kelly, C. P., Hansen, J., Theethira, T., Tariq, S., Dennis, M., & Leffler, D. A. (2014). *The American journal of gastroenterology*, *109*(9), 13041311. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/ https://doi.org/10.1038/ajg.2014.29 ; and "What is Celiac Disease?", Celiac Disease Foundation, https://celiac.org/about-celiac-disease/what-is-celiac-disease/ ; https://www.beyondceliac.org/invisible-illness-infographic/ .

[29] Testimony of Marilyn G. Geller, CEO, Celiac Disease Foundation (Los Angeles, CA), to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, April 9, 2019, https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/?.

[30] Leslie's migraines have continued through to the present, in spite of being under the continuous care and treatment of neurologists specializing in migraines.

Disease and 17 other disorders including Type 1 Diabetes, Crohn's disease, rheumatoid arthritis and ulcerative colitis.[31]

In addition, our request to label Gluten as a Major Food Allergen has been informed in part by many of the 1,576 thoughtful comments on labeling Gluten (and Celiac) submitted to the FDA in 2022 in response to the FDA's Draft Guidance, which will be addressed further herein.[32]

[31] https://www.allergicliving.com/2020/02/06/celiac-disease-and-its-sister-conditions/ ; https://celiac.org/about-celiac-disease/related-conditions/autoimmune-disorders/# ; and https://www.cureceliacdisease.org/faq/what-other-autoimmune-disorders-are-typically-associated-with-those-who-have-celiac-disease/

[32] https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac

III. Labeling of Gluten as a Major Food Allergen is in Alignment with International Food Safety Authorities & Experts, Including from the FDA

A. Overview

The FDA's Draft Guidance and moreover the current consumer protection law with the Food Allergen Labeling and Consumer Protection Act of 2004 appear to be inconsistent 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:

- **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" as detailed in the FDA's Draft Guidance and cited as "FDA Ref. 25").[33]
- **Food and Agriculture Organization of the United Nations/World Health Organization**. "Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 1: Review and validation of Codex priority allergen list through risk assessment." 2021 ("2021 FAO/WHO Expert Consultation"; also referred to as "FDA Ref. 45" in the FDA's Draft Guidance).[34] The 2021 FAO/WHO Expert Consultation was chaired by the FDA's Dr. Lauren Jackson, and in 2022, the 2021 FAO/WHO Expert Consultation's complete report was published, "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."[35]

  2021 FAO/WHO Expert Consultation, Chaired by the FDA's Dr. Lauren Jackson (top left)



[33] https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 124-128)
[34] http://www.fao.org/3/cb4653en/cb4653en.pdf
[35] http://www.fao.org/3/cb9070en/cb9070en.pdf

B. What is Food Allergy? Adverse Reactions to Gluten in Celiacs Are Immune-Mediated.

According to the FDA, "A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an 'allergen.'"[36] In answering the question, "What is Gluten?," the NIH's National Library of Medicine stated that Gluten is a food protein, and that Gluten containing grains include Wheat, Barley, Rye and Oats.[37] According to the NIAID's (National Institute of Allergy and Infectious Disease's) Sponsored Expert Panel found, "A food allergy is defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food."[38]

According to the FDA, "Food allergy is a form of food hypersensitivity. Adverse reactions to food due to food hypersensitivity can be broadly grouped into reactions that are mediated by either immune mechanisms (food allergic reactions) or non-immune mechanisms (primarily food intolerances). Adverse reactions that are immune-mediated can be caused by:

- IgE-mediated mechanisms (e.g., IgE-mediated anaphylactic reaction to peanuts);
- Non-IgE-mediated mechanisms (e.g., adverse reaction to gluten in the case of celiac disease);
- Mixed immune mechanisms (e.g., eosinophilic gastroenteropathies); or
- Cell-mediated mechanisms (e.g., contact dermatitis)."[39]

C. Summary of the "Big 8" Food Allergens from the 1999 Codex Criteria, FALCPA and the 2021 Ad Hoc Joint FAO/WHO Expert Consultation

	Food Allergen	Prevalence of Food Allergy in the U.S.	"The Big 8" - 1999 Codex Criteria	Top 8 Major Food Allergens - FALCPA 2004	2021 FAO/WHO Expert Consultation, May 2021
1	Cereals Containing Gluten	3.3+ million	X (Wheat, Barley, Rye, Oats)		X (i.e., Wheat and other Triticum species, rye and other Secale species, Barley and other Hordeum species and their hybridized strains) See note on Oats
2	Crustacea (Shellfish)	8.2 million	X	X	X
3	Egg	2.6 million	X	X	X
4	Fish (fin)	2.6 million	X	X	X
5	Milk	6.1 million	X	X	X
6	Peanuts	6.1 million	X	X	X
7	Sesame	0.7 million		X (as of 1/1/23)	X
8	Soybeans	1.9 million	X	X	
9	Tree Nuts	3.9 million	X	X	X (Almond, Cashew, Hazelnut, Pecan, Pistachio and Walnut)
10	Wheat	2.4 million		X	

Sources: Various[40]

[36] https://www.fda.gov/media/164194/download
[37] https://pubmed.ncbi.nlm.nih.gov/28244676/
[38] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf
[39] https://www.fda.gov/media/157637/download
[40] A) https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf (Annex 4, pages 124-128); http://www.fao.org/3/cb4653en/cb4653en.pdf . B) https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html ; Other Major Food Allergens: https://www.foodallergy.org/media/1012/download?attachment

D. 1999 FAO/WHO Expert Consultation – Label Gluten as Priority/Major Food Allergen
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."[41] (emphasis added)

E. 2021 FAO/WHO Expert Consultation – Label Gluten as Priority/Major Food Allergen
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**

Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. JAMA Network Open 2019; 2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144. C) Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. JAMA Network Open 2019; 2(1):e185630.doi:10.1001/jamanetworkopen.2018.5630. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720064 #: and
Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics 2018; 142(6):e20181235.
D) Oats - https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf (footnote 10)

[41] https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf

hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut)."[42] [43] (emphasis added)

While the 1999 FAO/WHO Expert Consultation (FDA Ref. 25) and the 2021 FAO/WHO Expert Consultation (FDA Ref. 45) are cited as sources in the FDA's Draft Guidance, the FDA's Draft Guidance omits key findings by the "scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry", and their conclusions to always declare (label) Gluten on food product labels in order to provide consumer protection for the Celiac community to whom ingesting Gluten is just like eating poison and potentially life-threatening.

The global implementation of 1999 FAO/WHO Expert Consultation and 2021 FAO/WHO Expert Consultation can be seen in how more than 85 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.[44]

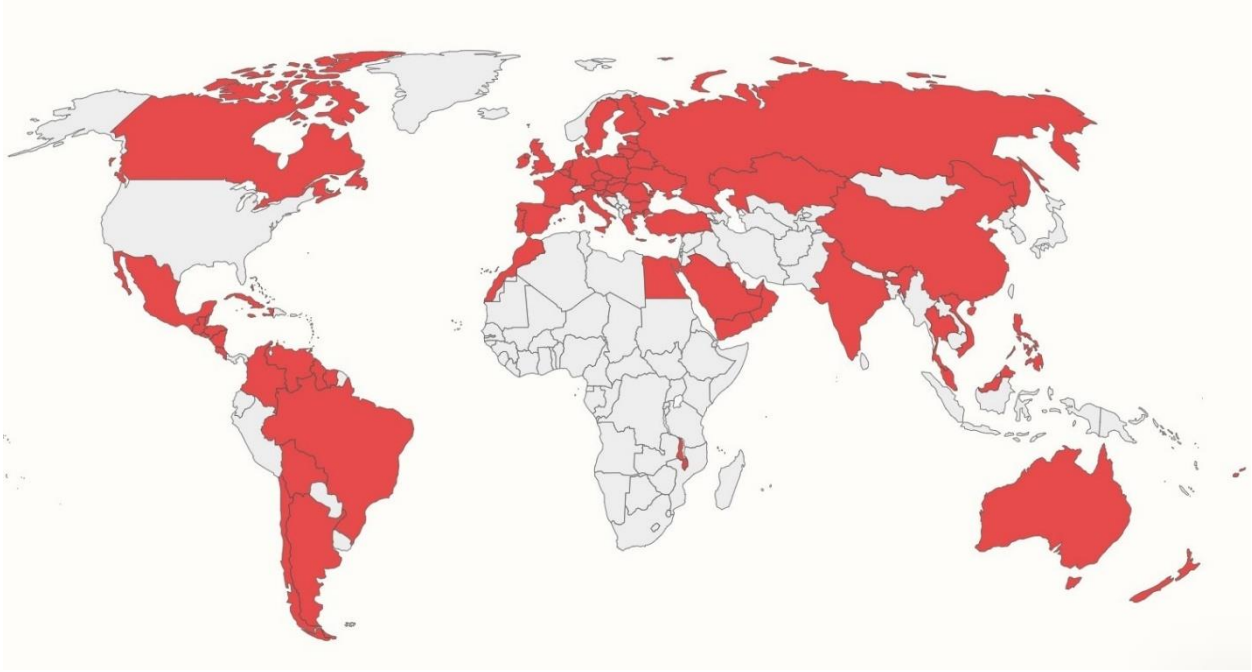
[42] "Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... **oats, ... should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries**." http://www.fao.org/3/cb4653en/cb4653en.pdf

According to research cited by the FAO and WHO, "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." Source: 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, https://www.fao.org/3/cb9070en/cb9070en.pdf , and https://www.tandfonline.com/doi/pdf/10.1080/19440049.2011.579626?

[43] http://www.fao.org/3/cb4653en/cb4653en.pdf

[44] https://farrp.unl.edu/IRChart

F. Gluten Is Required to Be Labeled as a Major Food Allergen on Packaged Foods in More than 85 Countries Worldwide (shaded in red), Not Including the United States



Source: Food Allergy Research and Resource Program at the University of Nebraska-Lincoln[45]

G. FALCPA Has Failed Celiacs Based on a Big Lie: FALCPA Negotiations Were Scientifically Flawed from the Start with Celiac Being Incorrectly Othered as a Gluten Intolerance and Not as a Food Allergy -- No One From FDA or HHS Spoke Up and Served as an Upstander to Protect Celiacs

On August 9, 2002, Inside Washington's (Health Policy's) FDA Week reported that Senator Kennedy floated an amendment to the FALCPA memorialized,

> "But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines... **Critics of the bill [in the food industry] had charged that scientifically, Gluten is an intolerance not an allergen**." (emphasis added)

On September 27, 2002, Inside Washington's (Health Policy's) FDA Week (page 5) memorialized,

> "Substitute [bill] pulls mandatory Gluten declaration... This week the Senate Health Committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. **The substitute version, unlike the underlying bill... would not require the declaration of Gluten**." (emphasis added)

This "science" was wrong then and it is wrong now. When FALCPA was signed into law in 2004, it had already left the Celiac community behind with a voluntary labeling scheme that would not be enacted until 2014, but moreover it was incongruent with the 1999 Codex Criteria

[45] https://farrp.unl.edu/IRChart

and how the international community was already starting to require the labeling of Gluten on all packaged foods. See section herein, "Historical Context of Celiacs Being Underserved and Marginalized by the Federal Government."

H. Perplexing Paradigm of Consumer Protection for 3.3 Million Celiacs: Included vs. Excluded

With the mitigation of the burden of chronic diet-related disease in mind, it is instructive to understand the following current perplexing paradigm. Unlike the FALCPA labeling scheme for the top 9 Major Food Allergens in the U.S. (Sesame as of January 1, 2023), Gluten Free labeling is permissive (voluntary) in the U.S. In other words, whereas sufferers of the current top 9 Major Food Allergens rely on what ingredients are included in required labeling disclosures of packaged foods, Celiacs must rely only on what ingredients are excluded in voluntary Gluten Free labeling disclosures on packaged foods.

Wheat is required to be labeled in the U.S., but Barley, Rye and Oats (collectively the other sources of Gluten with most Oats having had cross contact with Gluten containing grains) are not required to be labeled in the U.S. Imagine if for those with a Tree Nut allergy only Almonds were required to be labeled, but not other Tree Nuts such as Pecans and Walnuts, for example. That would create a massive food safety issue and gap that needed to be closed. Fortunately for those with a Tree Nut allergy that scenario is not the case. But that similar massive safety issue and gap does exist with voluntary Gluten labeling for 3.3 million American Celiacs.

I. Dr. Virginia Stallings, Professor of Pediatrics and Director of the Nutrition Center at the Children's Hospital of Philadelphia ("CHOP") Calls for Gluten to Be Labeled

We agree with the comments that Dr. Virginia A. 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" ("Finding a Path").[46] Finding a Path is a 574 page report was published by the National Academies Press, 2016 and cited as FDA Ref. 2 in the FDA's Draft Guidance to narrowly and incorrectly define food allergen and food allergy.[47]

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[46] https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf
As the Food Allergy Committee which Dr. Stallings 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)
"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,6 7 ['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)

[47] https://www.fda.gov/media/157637/download , page 7

Even though the taxpayer supported FDA Ref. 2 expressly stated that "Food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated" (page 4),[48] the FDA has defined Food Allergen based on two primary references that expressly excluded Celiac Disease in their scope of work and stated, "do not discuss celiac disease,"[49] as well as Celiac is "not covered in this report because they were beyond the scope of the statement of task."[50]

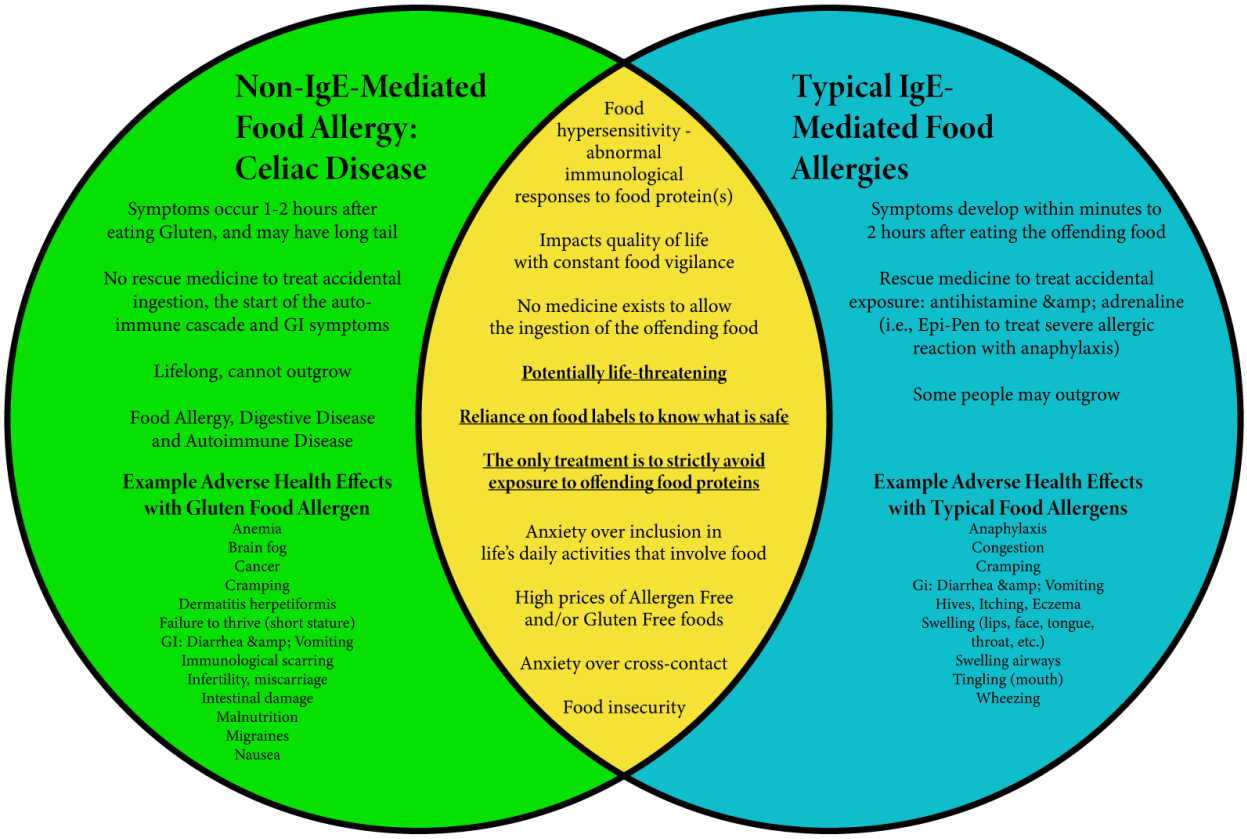
It is absolutely maddening that the FDA has othered the consumer protection needs of the Celiac community by lumping Celiac and lactose intolerance together, "*Immune-mediated mechanisms that are not IgE-mediated (such as mechanisms associated with celiac disease and contact dermatitis), and mechanisms that are not immune-mediated (such as lactose intolerance) typically are not associated with anaphylaxis or other immediately life-threatening conditions*."[51] In the FDA's Draft Guidance, the FDA relied exclusively on Ref. 1 and Ref. 2 to define "food allergy" in the FDA's Draft Guidance (page 7), and that is way too limiting. This is another example of how the Federal government has marginalized the healthcare, well-being and consumer protection needs of the Celiac community by not even believing that the evaluation of the public health importance of labeling Gluten as a Major Food Allergen is meritorious.

Attached please find a copy of Dr. Stallings letter to the FDA dated August 4, 2022 in which she opined regarding the FDA's Draft Guidance and the need to label Gluten as a Major Food Allergen:

> "Our Food Allergy Committee's work for the National Academy found that 'food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-1gB-mediated' (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 report, Celiac Disease was not covered in our report because it was 'beyond the scope of the statement of task' for the committee, not because Celiac Disease is not an essential food safety issue for the population…
>
> 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.

[48] https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf
[49] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf , page 5
[50] https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf , page 26
[51] https://www.fda.gov/media/157637/download

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.[52].”[53] (emphasis added)



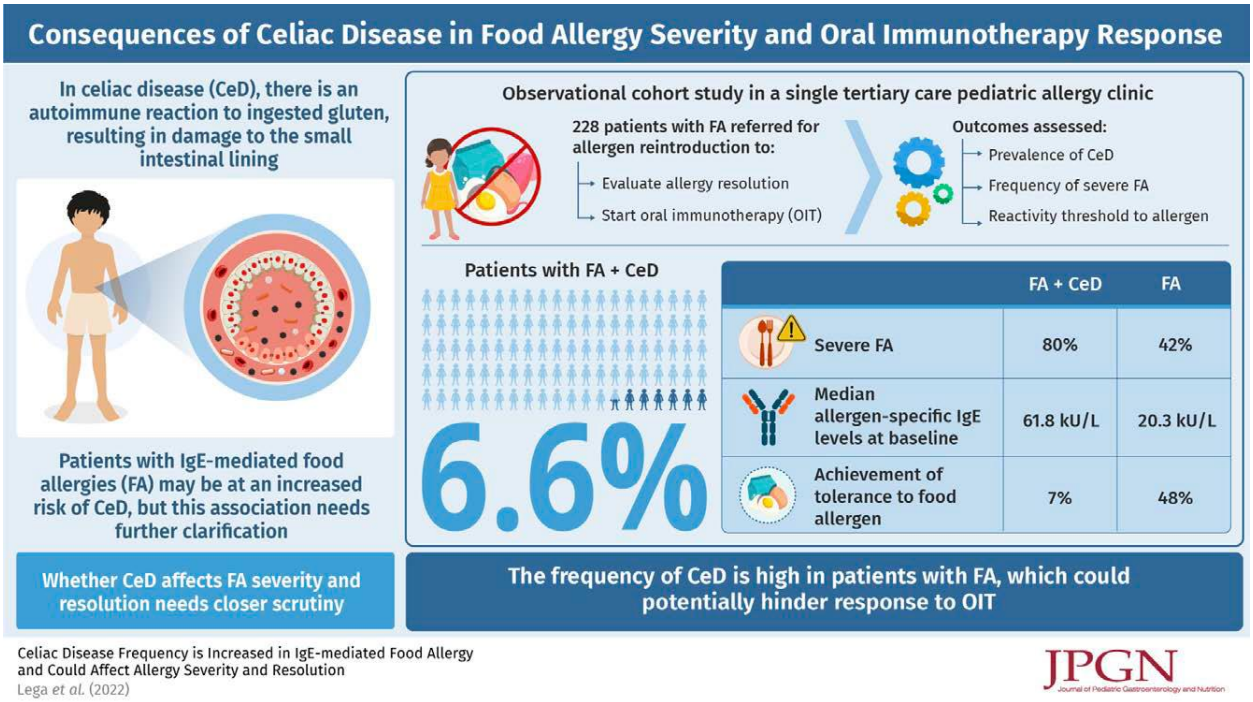
J. Celiac Disease Frequency Is Increased in IgE-Mediated Food Allergy and Could Affect Allergy Severity and Resolution

According to the Journal of Pediatric Gastroenterology and Nutrition in January 2023, Celiac Disease frequency (non-IgE-Mediated) is increased in IgE-Mediated food allergy and could affect allergy severity and resolution.[54]

[52] Food Allergy Research and Resource Program at the University of Nebraska-Lincoln, https://farrp.unl.edu/IRChart

[53] FDA Comment ID: FDA-2021-N-0553-1169, FDA Tracking Number: l6g-mawc-nbs8, August 5, 2022, https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

[54] Lega S, Badina L, De Leo L, Andrade S, Ziberna F, Gaita B, Di Leo G, Bramuzzo M, Barbi E, Not T, Berti I. Celiac Disease Frequency Is Increased in IgE-Mediated Food Allergy and Could Affect Allergy Severity and Resolution. Journal of Pediatric Gastroenterol Nutrition. 2023 January 1;76(1):43-48. doi: 10.1097/MPG.0000000000003629. Epub 2022 Sep 29. PMID: 36574002. https://pubmed.ncbi.nlm.nih.gov/36574002/



Celiac Disease Frequency is Increased in IgE-mediated Food Allergy and Could Affect Allergy Severity and Resolution
Lega *et al.* (2022)

JPGN Journal of Pediatric Gastroenterology and Nutrition

K. Dietary Spectrum: Celiac Disease Food Allergy Must Be Treated as Seriously as IgE-Mediated Food Allergies; Celiac Disease Must Not Be Conflated with Gluten Intolerance (Non-Celiac Gluten Sensitivity) or a Voluntarily Chosen Gluten Free Lifestyle

	Food Preference	**Food Intolerance (Sensitivity)**	**Food Allergy**
Potentially Life Threatening	N/A	N/A	Potentially Life-Threatening & Life-Debilitating
Bodily System	N/A	Digestive System	Immune System
Consequence of Exposure	Disappointment	Discomfort	Danger
Diet Adherence	N/A	Discretionary	Strict: Lifetime, No Cheating & No Breaks
Examples	**Gluten Free Lifestyle**, Dairy Free, Keto, Low Carb, Vegan, Vegetarian, etc.	**Gluten Intolerance (Non-Celiac Gluten Sensitivity),** Lactose Intolerance, Histamine Intolerance, etc.	**Gluten**, Milk, Eggs, Fin Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, Soybeans, Sesame, etc.
Symptoms	Annoyance, Bad Taste, Dissatisfaction, etc.	Cramping, Diarrhea, Gas, Heartburn, etc.	Anaphylaxis, Anemia, Brain Fog, Cancer, Congestion, Cramping, Diarrhea, Failure to Thrive, Immunological Scarring, Infertility, Intestinal Damage, Itching, Malnutrition, Migraines, Nausea, Swelling (lips, face, tongue, throat), Vomiting, Wheezing, etc.

IV. President Biden's Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government & President Biden's Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

A. Embedding Fairness in Decision-Making Processes

It is instructive to view these comments as well as all comments received on the FDA's Draft Guidance[55] about labeling Gluten through the lens of President Biden's "Executive Order 13985 On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government", dated January 20, 2021 and President Biden's Executive Order 14091: Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, dated February 16, 2023[56]

> "It is therefore the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Affirmatively advancing equity, civil rights, racial justice, and equal opportunity is the responsibility of the whole of our Government. Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity. By advancing equity across the Federal Government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone."[57]

B. Equity Definition: Section 2(a) of Executive Orders 13985 & 14901

Equity Definition: Section 2(a) of Executive Orders 13985 & 14901 provides that,

> "The term 'equity' means the **consistent and systematic fair, just, and impartial treatment** of all individuals, including individuals who **belong to underserved communities that have been denied such treatment**, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; **persons with disabilities**; persons who live in rural areas; and **persons otherwise adversely affected by persistent** poverty **or inequality**." Further, section 2(b) provides that, "**the term 'underserved communities' refers to populations sharing a particular characteristic**, as well as geographic communities, **that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life**, as exemplified by the list in the preceding definition of equity."[58] (emphasis added)

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[55] https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac

[56] https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal

[57] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/

[58] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government

C. The Celiac Community Represents an Underserved Community Which Shares a Particular Characteristic including a Chronic Disability

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability as per the Fourth Circuit Court of Appeals[59] and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences, etc. associated with the ingestion of Gluten. The Celiac community has been systemically denied a full opportunity to participate in aspects of economic, social and civil life as detailed below. See sub-section herein entitled, "Celiacs Have Been Denied Opportunity to Participate Fully in Economic, Social & Civic Life."

D. Celiac Impacts Several Major Life Activities

For someone with Celiac Disease, **eating, sleeping, thinking, learning and working are major life activities** that can be impacted on a daily basis, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary. As per the Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health as part of the White House Conference on Hunger, Nutrition, and Health, "diet-related diseases are some of the leading causes of death and disability in the U.S."[60]

E. Racial Disparities in Awareness, Diagnosis and Treatment of Celiac Disease for Black Americans and Other Minorities

According to Beyond Celiac, "in a study by the University of Chicago and Harvard School of Public Health, researchers found that Black Americans who have symptoms associated with Celiac Disease have 90% decreased odds of receiving the appropriate follow-up for diagnosis."[61] Additional findings from Beyond Celiac include:

- "Black Americans (63%) are significantly more likely than Hispanic Americans (49%) and White Americans (47%) to have no awareness of celiac disease and/or gluten-sensitivity, suggesting potential health inequities in both diagnosis and treatment, according to a nationwide benchmark survey conducted by The Harris Poll on behalf of Beyond Celiac, the leading catalyst for a celiac disease cure."[62]

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[59] In May 2019, in a case involving the disability rights of a child who has a severe allergy to Gluten, the U.S. Fourth Circuit Court of Appeals cited that "[t]he ADA [Americans with Disabilities Act] defines a 'disability' in pertinent part as 'a physical or mental impairment that substantially limits one or more major life activities'" and that "[e]ating is a major life activity." J.D., by his father and next friend, Brian Doherty, Plaintiff-Appellant v. Colonial Williamsburg Foundation, Defendant-Appellee, National Disability Rights Network; Disability Law Center for Virginia; Scott Hayes; Virginia Food Allergy Advocates, Amici Supporting Appellant. Vacated and Remanded -Appeal from the United States District Court for the Eastern District of Virginia, at Newport News. Rebecca Beach Smith, District Judge. (4:17-cv-00101-RBS-RJK); United States Court of Appeals for the Fourth Circuit, No. 18-1725, Argued: January 29, 2019; Decided: May 31, 2019, See www.celiacjourney.com/williamsburg and https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf

[60] https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf

[61] https://www.prnewswire.com/news-releases/beyond-celiac-identifies-health-disparities-in-celiac-disease-awareness-diagnosis-and-treatment-for-black-americans-301610858.html

[62] https://www.prnewswire.com/news-releases/beyond-celiac-identifies-health-disparities-in-celiac-disease-awareness-diagnosis-and-treatment-for-black-americans-301610858.html

- "Black, Hispanic, and Latino patients and those with public insurance presenting with celiac disease symptoms are less likely to receive appropriate follow-up compared to white patients and those with private insurance."[63]

F. Examples of How Celiacs Have Been Historically Underserved and Marginalized by the Federal Government

It is further instructive to understand how the Celiac community has been historically underserved and marginalized by our Federal government, including by way of example and not limitation:

- **NIH Research** - Underfunding NIH biomedical research for Celiac Disease over many years (on average, the Federal government spent about $3.4 million annually on Celiac research from 2011-2020, which is about $1.00 per American with Celiac per year, and that is way too low). Funding for Celiac research has been disproportionately low as compared with research funding for food allergies, digestive diseases, auto-immune diseases and/or foodborne illness, and in consideration of these factors: disease prevalence, treatment burden and other available treatment options.[64] According to a Congressionally mandated report "Enhancing NIH Research on Autoimmune Disease" published in May 2022 from the National Academy of Sciences, Engineering and Medicine, "There is a lack of long-term (20 years or more) population-based epidemiology studies on autoimmune disease, the committee found. Such studies would allow for, among other things, assessing trends, risk factors, and costs of disease; identifying differences among population subgroups; and **determining the prevalence of under-researched autoimmune diseases, such as celiac disease**."[65] (emphasis added)
- **Voluntary Gluten Labeling Scheme** - Labeling Gluten only with a voluntary scheme since 2014. Under FALCPA, mandatory labeling of the top 8 Major Food Allergens started on January 1, 2006. In contrast, the FDA delayed action on the FDA's final rule for Gluten Free labeling until August 5, 2014, in spite of a FALCPA deadline of August 2, 2008,[66] and that on January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products that for all intents was the final rule ultimately enacted on August 5, 2014.[67]
- **Military Service** - Disqualifying Celiacs from service in the military.[68] On February 16, 2016, Senator Ted Cruz (who was then a Republican presidential candidate) even went so far as to pledge that if elected, he would not to provide gluten-free military meals – "That's why the last thing any commander should need to worry about is the grades he is getting from some plush-bottomed Pentagon bureaucrat for political correctness or social experiments -- or providing gluten-free MREs [Meal, Ready to Eat]."[69]

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[63] https://www.beyondceliac.org/celiac-news/beyondceliac-takeda-healthcare-equity-initiative/
[64] http://www.celiacjourney.com/briefing
[65] https://www.nationalacademies.org/news/2022/05/nih-should-create-an-office-of-autoimmune-disease-research-says-new-report
[66] https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf , pages 79-96; https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods
[67] https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf
[68] U.S. Department of Defense, DoD Instruction 6130.03, Medical Standards for Appointment, Enlistment, or Induction into the Military Services, Section 5.12.c.(3), May 6, 2018, https://www.esd.whs.mil/DD/
[69] https://time.com/4225884/ted-cruz-military-gluten-free-meals/

- **CDC's Index of Diseases** - Excluding Celiac Disease from the CDC's Index of Diseases & Conditions[70]
- **Medicare** - Excluding Celiacs from Medicare coverage for medical nutrition therapy (MNT) which is currently limited to patients with diabetes and kidney failure, leaving millions of older Americans with leading diet-related diseases, without access to nutrition counseling.[71]
- **FDA Research** - Excluding Celiac Disease from "beyond the scope of the statement of task" from the Federally funded[72] 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."[73]

  According to Dr. Virginia Stallings, the Editor and Chair of Finding a Path, "Our Food Allergy Committee's work for the National Academy found that "food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-1gB-mediated" (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 report, Celiac Disease was not covered in our report because it was 'beyond the scope of the statement of task' for the committee, not because Celiac Disease is not an essential food safety issue for the population."[74] In other words, the Federal government paid for this seminal report which excluded Celiac from the statement of task, and then the FDA relied upon Finding a Path to exclude Gluten from evaluating the public health importance of food allergen other than the Major Food Allergens.[75]

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[70] https://www.cdc.gov/health-topics.html#f , and https://www.cdc.gov/health-topics.html#cdc-atozlist

[71] https://www.dropbox.com/s/2qxco3pc1i5xg49/Tufts_WhiteHouseReport_R16_IP22_082122.pdf?dl=0

[72] Finding a Path "was supported by federal sponsors: the Food and Drug Administration (Contract No. HHSP233201400020B/HHSP23337025), the Food and Nutrition Service of the U.S. Department of Agriculture (Grant # FS_NAS_IOM_FY2015_01), and the National Institute of Allergy and Infectious Diseases. Source: Page ii, https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf

[73] https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf
As the Food Allergy Committee which Dr. Stallings 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)
"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,6 7 ['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)

[74] https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

[75] https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

- **FDA's 2022 Food Code** - Excluding Celiac Disease and Gluten from the FDA's 2022 Food Code.[76] According to the 2022 Recommendations of the United States Public Health Service and Food and Drug Administration, "The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service."[77] The 2022 Food Code is 668 pages, and includes sections on "Food Labels and Other Forms of Information,"[78] "List of Ingredients,"[79] "Food Allergen Labeling"[80] and "Food Allergens As Food Safety Hazards."[81] However, the FDA's 2022 Food Code does not mention Celiac Disease at all,

[76] "This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model." Source: 2022 Food Code, January 18, 2023 Version, https://www.fda.gov/media/164194/download

[77] 2022 Food Code, January 18, 2023 Version, https://www.fda.gov/media/164194/download

[78] "Food labels serve as a primary means by which consumers can make informed decisions about their food selections... Unintended food allergen food allergen exposures poses a serious risk to consumers with food allergies. Consumers with food allergies depend on allergen information that is made available either verbally or written by the food establishment. To address consumer notification of major food allergens in unpackaged foods served or sold within food establishments, the Conference for Food Protection, Issue 2020-II-015, recommended that a new provision be added." 3-602.12, Annex 3-144, https://www.fda.gov/media/164194/download

[79] "A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food." 3-602.12, Annex 3-144, https://www.fda.gov/media/164194/download

[80] Annex 3-145, https://www.fda.gov/media/164194/download

[81] "Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an allergen. For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.
Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies: Milk, Egg, Fish (such as bass, flounder, or cod), Crustacean shellfish (such as crab, lobster, or shrimp), Tree nuts (such as almonds, pecans, or walnuts), Wheat, Peanuts, Soybeans, and Sesame.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not

and it only mentions Gluten in two passing references including in a Web site address[82] and an historical reference to FALCPA.[83] The 2022 Food Code also misleadingly states that the "FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies."[84] This 90% statistic is misleading in that it only includes IgE-Mediated food allergies and excludes Celiac Disease (see section herein entitled "Question: Are 90% of Food-Sensitive Americans Helped by the Food Allergen Labeling and Consumer Protection Law? Answer: NO!".

- **NIH's Research, Condition, and Disease Categories List** - Excluding Celiac Disease (through June 2022) from the NIH's "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)"[85] that provides research and funding data on how NIH allocates its financial resources. Celiac was finally added to the RCDC list in July 2022 following the House Appropriations Committee distributing its FY2023 budget report which included the following language about Celiac Disease: "The Committee thanks NIH for establishing a Research Condition, Disease Categorization (RCDC) for celiac disease."[86]
- **DoD** - Excluding Celiac Disease research funding (from 1992 through December 2022) from the U.S. Department of Defense Congressionally Directed Medical Research Program (DoD-CDMRP)[87] Peer Review Medical Research Listing. The DoD-CDMRP describes its Peer Review Medical Research Program ("PRMRP") this way: "Each year, the PRMRP solicits research applications under topic areas directed by Congress, which address a wide range of fields of study. The PRMRP is committed to supporting research that has the potential to profoundly impact the development and implementation of medical devices, drugs, and clinical guidance that will enhance the precision and efficacy of prevention, diagnosis, and treatment across a wide range of disciplines including autoimmune diseases and immunology…"[88] According to the U.S. Army Medical Research and Development

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intended as an ingredient of the food during processing and preparation." Annex 4-11, https://www.fda.gov/media/164194/download

[82] Annex 2-10:
Food Allergen Labeling and Consumer Protection Act of 2004. Public Law 108-282 https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa

[83] Annex 4-12: "Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term "gluten-free" on food labeling." For the record, the FDA Food Code does not acknowledge that on January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products (https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf) that for all intents was the final rule ultimately enacted on August 5, 2014, and that the U.S. lagged way behind our peer countries which had all set labeling standards for Gluten Free foods and followed the 1999 Codex Criteria to label Gluten as a Priority/Major Food Allergen. Notwithstanding the statutory requirement to implement a final rule by August 2, 2008, the FDA was delayed in doing so by more than 6 years, all the white the Celiac community was left in limbo.

[84] Annex 3-145, https://www.fda.gov/media/164194/download

[85] https://report.nih.gov/funding/categorical-spending#/

[86] https://www.govinfo.gov/content/pkg/CRPT-117hrpt403/html/CRPT-117hrpt403.htm

[87] https://crsreports.congress.gov/product/pdf/IF/IF10349?eType=EmailBlastContent&eId=f11b707e-ca9a-4b10-b6df-afea47b3cb2e

[88] https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf

Command, autoimmune "disorders impact U.S. Service Members, Veterans, and their beneficiaries and can produce a range of debilitating symptoms that interfere with an individual's daily duties and require long-term care, incurring significant costs for the Military Health System. As a result, autoimmune disorders pose a risk to the effectiveness and readiness of the military force. The PRMRP Autoimmune Diseases and Immunology portfolio supports research into the underlying mechanisms and treatment identification for these disorders with the goal of reducing morbidity. During FY16-FY20, the PRMRP funded 44 awards related to autoimmune disorders and food allergies totaling $59.9M."[89] In other words, from 1992-2022, the PRMRP never studied Celiac Disease (including from 2016-2020 when almost $60 million was spent on "Autoimmune Diseases and Immunology" including on food allergies).[90] Advocacy by Celiac Journey along with other Celiac Disease advocacy organizations and the Defense Research Health Consortium ("DHRC") finally turned the tide with the PRMRP starting in 2023 so that access to funding for Celiac research will be made available through the DoD-CDMRP's Peer Review Medical Research Listing.[91]

- **NIAID Autoimmune Diseases Coordinating Committee** - Excluding representation from Celiac Disease advocacy organization(s) on the National Institute of Allergy and Infectious Diseases ("NIAID") Autoimmune Diseases Coordinating Committee ("ADCC") from 1998-2020.[92] As of May 29, 2020, there were 35 members from the Federal government (primarily from the NIH, but also the FDA), as well as 17 members from patient advocacy organizations represented on the ADCC. "NIAID chairs the NIH Autoimmune Diseases Coordinating Committee (ADCC), which was established in 1998 at the request of Congress. The purpose of the ADCC is to facilitate coordination of research across the National Institutes of Health (NIH), federal agencies, professional societies, and patient and advocacy organizations with an interest in autoimmune diseases."[93] It was not until after the "Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting" on May 29, 2020[94] that the Celiac Disease Foundation and Beyond Celiac were invited to join the ADCC.[95]

  On May 29, 2020, NIAID's "Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting" was held and Marilyn Geller, CEO of the Celiac Disease Foundation presented. After Ms. Geller completed her remarks, Dr. Annette Rothermel, Section Chief, Autoimmune and Primary Immunodeficiency Diseases Section, Division of Allergy Immunology and Transplantation at the NIH said, "I'm just going to ask the question because

[89] https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf
[90] https://cdmrp.health.mil/prmrp/pbks/prmrppbk2022.pdf
[91] https://celiac.org/about-the-foundation/featured-news/2023/01/marilynsmessagejanuary2023/
[92] As of July 1, 2020, of the 52 members of the ADCC, there were 17 members representing specific diseases. A full one third of the ADCC members came from patient advocacy organizations outside of the NIH. There were no representatives of any organization or physician/scientist representing the Celiac Disease community. However, there were multiple non-NIH employees on the ADCC including representatives for the following: Crohn's/Colitis (3 people); Type 1 Diabetes (2 people), Juvenile Diabetes (1 person); Sjogren's Syndrome (2 people), Lupus (1 person), Arthritis (1 person); Multiple Sclerosis (1 person), Psoriasis (1 person), Neuromyelitis Optica (NMOSD)/Devic disease (1 person).
Source:
https://web.archive.org/web/20200713010533/https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee
[93] https://www.niaid.nih.gov/about/autoimmune-diseases-committee
[94] https://www.niaid.nih.gov/sites/default/files/2020-ADCC-Agenda.pdf
[95] https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee-members

I think maybe for this audience, it might be surprising to them that the Gluten Free diet is not the be all and end all, it's not, it really doesn't limit; I mean it [Gluten Free diet] isn't working as well as I think most of us thought it would."[96] This was a shocking admission that suggests the pernicious impact that the lack of Federal research funding for Celiac has had with regard to how the NIH has been prioritizing its research focus and allocation of funding based on treatment burden, treatment options and disease prevalence. In other words, Dr. Rothermel's comments suggest that the Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available. Dr. Rothermel's candid comment also suggests how this pernicious impact has extended to other government agencies such as the FDA when it comes to implementing consumer protection with voluntary labeling of Gluten.[97]

- **National Strategy on Hunger, Nutrition and Health** - Excluding Celiac Disease, Gluten and Food Allergies from the Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health as part of the White House Conference on Hunger, Nutrition, and Health.[98] [99]

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[96] https://www.dropbox.com/s/lb8ztfpyw1or2q1/ADCC%2005292020%20Zoom%20Meeting%20Recording%205-29-20.mp4?dl=0 ; 32:10-33:57 mark

[97] In a follow up email from Dr. Rothermel to Jon Bari, Dr. Rothermel clarified her comments by stating, "As to your question about who commented that it might be surprising that the GFD is not working so well for many celiac patients, I did make a comment to the effect that the audience [NIAID's Auto-immune Disease Coordinating Committee] might have found it surprising that the gluten free diet in not a cure and really isn't working as many think it does. I made this comment to emphasize the point for meeting participants not expert in celiac disease, as I thought many would find this surprising. My intent was to hit home that the gluten free diet is not a cure as many may think." July 20, 2020.

[98] https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf

[99] While the authors of this Memo to Secretary Becerra recognize that the National Strategy is a framework, many in the food allergy community, including the authors, had provided comments to help inform the National Strategy, and were thus very disappointed that there was no express reference to "food allergies" including Celiac Disease, in the National Strategy. We were also disappointed in the placement of food labels only in Pillar 3 in the context of making "healthy choices," in addition to looking at it through the lens of nutrition and health in Pillar 2.

For example, there was only one reference in the National Strategy to food allergens (i.e., "ingredient, and allergen information"), and this was in the context of online sales, "Facilitate making nutrition information easily available when grocery shopping online. While consumers increasingly use e-commerce to shop for groceries, nutrition information is not uniformly presented or always made easily accessible. HHS FDA will publish a request for information to gather public input regarding industry practices, technology, and current challenges to inform guidance for the food industry on nutrition, ingredient, and allergen information that should be available for groceries sold online." (National Strategy, page 22)

This suggests at least two biases against Celiacs:

A) The list of Major Food Allergens currently required to be labeled is finite (already established) and adequately informs and safeguards the public about potentially life-threatening food allergens on the product labels themselves, notwithstanding the FDA asking for public comments in April 2022 on evaluating the public health importance of food allergens other than

- **USDA's Dietary Guidelines** - Excluding Celiac Disease from the USDA's 164 page "Dietary Guidelines for Americans 2020 - 2025, Make Every Bite Count with the Dietary Guidelines"[100] In spite of discussion over other food allergens, there was not one mention Celiac Disease or Gluten.
- **HHS Secretary Alexander Azar Has Celiac Disease, But Did Not Do Nearly Enough to Meaningfully Improve the Lives of Those with Celiac** – In spite of former HHS Secretary

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the Major Food Allergens (FDA Docket FDA-2021-N-0553). In total, there were 1,907 comments submitted to the FDA, and 1,576 comments mentioned Celiac and/or Gluten as a food allergen (82.6%).

B) This goal in the National Strategy is a retailing/IT issue in terms of digital merchandising of content (i.e., label contents for nutritional and allergen information), as opposed to a food manufacturer issue.

Putting labeling in just Pillar 3 of the National Strategy, and the manner in which it was done, suggests that this is more about nutrition than ingredients including allergens, and as such, it appears to be more about a "nice to have" or "should have" as opposed to a "must have."

Nutrition is fundamental for everyone, and it is important to understand nutritional elements (i.e., sodium, trans fat, sugar, etc.). However, for those with food allergies, the concept of making healthy choices is secondary to making safe choices that are free of the said allergen to which their immune system mounts a potentially life-threatening and life-debilitating response. In other words, before even worrying about the nutritional value, those with food allergies must cross a safety threshold as to safe ingredients. Just because some food may be healthy for some, that does not mean that these are safe choices for the those with food allergies.

As U.S. Senator Royal S. Copeland, MD (D, NY, 1923-1938) said, "What is food for one is poison for another." (Source: "Hearing Before the Senate Comm. on Commerce, 73d Cong. (1934), reprinted in Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record 1176 (1987).], at 1176." https://biddle.on.worldcat.org/search/detail/577790092?queryString=no%3A577790092)

For example, 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: anemia, cancer, heart disease, immunological scarring, intestinal damage and malnutrition. Personally, my son Jax had severe intestinal damage at age 5 from eating Gluten for some extended period of time (we just do not know how long he had Celiac for prior to be diagnosed) which caused malnutrition and anemia. The ingestion of Gluten also caused to failure to thrive, and his intestine took years to heal (although he is still anemic), but every time he accidentally gets Glutened (like he was on April 12, 2023 as illustrated on the cover of this Memo), he gets violently ill (like food poisoning) and the auto-immune response repeats to attack his small intestine.

Adding labeling of Gluten to the National Strategy in Pillar #2 makes more sense for those with a Celiac Disease, "Integrate nutrition and health: Prioritize the role of nutrition and food security in overall health, including disease prevention and management, and ensure that our health care system addresses the nutrition needs of all people."

[100] https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf

Alexander Azar having Celiac Disease himself, and his children having a greater percentage chance of developing Celiac, Secretary Azar referred to Celiac as an "incurable, hereditary disorder that millions of Americans, including myself, live with." Secretary Azar's tenure represented a once in a generation opportunity to meaningfully move the ball down the field with biomedical research to find treatment(s) other than a strict Gluten Free diet for life and moreover for a cure. Instead, Secretary Azar presided over a continued period of historic underfunding of Celiac research that was disproportionate to its prevalence, treatment burden and lack of any other treatment options. Toward the end of his tenure, Secretary Azar focused on finalizing the Gluten Free labeling rule for foods containing fermented hydrolyzed ingredients, yet he seemed indifferent to calls for labeling Gluten as a Major Food Allergen which would have had a much more meaningful impact for consumer protection.[101] Instead, Secretary Azar's actions seemingly doubled-down on that: 1) A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available to treat Celiac Disease, and 2) With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.

- **Gaslighting Gluten** – The Federal government has historically gaslighted Gluten as a second class food allergen and Celiac as not a food allergy when it comes to consumer protection with labeling Gluten as a Major Food Allergen in the US.[102] Biomedically, conversationally and legally, it is time for regulators, scientists, doctors, consumers and the food allergy community (even including the Celiac community) to stop gaslighting Gluten. With respect to the consumer protection needs of the Celiac community with food labeling, Celiac Disease is a food allergy and Gluten is a food allergen. Period. Full Stop.

- **Federal Funding & Bias Via Blind Spots** - Funding various agencies, facilities, schools, programs, etc. that exclude Celiacs from full and equal participation in life's daily activities that involve food, etc. Even though the Biden-Harris Administration, which has celebrated inclusivity and accommodations for many marginalized and underserved communities, has unfortunately fallen short for those with potentially life-threatening food allergies including Celiacs.[103] For example, President Joe Biden's M&M's epitomize the need to label Gluten as a Major Food Allergen to eliminate fear and danger.[104] The Washington Post reported that the "White House Easter Egg Roll celebrates education, inclusivity."[105] However, our lived experience in attending the 2023 Easter Egg Roll was that the event fell way short of accommodating those with food allergies, including Celiac.[106]

G. Universal Declaration of Human Rights - The Right to Feed Oneself in Dignity

The Preamble to the Universal Declaration of Human Rights is predicated in part on "the dignity and worth of the human person" and "the inherent dignity and of the equal and inalienable rights

[101] https://celiacjourney.com/azar
[102] www.celiacjourney.com/gaslighting
[103] https://www.celiacjourney.com/whitehouse2
[104] www.celiacjourney.com/mms
[105] https://www.washingtonpost.com/dc-md-va/2023/04/10/white-house-easter-egg-roll/
[106] https://www.instagram.com/p/Cq8P-NKLelU/

of all members of the human family."[107] To those ends, the intent of the United Nations Charter is to "promote social progress and better standards of life…"[108]

As a preface, for Celiac Disease patients and their caretakers, the "right to feed oneself in dignity"[109] underpins the human right to adequate (safe) food, and these rights can be greatly impacted by perpetual circumstances including:

- **Consuming Poison** - Being poisoned by the consumption of Gluten (i.e., being "glutened") and suffering from a myriad of symptoms including vomiting, diarrhea, cramping, joint pain, fatigue, brain fog, etc. (and not having any medicine that can stop, mitigate, or treat the auto-immune cascade response triggered from the ingestion of Gluten). In addition, there is the constant anxiety about the potential for cross-contact.[110]
- **Anxiety** - Worrying about cross contact with every bite, every day with short term sickness and long-term damage to one's small intestine.
- **Stigma - Being stigmatized and feeling isolated from not fully participating in economic (professional), social, civic, and/or educational activities that involve food, often with no Celiac safe Gluten Free options**.[111] [112] According to Dr. Priyanka Chugh, "The feeling of being bullied and stigmatized does not end as children age into adults: bullying and a sense of loneliness are ubiquitous in many of the lives of those with food restrictions."[113]
- **Food Insecurity** - Scrutinizing voluntary Gluten Free labeling and other food labels for accurate and comprehensive ingredient lists.
- **Food Insecurity** - Navigating various food label disclaimers (i.e., there are no Gluten containing ingredients, but the product has not been tested for Gluten and/or may be at risk for Gluten cross-contamination due to the way it was manufactured or processed).

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[107] "Universal Declaration of Human Rights," United Nations. 10 December 1948. https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf

[108] https://www.ohchr.org/en/development/milestone-events-right-development#

[109] https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf

[110] https://www.instagram.com/p/CqnYV7lrRR4/

[111] "**Along with the high prevalence of depression and anxiety symptoms for people diagnosed with celiac disease, there also is social stigma of being diagnosed with celiac as well**. Social scientists define stigmatized persons as 'any individual who possesses a characteristic, temporary or permanent, that other individuals view as unfavorable, negative, or unacceptable' (Schroeder & Mowen, 2014, p. 475). Stigmatized individuals are more likely to suffer from low levels of self-esteem, increased rates of depression and anxiety, alcohol use, and other psychological issues including increased feelings of anger and hostility. Related to health stigmas, studies have found that individuals with chronic diseases, such as cancer and epilepsy, become significantly more likely to develop depression and negative self-perception at the point their chronic disease becomes a dominant aspect in their life (Schroeder & Mowen, 2014). **People with celiac disease often suffer from stigma, feelings of inadequacy, and exclusion from normal social roles. Stigmas also interfere with maintaining positive self-concepts, which tends to lead to reduction in social network and support systems**." Source: VISTAS Online, "Celiac Disease: Depression, Anxiety, Social Stigma, and Implications for Counselors" by Rachelle Buchanan and John Arman https://www.counseling.org/docs/default-source/vistas/celiac-disease-depression-anxiety-social-stigma-and-implications-for-counselors.pdf?sfvrsn=8

[112] https://www.aafa.org/wp-content/uploads/2022/08/aafa-my-life-with-food-allergy-parent-survey-report.pdf

[113] https://www.huffpost.com/entry/living-with-food-allergies_b_4480918

- **Hunger** - Being hungry and not being able to find safe Gluten Free food options (i.e., eating away from home including at school or work and while travelling).
- **Gluten Free Tax** - Affording the high cost of the Gluten Free diet and being able to maintain adherence to the Gluten Free diet due to high cost and availability challenges, which can then lead to further serious adverse health complications.
- **Othered** - Having the medical requirements of a strict Gluten Free diet not be taken as seriously as the medical requirements with the Major Food Allergens by government and society.

H. Convention on the Rights of the Child

According to the **United Nations "Convention on the Rights of the Child":**[114]

- "In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, **administrative authorities** or legislative bodies, **the best interests of the child shall be a primary consideration**." (emphasis added) **(**Article 3.1)
- "States Parties **recognize the right of the child to the enjoyment of the highest attainable standard of health** and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services." (Article 24.1)

To address the historical inadequacies of the voluntary labeling Gluten and the underfunding of Celiac Disease, including with Federal research funding, the "legislative bodies" such as the U.S. Congress and the "administrative authorities" such as the President, NIH and CDC should use the Convention on the Rights of the Child as a guiding principle in the allocation of funding resources: "the best interests of the child shall be a primary consideration."[115]

I. Celiacs Have Been Denied Opportunity to Participate Fully in Economic, Social & Civic Life

Accordingly, our Celiac community regularly shares their lived experiences of how they have **systematically been denied the opportunity to participate fully in aspects of economic, social, and civic life** when by way of example and not limitation:

- **Major Life Activities Impacted** - Celiacs are glutened regularly and have their major life activities such as eating, sleeping, thinking and/or learning impacted on an ongoing basis. Beyond Celiac reported that 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month.[116]
- **Ongoing Symptoms on a Strict Gluten Free Diet** - According to Digestive Disease Week, even when on a strict Gluten Free diet "more than half of those with Celiac Disease remained symptomatic during the five years after diagnosis.[117]
- **Constant Anxiety and Questioning** - Celiacs constantly question food labels for inadequate and incomplete ingredient lists.

[114] https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf
[115] https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf
[116] https://twitter.com/abast/status/1551780196243603457
[117] https://www.beyondceliac.org/research-news/five-years-after-diagnosis-more-than-half-have-symptoms/

- **Food Prices Are Disproportionately Higher** - Celiacs spend 2x-6x more on Gluten Free food products when compared to the food products' Gluten containing counterparts, on both a per unit price and per ounce price.[118] [119]
- **Military Disqualification** - Celiacs cannot serve in the U.S. military.
- **Treatment Burden** - Celiacs report a higher negative impact on their quality of life (treatment burden) than do people with Type 2 Diabetes, congestive heart failure, hypertension, and inflammatory bowel disease.[120] Celiac patients report that they miss, on average, 23 days of work and school annually, resulting in excess utilization of our healthcare resources.[121]
- **Choosing Schools/Camps on Safe Food Criteria** - Celiacs and/or their parents and caretakers select an educational institution (K-12, college, university, etc.) or camp based on whether they believe that the school/camp can safely accommodate their dietary requirements, and they can eat safely at that their school (this is in addition to the "typical" criteria such as academics, athletics, location, major(s), size, cost, location, culture, professional pathway, etc.).[122] Celiac students are often required to pay for meal plans at their selected college, even if there are not Celiac-safe options for them to consume and/or they get sick from being glutened due to cross contamination. There are numerous lived experience accounts including from student newspapers and litigation dockets of the failures at various schools to keep Celiac students safe, included and nourished, including at Harvard,[123] University of Maryland,[124] UCLA,[125] University of Pennsylvania,[126] Williams,[127] Yale,[128] etc.

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[118] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf , pages 130-143.
[119] https://www.celiacjourney.com/readout
[120] "Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions," PMC, National Library of Medicine, National Institutes of Health, Shah, S., Akbari, M., Vanga, R., Kelly, C. P., Hansen, J., Theethira, T., Tariq, S., Dennis, M., & Leffler, D. A. (2014). *The American journal of gastroenterology*, *109*(9), 13041311. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/ https://doi.org/10.1038/ajg.2014.29 ; and "What is Celiac Disease?", Celiac Disease Foundation, https://celiac.org/about-celiac-disease/what-is-celiac-disease/ ; https://www.beyondceliac.org/invisible-illness-infographic/ .
[121] Testimony of Marilyn G. Geller, CEO, Celiac Disease Foundation (Los Angeles, CA), to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, April 9, 2019, https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/?.
[122] https://www.celiackidsconnection.org/2016/11/13/choosing-a-college/ ; https://educationaladvocates.com/navigating-the-college-search-for-student-with-celiac-disease-and-food-allergies/ ; https://www.gfreefriends.com/post/celiac-complicates-your-college-search ; and https://www.beyondceliac.org/wp-content/uploads/2020/08/College-Toolkit.pdf
[123] https://www.thecrimson.com/article/2020/2/14/graham-when-dining-is-dangerous/
[124] Hannah Smith v. University of Maryland, College Park, U.S. District Court for the District of Maryland, Case 8:20-cv-00433, Doc 1, February 20, 2020.
[125] https://dailybruin.com/2019/01/24/ucla-dining-services-fails-students-with-insufficient-gluten-free-considerations
[126] https://www.thedp.com/article/2016/03/freshman-celiac-disease-meal-plan-dining
[127] https://williamsrecord.com/457920/opinions/the-struggles-of-following-a-special-diet-at-the-college/
[128] https://yaledailynews.com/blog/2020/02/10/gluten-intolerant-students-navigate-dining-halls/

- **Social Life** - Celiacs have been systematically denied a full opportunity to participate in aspects of social life. Think about the number of life's activities that involve food, many of which occur spontaneously.
    - According to an FDA, "Impactful symptoms: The celiac patients and caregivers described a variety of symptoms that impact their daily life:... **Patients have found it difficult to participate in social activities that involve food and beverages because of the risk of accidental ingestion of gluten or cross-contamination in food preparation. Patients will often pack their own food when eating outside of their homes, but this can be challenging with travel. Patients cannot always trust gluten-free options at restaurants**."[129]
    - "Food and socializing are very intimately intertwined, and it is always a bummer to be excluded from the food portion, as one then has to make a choice between being present and hungry or absent while taking care of one's own needs."[130]
    - In a national benchmarking survey conducted on behalf of Beyond Celiac by The Harris Poll from February 8-10, 2022 among 2,039 adults, research showed that **53% of Americans say that foods are not always clearly labeled as gluten-free or not**, and 53% of Americans know it can be hard to find Gluten Free food options when away from home, including at school and when travelling.[131]
- **Career Choices** - Celiacs cannot pursue certain careers when they must eat out all the time and cannot safely and effectively control their diet.[132]
- **Travel Limitations and Obstacles** - Celiacs cannot travel as freely as others without food allergies since they do not know where their next safe meal away from home will come from since our travel infrastructure including airports and highway rest stops are inequitable in terms of not providing safe Gluten Free food to eat.[133]
- **Oral Health & Dental Defects** - According to the NIH's National Institute of Diabetes and Digestive Diseases and Kidney Diseases, "Dental enamel problems stemming from celiac disease involve permanent dentition and include tooth discoloration—white, yellow, or brown spots on the teeth—poor enamel formation, pitting or banding of teeth, and mottled or translucent-looking teeth. The imperfections are symmetrical and often appear on the incisors

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[129] https://www.fda.gov/media/127706/download

[130] https://medium.com/@bethleyba/navigating-ableism-with-invisible-disabilities-82636c50a09c

[131] "The Mystery of Celiac Disease: The Need for Greater Awareness and Accelerating the Quest for a Cure", May 2022, https://www.beyondceliac.org/wp-content/uploads/2022/05/2022-Beyond-Celiac-Survey-FINAL.pdf . Note that "[t]he sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data is accurate to within + 2.8 percentage points using a 95% confidence level. For complete survey methodology, including weighting variables and subgroup sample sizes, please contact cbaker@beyondceliac.org."

[132] Testimony of Marilyn Geller, CEO of the Celiac Disease Foundation about her 26-year-old son Henry's experience in college and as a travelling consultant, "And then he unfortunately had to make the decision to switch careers because as he said, in this particular line of work where you have to eat out all the time, it was absolutely impossible. So, while I thought over the last eight years, wed figured it out, you know, it's still coming back to the fact that as an adult his actual career choices are dependent upon whether or not he can eat safely." Celiac Disease-Focused Autoimmune Disease Coordinating Committee Meeting May 29, 2020, 32:10-33:57, https://www.dropbox.com/s/lb8ztfpyw1or2q1/ADCC%2005292020%20Zoom%20Meeting%20Recording%205-29-20.mp4?dl=0

[133] www.celiacjourney.com/pete

and molars."[134] In other words, in addition to Celiacs constantly facing food insecurity, Celiacs also have dental problems that can cause translucent teeth and chipping, even in a 10 year old boy like my son.[135] In a Cigna Dental Report published in November 2019 entitled "Behind the Smile, Oral Health Impacts Self-Esteem, Confidence and Employability," Cigna found that, "The impact that oral health and one's feelings about their smile has on self-confidence is alarming. But the cause and effect of oral health and smile satisfaction doesn't stop at self-confidence. The insecurities about smiles and oral health have had a direct impact on employment opportunities for many of the people included in this study." In addition, the study found, "It's clear there is a connection between oral health and smile satisfaction, and how confident people feel. And this connection can have a direct impact on a person's life, including lower employability, lower levels of satisfaction with their appearance, and an increased sense of stress or discomfort in a variety of settings because of how they feel about their smile or oral health."[136]

- **Dating & Intimacy** - Celiacs carry a very heavy social burden in the dating world whereby almost half of people 18 years and older who have experienced dating hesitate to go on dates. One in five Celiacs surveyed said the overall dating experience is not enjoyable. Nearly 40 percent are uncomfortable on a date when they have to explain their need for Gluten Free food to restaurant servers. Nearly 30 percent take risks when eating and eight percent have eaten gluten knowingly. Young adults, those 23 to 35 years old reported a moderate to major impact on their lives (as compared to those older than 65 years). "Among about 600 survey participants who answered these specific questions, about 40 percent are hesitant to kiss, about 23 percent feel symptoms interfere with being physically intimate and 12 percent feel their partner needs to be on a gluten-free diet."[137]
- **Celiac Children and Adults Are Bullied** - Celiacs are often bullied because of their food allergy[138]; About one-third of kids with food allergies report that they have been bullied because of their allergies, including my 10-year-old son.
- **Celiacs Are Ridiculed** - The only available treatment for Celiac – a strict lifetime Gluten Free diet – and Celiacs are too often the punchline of jokes in the media and entertainment industries.[139] On February 2, 2015, Maura Judkis from the Washington Post helped normalize and popularize making fun of the Gluten Free diet in an article entitled, "Nick Offerman pitches NASCAR in hilarious Super Bowl 2015 commercial" when she wrote,

> "The premise: Americas favorite lumbersexual, Nick Offerman, makes the pitch for NASCAR, which is a genius casting move: His red meat-eating, wilderness-loving ways are in lockstep with NASCARs typical audience, but he's beloved by Millennial urbanites, who are less likely to be interested in watching cars zoom around a track, unless they're doing it ironically.

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[134] https://www.niddk.nih.gov/health-information/professionals/clinical-tools-patient-management/digestive-diseases/dental-enamel-defects-celiac-disease
[135] https://pubmed.ncbi.nlm.nih.gov/19687752/
[136] https://images.connecting.cigna.com/Web/CIGNACorporation/%7B1068fec3-a6d7-48c1-9664-05ccebba3710%7D_930138_Self_Esteem_Article_Dental_flyer.pdf
[137] https://www.beyondceliac.org/research-news/dating-doesnt-read-like-romantic-novel/
[138] https://glutendude.com/party-city-calls-celiacs-gross/
[139] By way of example, see www.celiacjourney.com/mean
https://glutendude.com/why-the-jimmy-kimmel-video-matters/
https://glutendude.com/netflix-do-revenge-celiac/
https://glutendude.com/barstool-sports-gluten-free-people-are-weak/
https://glutendude.com/grinch-ad-campaign-gluten/

The punchline: He kicks it off by imploring Americans to do a gut-check: When our idea of danger is eating gluten, there's trouble afoot. Then, Offerman teaches us how to be a True American Patriot in a series of vignettes that would make our Founding Fathers proud..."[140] (emphasis added)

J. Historical Context of Celiacs Being Underserved and Marginalized by the Federal Government

To better understand the history of how the Celiac community has been underserved, please see the Comments of Bari Consulting Group, Celiac Journey and Gluten Free Finds to the FDA's Draft Guidance, August 16, 2022 including these key excerpts (some of which have been summarized in our presentation and this letter):

- **"Section I – Executive Summary"**[141] (pages 3-12)

- **"Section I [sic] Preliminary Statement on the Food Allergen Labeling and Consumer Protection Act"**[142] (pages 12-16) – Included in this section are details on how the FALCPA does not define "allergy", "food allergy", "allergen", "allergic reaction" or "major allergen". FALCPA also does not mention "immunoglobulin E", "IgE", "IgE-Mediated", "Non-IgE-Mediated" "antibodies" or "anaphylaxis." Moreover, there is no express requirement in the FALCPA that a "Major Food Allergen" must include symptoms compatible with IgE-mediated mechanisms, including anaphylaxis. (See page 15)

- **"Section VIII – What's in A Name? Celiac is a Food Allergy!"** (pages 50-68)[143] – please pay special attention to page 56 on the "History of Food Allergy Terminology" which cites detailed research from Dr. Matthew Smith's book "Another Person's Poison" on how the "orthodox allergists" worked to define food allergy in the US as limited to IgE-Mediated reactions that can cause anaphylaxis and in turn excluded Celiac Disease, which is a Non-IgE-Mediated food allergy, from the same consumer protections as IgE-Mediated food allergies.[144]

  According to Dr. Smith, the orthodox allergist movement was "represented by the AAAAI" and "worked with the food industry to reinforce their narrow definition of food allergy, a definition that was epitomized by peanut allergy. Forgotten in the focus on the acute, anaphylactic reaction to foods that food allergists had long argued were more common and problematic. Although some of these patients' problems came to be understood in terms of intolerances to lactose or gluten, symptoms connected with food additives and refined foods continued to be viewed with suspicion in the face of mounting evidence that they could be harmful. Despite making food allergy a legitimate health concern, the rise of peanut allergy

[140] https://www.washingtonpost.com/news/arts-and-entertainment/wp/2015/02/02/nick-offerman-pitches-nascar-in-hilarious-super-bowl-2015-commercial/
[141] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[142] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[143] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[144] https://celiacjourney.com/gaslighting

also helped to transform food allergy into a very specific, attenuated, and limited phenomenon, adhering to the way orthodox allergists had defined it all along."[145]

Also, see "Let's Stop Gaslighting Gluten as a Second-Class Food Allergen & Celiac as Not a Food Allergy!"[146]

- **"Section X – FALCPA Fell Short in Protecting Celiacs"** (pages 72-79)[147] - It is instructive to note that when FALCPA was introduced by Senator Ted Kennedy (D, MA), Senator Hillary Clinton (D, NY)[148] and Rep. Nita Lowey (D, NY-18),[149] FALCPA included express language to require the labeling of Gluten as a Major Food Allergen on all packaged foods. However, on August 9, 2002, "Inside Washington's FDA Week" reported that Senator Kennedy floated an amendment to the FALCPA,

  > "But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines... **Critics of the bill [in the food industry and "orthodox" allergists] had charged that scientifically, Gluten is an intolerance not an allergen**."[150] (emphasis added)

  This was a false premise which was unfortunately not rebutted circa 2002, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate, and incongruent with the 1999 Codex Criteria. The lobbyists conflated Celiac Disease (a potentially life-threatening food allergy, auto-immune disease and digestive disease) with Gluten intolerance (i.e., lactose intolerance; a non-immune-mediated sensitivity that "is inconvenient but not life-threatening"[151]).

  According to Inside Washington's (Health Policy's) "FDA Week", September 27, 2002 (page 5),

  > "Substitute [bill] pulls mandatory Gluten declaration... This week the Senate Health Committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. **The substitute version, unlike the underlying bill... would not require the declaration of Gluten**."[152] (emphasis added)

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[145] Smith, Matthew. "Another Person's Poison: A History of Food Allergy." New York: Columbia University Press, 2015. Print, pages 155-156.
[146] https://www.celiacjourney.com/gaslighting
[147] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[148] https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00
[149] https://www.congress.gov/bill/107th-congress/house-bill/4704
[150] https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf
[151] https://my.clevelandclinic.org/health/diseases/21688-food-intolerance
[152] https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf

- **"Section XI – The FDA Fell Short for a Decade in Protecting the Celiac Community"** (pages 79-96)[153] – This section includes a detailed historical analysis including how there was a Citizen Petition filed on September 10, 2008 to label Gluten and how the FDA took a decade to then summarily deny this request "because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies (Ref. 22)."[154] (see pages 90-91)

- **Section XX - The Only Available Treatment for Celiac Gluten Free Food Must Be Viewed as a Human Right** (pages 124-130)[155]

- **Section XXI – The Economics of Celiac Disease the Financial Burden of the Gluten Free Diet** (pages 130-144).[156] Please note the analysis discussing that the 2022 baby formula shortage is instructive to understand food insecurity and market forces in the context of food for those with special dietary requirements such as Gluten Free foods potentially disappearing from market shelves. From the baby formula crisis, we have learned that markets for specialized foods (i.e., "specially formulated powders, much of it made by Abbott, to compensate for a variety of ailments, from malformed bowels and allergies to problems processing nutrients like protein"[157]) can be disrupted by various factors including macro-economic, micro-economic, supply chain, and operational shock issues. Additionally, in the event that fad diets change (as history informs us, they likely will, i.e., Scarsdale, Atkins, South Beach) and the market for Gluten Free food declines among those consumers who voluntarily elect to pay these premiums (i.e., the "Gluten Free tax") to consume Gluten Free food, then the supply of available safe Gluten Free food will also likely shrink. Moreover, in the absence of required labeling of Gluten on all packaged foods, and in the event that the Gluten Free lifestyle market declines or fades away and people without a medical necessity to eat Gluten Free food declines, the Celiac community will be left with even fewer choices to eat adequately and safely. This will likely force prices even higher on a more limited array of Gluten Free foods. This is another reason that Gluten should be labeled on all packaged foods in the U.S. since there are many products that are free from Gluten but just not labeled since there is no mandatory labeling scheme. (pages 142-144)

[153] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[154] FDAs Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-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
[155] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[156] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf
[157] https://www.washingtonpost.com/health/2022/06/03/baby-formula-shortage-metabolic-disorder/

V. Question: Are 90% of Food-Sensitive Americans Helped by the Food Allergen Labeling and Consumer Protection Law? Answer: NO!

A. Overview

In 2006, the Food & Drug Law Journal published the seminal article entitled, "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004" ("When Food Is Poison").[158] "When Food Is Poison" answered this question in contemporaneous fashion – "Are Ninety Percent of Food-Sensitive Americans Helped by the FALCPA?",

> "The FALCPA touts a statistic that the Big Eight allergens are responsible for ninety percent of 'food allergies.'[159] Congress, FDA, and the media all seized on this figure that implies that the FALCPA alleviates problems faced by ninety percent of food sensitive individuals. Does the FALCPA actually help ninety percent of people with food sensitivities?
>
> This question is worth exploring insofar as it sheds light on why the FALCPA requires the declaration of only eight foods. Also, **the meaning and accuracy of this statistic is important because it may generate a sense of complacency by FDA, the food industry, and Congress with regard to expanding the list of allergens warranting attention**; the belief that problems have been remedied for ninety percent of food sensitive individuals lessens the impetus to work to provide more widespread labeling coverage.
>
> First, it is inaccurate to view the statistic as asserting that ninety percent of Americans with food sensitivities are helped by the FALCPA. As the term 'food allergies' may make plain to the initiated, **this ninety percent figure refers only to people with IgE-mediated, immediate hypersensitivity reactions to food, not to people with delayed hypersensitivity reactions such as those with celiac disease**. The ninety percent claim, thus, is an assertion limited to people with food allergies proper.
>
> Second, the history behind this statistic reveals that it is not the case that an estimated ninety percent of food-allergic people are allergic to Big Eight allergens, as the FALCPA's preamble itself suggests;[160] rather, Big Eight allergens are responsible for

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[158] Derr, Laura E. "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004." *Food and Drug Law Journal*, vol. 61, no. 1, 2006, pp. 65–165. JSTOR, https://www.jstor.org/stable/i26659390

[159] FALCPA 202(2)(a), 21 U.S.C.A. 343(note).

[160] "See the imprecise language employed in the FALCPA. Section 202(2)(a) states that the Big Eight allergens 'account for 90 percent of food *allergies*' (emphasis added); see also, e.g., FDA, Advice to Consumers, supra note 5 ('[T]he eight major food allergens identified by FALCPA account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.'" ["See S. Allan Bock et al., Fatalities Due to Anaphylactic Reactions to Foods, 107 J. Allergy Clin. Immunol. 191, 193 (2001); FDA, Advice to Consumers: Food Allergen Labeling and Consumer Protection Act of 2004, Questions and Answers (Dec. 12, 2005), https://web.archive.org/web/20060810114209/http://www.cfsan.fda.gov/~dms/alrgqa.html [hereinafter FDA, Advice to Consumers] ("Approximately 30,000 consumers require emergency room treatment and 150 Americans die each year because of allergic reactions to food."). Peanut

about ninety percent of adverse reactions.[161] Although ninety percent of allergic reactions may be caused by the Big Eight, that does not mean that ninety percent of allergy sufferers are helped. People could experience multiple reactions and be counted multiple times, meaning the percent of food-allergic individuals with a Big Eight allergy actually is less than ninety."[162]

Additionally, When Food Is Poison memorialized,

> "How many allergens and which ones potentially should be subjected to mandatory disclosure was debated at the 2001 Public Meeting. When FAAN's [The Food Allergy & Anaphylaxis Network] Munoz-Furlong asked whether the eight major allergens should be the appropriate focus of labeling whether additional efforts should be placed on less common allergens, she stated, '**My belief is that if we focus on the eight major allergens, we've covered 90 percent of problem, and once we clear that up, we**

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allergies alone account for 50 to 100 deaths per year. See Teen With Peanut Allergy Dies After Kiss, Associated Press, Nov. 28, 2005, available at https://web.archive.org/web/20060421075602/http://www.msnbc.msn.com/id/10243950/ "

[161] "See, e.g., H.R. 4704, 107th Cong. 2 (2d Sess. 2002) ('Eight major foods -- milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soy beans cause 90 percent of allergic reactions') (emphasis added); FAO Consultation, [Report of the FAO Technical Consultation on Food Allergies, Annex 4: Consideration by Codex of Food Allergies and Hypersensitivity 4 (Nov. 13-14, [hereinafter FAO Consultation]: The current deliberations of the [Codex Committee on Food Labeling] in respect of the problem of food allergens dates from the nineteenth session in 1987 when the Committee took note of the availability of a reliable method for the determination of gliadin, which had been identified as the causative agent of gluten intolerance in celiac disease, and agreed that this and similar problems of food allergy and intolerance and their relationship to the adequacy of the ingredient listing requirements in the General Standard should be considered at a future meeting.]; Hefle et al., supra note 4 ["Adverse reactions vary depending on numerous factors, including the specific sensitivity, the amount of unsafe food ingested, and the individual's particular body chemistry. See, e.g., Hugh A. Sampson & Dean D. Metcalfe, Food Allergies, 268 JAMA 2840, 2841 (1992); Susan L. Hefle et al., Allergenic Foods, 36(S) Crit. Rev. Food Sci. & Nutrition S69, S70, S81 (1996); Hugh A. Sampson, Food Allergies, 278 JAMA 1888-94 (1997) (discussing a variety of symptoms/adverse reactions associated with different types of food sensitivities); Jean Bousquet et al., Food Allergy, in Report of the Food and Agriculture Organization (FAO) Technical Consultation on Food Allergies, Annex 3, at 5-6 (Nov. 13-14, 1995) (on file with author [Ms. Derr]); see also infra note 78. This list includes some symptoms associated only with food allergies (e.g., anaphylaxis), some symptoms associated only with celiac disease (e.g., malabsorption and increased risk of cancer and osteoporosis), and many symptoms associated with both types of food sensitivity."] Even though the impression left by the media and congressional debate frequently was that 90% of people with food allergies would be helped by the FALCPA, FDA tended to employ more accurate terminology that indicated that the Big Eight represent the allergens most frequently responsible for serious adverse reactions. See, e.g., 66 Fed. Reg. 38,591, 38,592 (July 25, 2001) ('FDA's allergen awareness efforts are currently focused on the eight foods that are most frequently implicated in serious allergic responses ...')" (emphasis added)"

[162] Derr, Laura E. "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004." Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, http://www.jstor.org/stable/26660870 . Accessed 13 May 2022.

> **should start looking in other areas**, but keep the eight so that we can focus there.'[163] **In contrast, Dr. Michael Jacobson, co-founder and Executive Director of CSPI [Center for Science in the Public Interest], advocated for more expansive allergen disclosure, 'We urge FDA to require disclosure not just of the major eight allergens, but others as well**.'[164],[165]

The following comments from the FDA's Stefano Luccioli, M.D. suggest that the FDA, even as of May 5, 2021, inaccurately believe that the Big Eight allergens in 2004 were responsible for ninety percent of food allergies,

> "**The eight major food allergens were selected because, at the time the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was passed, they were responsible for 90 percent of food allergies** and thus were the most common causes of severe food reactions in the United States."[166]

To that end, this misperception that the top 8 Major Food Allergens account for over 90% of food allergies has unfortunately helped perpetuate a sense of complacency by FDA, the food industry, and Congress with regard to expanding the list of allergens requiring attention to include Gluten. In other words, in spite of Dr. Luccioli's great work as part of the 2021 FAO/WHO's Expert Consultation in May 2021 and recommendations to always declare Gluten, the comments about FALCPA's impact suggest a perpetuation of an inaccurate understanding and appreciation for the potentially life-threatening adverse reactions of Gluten ingestion for those with Celiac Disease.

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[163] "FDA, 2001 Public Meeting Transcript, supra note 44 [The Challenge of Labeling Food Allergens 32 (August 13, 2001)], at 106 (statement of Anne Munoz-Furlong, FAAN); see also id. at 158 (statement of Anne Munoz-Furlong, FAAN): 'I know that there's a study that's been done that looked at the foods that had been implicated in reactions, and there were somewhere around 160 foods on that list. That's an enormous task. What we would recommend again is to stay focused on the 90 percent of that problem. Once we figure out what the solutions are there, we can hopefully then quickly come by and address some of these other issues.'"

[164] FDA, 2001 Public Meeting Transcript, supra note 44 [The Challenge of Labeling Food Allergens 32 (August 13, 2001)], at 135 (statement of Michael Jacobson, CSPI).

[165] Derr, Laura E. "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004." Food and Drug Law Journal, vol. 61, no. 1, 2006, pp. 65–165, http://www.jstor.org/stable/26660870 . Accessed 13 May 2022.

[166] https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape

VI. FDA's Draft Guidance Illustrates Bias Against Celiac Disease

A. An Inequitable Decision-Making Framework

The FDA's Draft Guidance serves as an illustrative example of the Federal government not providing consistent and systematic fair, just, and impartial treatment of Celiacs who belong to an underserved community and who have been historically denied such treatment.

The FDA's Draft Guidance presents an inequitable evaluation framework, as well as perpetuates flawed and ingrained scientific, governmental and societal biases including:

1. A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available to treat Celiac Disease.
2. With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme[167] sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.
3. Othering the consumer protection needs for Celiacs in the United States with not evaluating the public health importance of Gluten as a food allergen because this Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, while seemingly ignoring that Celiacs face potentially life-threatening and severe adverse health effects[168] that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.[169]

On November 13, 2021, January 13, 2021, and November 9, 2022, the U.S. Department of Health and Human Services posted the following to Instagram and Facebook, "**Going gluten-free? It's easier than ever. #GlutenFreeAwarenessMonth**"[170] The post does not expressly mention Celiac Disease, and moreover the messaging asks a question ("Going gluten-free?") and suggests that the post is targeted towards those who are voluntarily considering the adoption of a gluten-free lifestyle. For those with Celiac, there is no question mark for a strict Gluten Free diet since it is the only treatment that has ever been historically available. To suggest that a Gluten Free diet is "easier than ever" trivializes the treatment burden for Celiac patients and parents. It is insensitive at best and at worst shows a deep disconnect from HHS to the unmet medical needs of the Celiac community and illustrates another example of how the Celiac community has been

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[167] The FDA's final rule defining Gluten Fee for food labeling became effective on September 4, 2013, and August 5, 2014 was the date when FDA-regulated foods labeled Gluten Free must comply with all requirements established by the final rule.
https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods , and
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-gluten-free-labeling-foods#

[168] https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says

[169] FDA Comment ID: FDA-2021-N-0553-1169, FDA Tracking Number: l6g-mawc-nbs8, August 5, 2022, https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf

[170] The November 9, 2021 examples are for all intents and purposes the same, including with the same image and primary messaging, but with some differing language in the post's text.
https://www.instagram.com/p/CkviWsrOFI2/ and
https://www.facebook.com/HHS/posts/pfbid02TGK5MHzrht83F28UmwxbZNYfbmDwY3fbfZ9d8ycxyKN3GpDy8NtKhgkAREwSH5S5l

historically underserved by the Federal government. Ironically, the HHS social media posts link to a page on the NIH's National Library of Medicine which states in part,

> "**On this [Gluten Free] diet,** you need to learn which foods contain gluten and avoid them. **This is not easy, because gluten is in many foods and food products**… Because so many foods contain gluten, **this can be a hard diet to follow**. It can feel limiting when you shop or eat out."[171] (emphasis added)

A search of Facebook suggests that the last time that HHS posted anything on Facebook expressly about Celiac Disease was more than eight years ago on August 13, 2014.[172]

B. A Tale of Two Evaluation Frameworks Whereby FDA's Draft Guidance is Inequitable and Biased

It is instructive to review the differences in the language between the following frameworks from the FDA and the FAO/WHO, even though the 2021 FAO/WHO Expert Committee and the FAO and WHO 2022 Risk Assessment of Food Allergens was chaired by the FDA's Dr. Lauren Jackson. Specifically, it is instructive to review how the FDA's requirement for the evaluation of the public health importance of labeling food allergens other than the Major Food Allergens is a function of the food allergen being capable of triggering anaphylaxis through an IgE-Mediated mechanism. The FDA's requirement is arbitrary, exclusionary, outdated and dangerous.

Document	FDA's "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", Docket: FDA-2021-N-0553, April 19, 2022	"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." Chaired by the FDA's Dr. Lauren Jackson
Language	"As discussed in section III.A, **this document addresses the food allergies that have been most studied and understood clinically i.e., -- IgE-mediated food allergies. Therefore, the initial question for us to address when we evaluate the public health importance of a food or component of food as a food allergen is whether there is robust evidence that an adverse reaction to the food or component**	"**The Expert Committee identified that food hypersensitivity disease consideration for the established criteria would primarily be given to IgE-mediated food allergies and coeliac disease**[174] **[Non IgE-Mediated] since these diseases are well documented to cause serious adverse public health outcomes**. While food allergen data in relation to other immune-mediated responses to food (e.g. eosinophilic gastroenteropathies, food protein-induced enterocolitis syndrome) exist and were also considered in the criteria

[171] https://medlineplus.gov/ency/patientinstructions/000813.htm?linkId=100000161686901
[172] https://www.facebook.com/HHS/photos/a.577318915631772/803728956324099
[174] "Coeliac" is the Greek spelling of Celiac which is used in some parts of the world.

	of food is IgE-mediated (Factor #1)"[173] (emphasis added)	assessment for prevalence (and severity), these data were not found to be sufficiently robust with regards to prevalence, potency or severity and thus were only secondary considerations. Non-immune-mediated diseases like lactose intolerance and fructose malabsorption were not considered by the Committee owing to lack of sufficient comparative food allergen data and lack of documented evidence that these diseases cause serious adverse public health outcomes (Figure 1)."[175] (emphasis added)

The FDA's Draft Guidance suggests an admission of the pernicious impact that the lack of Federal research funding for Celiac has had with regard to how the FDA assesses and implements consumer protection. In other words, since Celiac research (Non-IgE-Mediated food allergy) has historically been underfunded, including from the NIH and Department of Defense, Celiac is not as well studied (arguably one of the least studied food allergies) and understood clinically. Therefore, the FDA's Draft Guidance suggests that Non-IgE-Mediated food allergies are not as important and do not deserve the same consumer protections with labeling as typical IgE-Mediated food allergies which are better funded and "have been the most studied and understood clinically." The FDA's Draft Guidance further suggests a classic negative feedback loop indicating how the Celiac community has been historically underserved by the Federal government, and moreover, how it will continue to be underserved based on being underserved in the past.

C. Mechanism in Action – Cognitive Mechanism

In medicine, mechanism in action is used to describe how a drug or other substance produces an effect in the body.[176] When it comes to consumer protection and requiring that Gluten be labeled for those with a Celiac food allergy to Gluten, the FDA's Draft Guidance seems incorrectly anchored on whether or not a food allergy is an IgE-Mediated Mechanism or Non-IgE-Mediated Mechanism.

I would suggest that the FDA view this evaluation of the public health importance of food allergens other than the Major Food Allergens through a more equitable lens and also focus on cognitive mechanisms. With respect to selecting safe foods to consume, including reading food labels, cognitive mechanisms involve the ways in which people receive information, and the ways in which people think about, interpret, evaluate and therefore act upon that information received on food labels ("Cognitive Mechanism"). In marketing, we refer to that as part of consumer behavior.

Before there can be an IgE-Mediated or Non-IgE-Mediated mechanism, there is a Cognitive Mechanism that takes place with selecting safe foods to consume and reading labels. What

[173] https://www.fda.gov/media/157637/download , page 38.
[175] https://www.fao.org/3/cb9070en/cb9070en.pdf , page 7.
[176] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action

happens inside the body is a secondary mechanism in action, and as such, cannot be exclusively viewed through that downstream mechanism lens without regard to the initial and primary Cognitive Mechanism, followed by an Ingestion Mechanism.

According to the research entitled, "The Food Allergy Consumer Journey, Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success" conducted by McKinsey & Company, Northwestern University and Global Strategy Group for Food Allergy Research & Education (FARE), 71% of consumers "check food labels every time they shop – some for 3-5 minutes per product."[177] We can personally attest to that time commitment per product that we spend in trying to purchase safe food products for our 9 year old son, especially in the absence of mandatory labeling of Gluten.

Watch 5th grader Ava Z. from Maryland tell World News Tonight with David Muir how hard it is with the voluntary labeling scheme for Gluten,

> "A gluten-free diet is really hard because not all packaged foods are clearly labeled as containing gluten. This makes it really hard to find safe, gluten-free food for people with Celiac disease," said Ava.[178]

D. It Takes a Village – 1,576 Comments Submitted to the FDA on Labeling Gluten

In addition to the comments to the FDA's Draft Guidance summarized above, by August 17, 2022 when the comment period closed, there were a total of 1,903 comment submissions on the FDA Draft Guidance.[179] Of those, 1,576 comments discussed Celiac Disease and/or Gluten.[180] In other words, 82.8% of the comments submitted to the FDA were about the unmet need for labeling Gluten on all packaged foods as a Major Food Allergen in the United States.

To the best of my knowledge, there were no automated systems in place to help people generate form letter comments to the FDA and from a review of many of the submitted comments, there were very heartfelt and personal lived experiences shared. We worked with various national advocacy groups, physician scientists and individuals on a real grassroots effort[181] to help generate the 1,576 comments including from:

- Bari Consulting Group, Celiac Journey and Gluten Free Finds, August 16, 2022.[182]
- Beyond Celiac, August 12, 2022.[183]

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[177] https://www.foodallergy.org/fare-consumer-journey-infographic ; and https://www.foodallergy.org/food-allergy-consumer-journey

[178] https://youtu.be/MSySXOE17k8?t=63

[179] https://www.regulations.gov/docket/FDA-2021-N-0553/comments

[180] https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac

[181] https://twitter.com/GFWatchdog/status/1560633576529752065?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1560633576529752065%7Ctwgr%5Edcb3ca6a9147117802409ba4a1780ea2cb3b8210%7Ctwcon%5Es1_&ref_url=https%3A%2F%2F36aae226-db3c-4195-a692-21ab2322143d.usrfiles.com%2Fhtml%2Fdb9376e69cfa487ea0fa0b912ae51a4f_v1.html

[182] FDA Comment ID: FDA-2021-N-0553-1584, FDA Tracking Number l6w-qe9m-4tjy, https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf

[183] FDA Comment ID: FDA-2021-N-0553-1353, FDA Tracking Number: l6q-v6ic-9kfi, https://downloads.regulations.gov/FDA-2021-N-0553-1353/attachment_1.pdf

- Celiac Community Foundation of Northern California, August 17, 2022.[184]
- Gluten Free Watchdog, May 9, 2022.[185]
- Dr. Amanda Muir, August 8, 2022.[186] Dr. Muir is a Pediatric Gastroenterologist in the Division of Gastroenterology, Hepatology and Nutrition at the Children's Hospital of Philadelphia.[187]
- National Celiac Association, June 14, 2022.[188]
- Dr. Arunjot Singh, August 17, 2022.[189] Dr. Singh is Assistant Professor of Clinical Pediatrics, Co-Director, Children's Hospital of Philadelphia's Center for Celiac Disease, Division of Gastroenterology, Hepatology & Nutrition, Perelman School of Medicine - University of Pennsylvania.
- University of Chicago Celiac Disease Center, August 3, 2022.[190]

[184] FDA Comment ID: FDA-2021-N-0553-1691, FDA Tracking Number: l6x-3son-9p1o, https://downloads.regulations.gov/FDA-2021-N-0553-1691/attachment_1.pdf
[185] FDA Comment ID: FDA-2021-N-0553-0179, FDA Tracking Number l2u-t68j-qa01 , https://downloads.regulations.gov/FDA-2021-N-0553-0179/attachment_1.pdf
[186] FDA Comment ID: FDA-2021-N-0553-1587, FDA Tracking Number l6w-qnl1-geu8, https://downloads.regulations.gov/FDA-2021-N-0553-1587/attachment_1.pdf
[187] Dr. Muir is a physician-scientist with a laboratory studying mechanisms of inflammation in Non-IgE mediated food allergy (specifically eosinophilic gastrointestinal disorders), and she has a clinical practice dedicated to taking care of children with these disorders. According to Dr. Muir's FDA Comments, "Eosinophilic esophagitis, or EoE, is a chronic allergic disease that affects pediatric patients and adults alike. In the setting of exposure to foods that are ubiquitous in the American diet, most commonly milk and gluten, an inflammatory process occurs in the esophagus leading to esophageal damage and narrowing. Celiac Disease is an autoimmune disorder in which exposure to gluten containing foods, causes, '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.' Taken together, these two entities, Celiac Disease and EoE represent non-IgE mediated food allergies that would greatly benefit from specific gluten labeling."
[188] FDA Comment ID FDA-2021-N-0553-0822, FDA Tracking Number: l4e-cf9x-ka7n , https://downloads.regulations.gov/FDA-2021-N-0553-0822/attachment_1.pdf
[189] FDA Comment ID: FDA-2021-N-0553-1681, FDA Tracking Number: l6x-2tjb-tdx0, https://downloads.regulations.gov/FDA-2021-N-0553-1681/attachment_1.pdf
[190] FDA Comment ID: FDA-2021-N-0553-1083, FDA Tracking Number l6d-sfof-noog

VII. Cost Estimates with Naming Gluten as A Major Food Allergen

A. Congressional Budget Office – FASTER Act Benchmark, Sesame Allergen

It is instructive to look at the Congressional Budget Office ("CBO") Cost Estimate for H.R. 2117 (which was the predecessor Bill to the FASTER Act which required the labeling of Sesame) dated November 20, 2020. The CBO's Cost Estimate for H.R. 2117, including for the Federal government and private sector, with labeling Sesame may likely be similar to the costs involved in naming Gluten as a Major Food Allergen.

> "H.R. 2117 also would add sesame to the definition of major allergens, would permit the Secretary of Health and Human Services to add food ingredients to that definition, and would require FDA to add a section to a report that the agency produces under current law. Using information from FDA, CBO expects the agency would require, on average, the equivalent of three additional full-time employees in each fiscal year from 2021-2025 to implement regulations and guidance that add sesame as a major food allergen and to evaluate whether new ingredients should be added to the list of major allergens. CBO estimates the new staffing and related expenses would cost about $5 million over the 2021-2025 period.
>
> H.R. 2117 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring manufacturers of food products containing sesame to include additional information on the products label. **Because the mandate would require a minor change to existing labels, CBO estimates that the cost of the mandate would not exceed the annual private-sector threshold established in UMRA ($168 million in 2020, adjusted annually for inflation)**."[191] (emphasis added)

B. Food Safety Magazine – Sesame Allergen Benchmark

It is also instructive to read the following as reported in Food Safety Magazine on June 29, 2021,

> "For most manufacturers, **the addition of sesame or any other ingredient to the major food allergen list will not present much of a logistical challenge**. It is likely that manufacturers are already listing other ingredients in compliance with the Federal Food, Drug, and Cosmetic Act and will only need to modify the labels to include sesame and any other ingredient that may be added to the major food allergens list."[192] (emphasis added)

[191] https://www.cbo.gov/system/files/2020-11/hr2117.pdf

[192] Matayoshi, Kelly; Lopez, Maryjo. The FASTER Act: What Companies Need to Know about the New Food Allergy Law. Food Safety Magazine, June 29, 2021. Last Accessed: November 16, 2022. https://www.food-safety.com/articles/7223-the-faster-act-what-companies-need-to-know-about-the-new-food-allergy-law

VIII. What's Past Suggests Prologue and That's Why We Need President Biden's and Secretary Becerra's Help

On October 13, 2022, there was an "Ask the FDA Webinar" in which Marilyn Geller, CEO of the Celiac Disease Foundation, asked Robin McKinnon, PhD, Senior Advisor for Nutrition Policy, FDA Center for Food Safety and Applied Nutrition (CFSAN), about whether Gluten would ever be declared as a Major Food Allergen and how the FDA's Draft Guidance seemingly precluded such evaluation of the public health importance of the labeling of Gluten.

The answer from Dr. McKinnon was disheartening, especially since this was two months after the period for submission of comments on the FDA's Draft Guidance closed on August 16, 2022, and that Dr. McKinnon did not even acknowledge that in light of the 1,576 comments submitted (82.8% of all comments submitted) regarding the labeling of Gluten and/or Celiac Disease that the FDA was even contemplating revising the FDA's Draft Guidance to include Non-IgE-Mediated food allergy with Gluten. Instead, Dr. McKinnon's response suggested a doubling down on the IgE-Mediated requirement in the FDA's Draft Guidance for the FDA to even evaluate of the public health importance of food allergens other than the Major Food Allergens. Dr. McKinnon stated, "The draft guidance includes information on how stakeholders can submit requests to FDA on those allergens and how FDA will evaluate the data in those submissions. It does not prevent others from submitting requests like citizen petitions or letters to FDA."[193]

However, the FDA's Draft Guidance expressly states, "This guidance is intended for:

- FDA staff who are responsible for evaluating, on FDA's initiative or in response to a citizen petition submitted in accordance with 21 CFR 10.30, the public health importance of a non-listed food allergen, which for the purpose of this guidance means a food allergen other than one of the major food allergens (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame2[194]) listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act); and
- Stakeholders who intend to submit a citizen petition asking FDA to establish regulatory requirements based on the public health importance of a non-listed food allergen ("applicable stakeholders") or who are interested in how FDA generally intends to evaluate the public health importance of such food allergens."[195]

Moreover, the FDA's actions with the citizen petition filed on September 10, 2008 to label Gluten suggests that past will be prologue in that any new citizen petition on the labeling of Gluten would be subject to the same decade long delay of no action only to be followed by being summarily denied "because the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies (Ref. 22)."[196]

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[193] https://youtu.be/Ay3h_4ArOqk?t=2259

[194] "In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) amended section 201(qq) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add sesame to the definition of major food allergen. This amendment applies to any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023 (Public Law 117-11)." https://www.fda.gov/media/157637/download

[195] https://www.fda.gov/media/157637/download

[196] FDAs Draft Guidance, and Ref. 18: Citizen Petition CP-2008-P-0509, received September 10, 2008, submitted by Hallie Jane Davis, Docket No. FDA-2008-P-0509, Document ID FDA-2008-P-0509-0001 and Ref. 22: Letter dated February 6, 2018, from Douglas Stearn of FDA to Hallie

According to Professor Adam Grant at the Wharton School, "Precedent is a poor reason for decisions. It calcifies the status quo without a compelling rationale. It doesn't matter how long a tradition has stood. If the old way is wrong, it should be challenged and changed. Progress lies in improving the future, not defending the past."[197]

IX. HHS Secretary Xavier Becerra Has Existing Statutory Authority to Label Gluten Now

A. FDA's Former Chief Counsel, Harvard Law Professor and Partner, Covington & Burling and Former Harvard Law Student Findings on HHS Secretary's Existing Statutory Authority in the Food & Drug Law Journal

According to the Food & Drug Law Journal's seminal article in 2006 that was published entitled, "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004" ("When Food Is Poison"),[198] FALCPA does not preclude the FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme.[199] Section 203(b) states that the labeling requirements established under new section 403(w) "**do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens**."[200] (emphasis added)

When Food is Poison was written by Laura Derr when she was a student at Harvard Law School, under the supervision of Lecturer on Law Peter Barton Hutt, Partner at Covington & Burling in Washington, D.C., for Harvard Law School's Winter 2005 Food and Drug Law course. Mr. Hutt was also former Chief Counsel to the FDA from 1971-1975. When Food is Poison won First Place in the 2005 H. Thomas Austern Memorial Writing Competition (long papers) sponsored by the Food and Drug Law Institute.[201]

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

[197] https://www.instagram.com/p/CjS8o9GuyA4/

[198] Derr, Laura E. "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004." *Food and Drug Law Journal*, vol. 61, no. 1, 2006, pp. 65–165. JSTOR, https://www.jstor.org/stable/i26659390

[199] When Food is Poison, Page 141, including footnotes 423-424: "See FALCPA 203(b), 21 U.S.C.A. 343(note); FALCPA 203(a), 21 U.S.C.A. 343(x). The Senate Committee Report states that it intends for any regulations issued by FDA requiring the identification of additional allergens to prescribe disclosure in 'a manner consistent with' the FALCPA. S. Rep. No. 108-226, at 10." (Source: https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf) "The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(x) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive ingredient that is, or includes as a constituent, a food allergen that is not a major food allergen. The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will require the food allergen to be identified on the label in a manner consistent with this legislation." https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf

[200] H.R. Rep. No. 108-608, at 18. (2004), https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf

[201] https://www.fdli.org/career/austern-writing-competition/

B. Labeling Gluten on All Packaged Foods in the U.S. Would Be in a Manner Consistent With the FALCPA

The labeling of Gluten on all packaged foods in the U.S. would be in a manner consistent with the letter and spirit of FALCPA. For example, FALCPA's Section 2, Findings ("FALCPA's Findings") expressly discuss Celiac Disease as one of its six key findings.[202] There are no other food allergens or diseases other than the Top 8 Major Food Allergens, Gluten and Celiac expressly mentioned in FALCPA's Findings. Adding Gluten to the list of Major Food Allergens would be in a manner consistent with the consumer protection law in how the other top 8 Major Food Allergens have been required to be labeled since January 1, 2006.

C. The ADA – There's More Work to Do

According to the Biden Harris Administration, there is more work to do to live up to the promise of the ADA and one of those areas arguably is providing consumer protection to Celiacs by labeling Gluten. "Grounded in four core outcomes of full participation, equal opportunity, independent living, and economic self-sufficiency, the ADA prohibits discrimination on the basis of disability in public accommodations, employment, transportation, and community living and provides recourse for people with disabilities who faced discrimination. The nation has made significant progress since the law was signed, but there is more work to do to live up to the promise of the ADA."[203]

D. White House Conference on Hunger, Nutrition, and Health

We believe that this once in a generational opportunity following the White House Conference to catalyze the public and private sectors around a coordinated strategy to accelerate progress and drive transformative change in the U.S. to eliminate hunger, improve nutrition, and reduce diet-related disease. To that end, we are asking the President to address the historically underserved and unmet needs of 3.3 million Americans with Celiac Disease with the naming of Gluten as a Major Food Allergen and the labeling of Gluten on all packaged foods in the U.S., just like it is done in 85 countries around the world. As President Biden has stated, "We are the United States of America. There is nothing beyond our capacity!" It is time to address the failed and incomplete labeling scheme of Gluten in the United States!

As President Joe Biden said at the White House Conference on Hunger, Health, and Nutrition,

> "[I]f a parent cannot feed a child, there's nothing else that matters for that parent. **If you look at your child and you can't feed your child, what the hell else matters?** I really mean it."[204] (emphasis added)

For 3.3 million American Celiacs, integrating nutrition and health and empowering all consumers to make and have access to healthy choices is a function of labeling Gluten as a Major Food Allergen.

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[202] https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers

[203] https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/26/fact-sheet-the-biden-%E2%81%A0harris-administration-marks-the-anniversary-of-the-americans-with-disabilities-act/

[204] https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/#

Let's label Gluten now as a Major Food Allergen and protect 3.3 million American Celiacs so that they can live their best lives. As President Biden said,

> "This is the United States of America. (Applause.) There is nothing -- nothing, nothing -- I really mean it -- there's nothing beyond our capacity when we work together, so let's work together."[205]

[205] https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/28/remarks-by-president-biden-at-the-white-house-conference-on-hunger-nutrition-and-health/

X. Key References:

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