WHITE HOUSE CONFERENCE ON HUNGER, NUTRITION, & HEALTH

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

Sharing Our Lived Experience:
Jon, Leslie, Jax and Lexi Bari
Celiac Journey & Gluten Free Finds

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April 17, 2023

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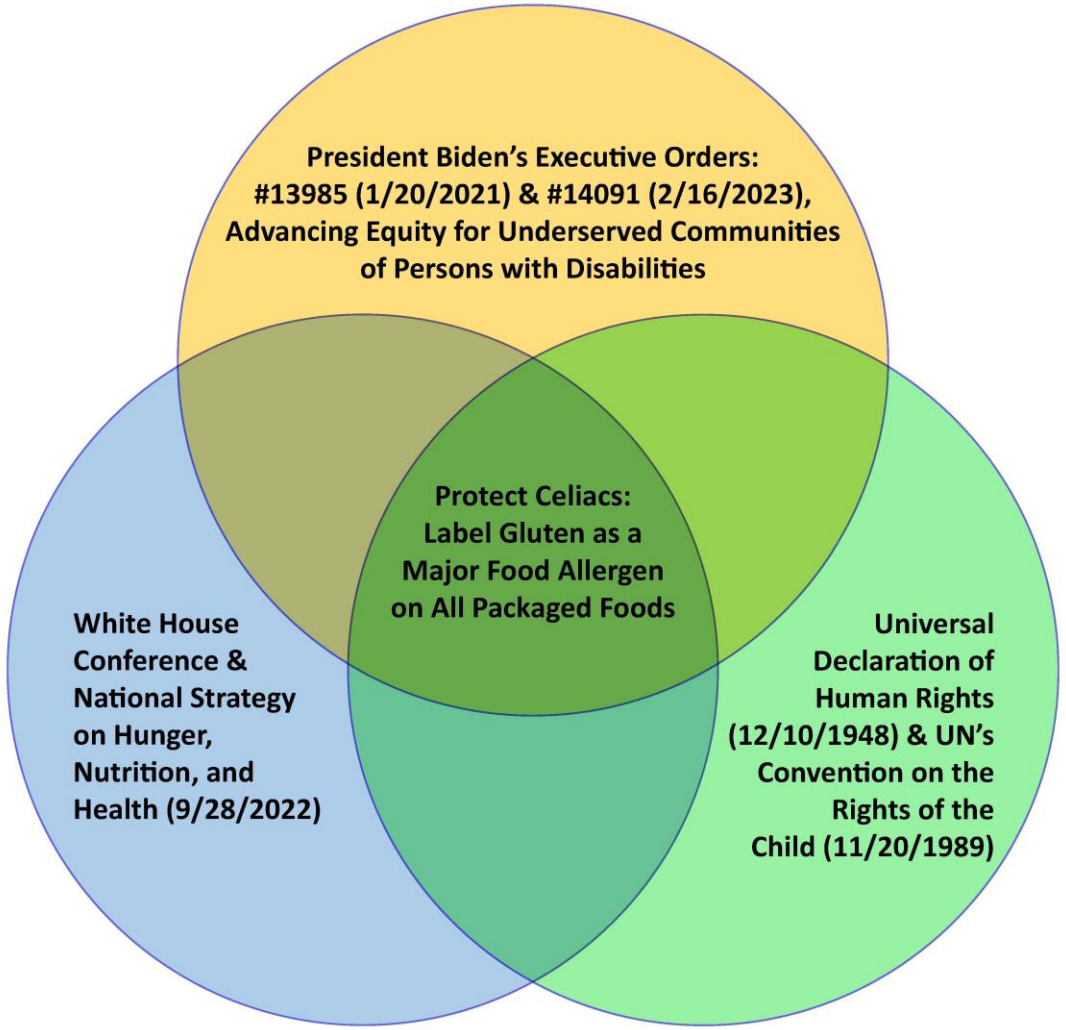
The Evaluation of the Public Health Importance of Labeling Gluten as a Major Food Allergen Should Be Conducted Now Through the Lens of President Biden's Executive Order 13985 (1/20/21) and Executive Order 14091 on "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal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

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

The labeling of Gluten as a Major Food Allergen also sits at the intersection of President Biden's Executive Orders on Advancing Equity for Underserved Communities for People with Disabilities; the White House Conference and National Strategy on Hunger, Health, Nutrition; and Human Rights.



Labeling Gluten as a Major Food Allergen, like it is done 85 countries around the world, 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 (“FAO”)/World Health Organization (“WHO”) 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; Celiac Journey; Celiac Disease Program at Children’s National Hospital; Children’s Hospital of Philadelphia Center for Celiac Disease; Davis Family (Shannon, Brian and Joshua); National Celiac Association; Gluten Free Watchdog; University of Chicago Center for Celiac Disease, etc. (Docket: FDA-2021-N-0553)

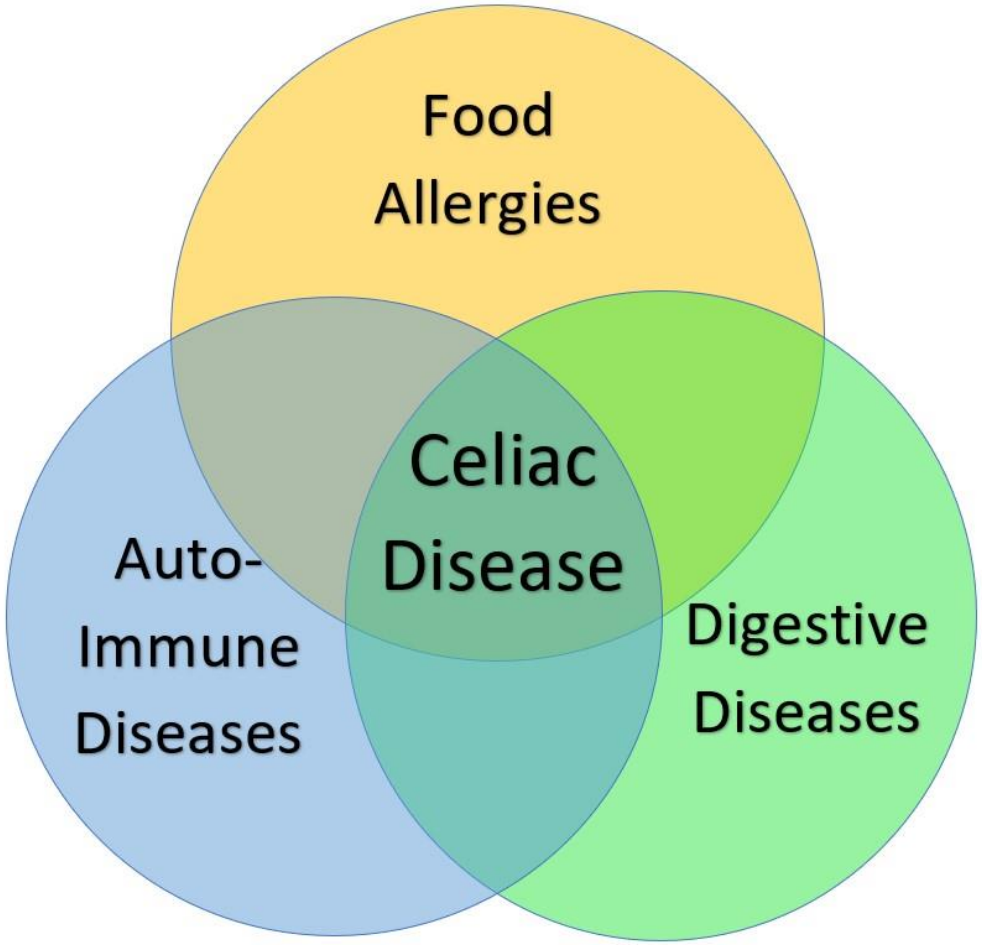
WHITE HOUSE CONFERENCE ON HUNGER, NUTRITION, & HEALTH

"If 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?"
-- President Joe Biden

"Our mission is to create opportunities for people with lived experience to be heard, and included in the design of equitable policy solutions… this Conference represents an historic opportunity to learn directly from those most impacted..."
-- Jimmieka Mills, Equitable Spaces
(Introducing President Biden on 9/28/22)

www.celiacjourney.com/takeaways
https://youtu.be/IYMM6KYyCno?t=3674
https://www.youtube.com/watch?v=IYMM6KYyCno&t=2299s
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/#

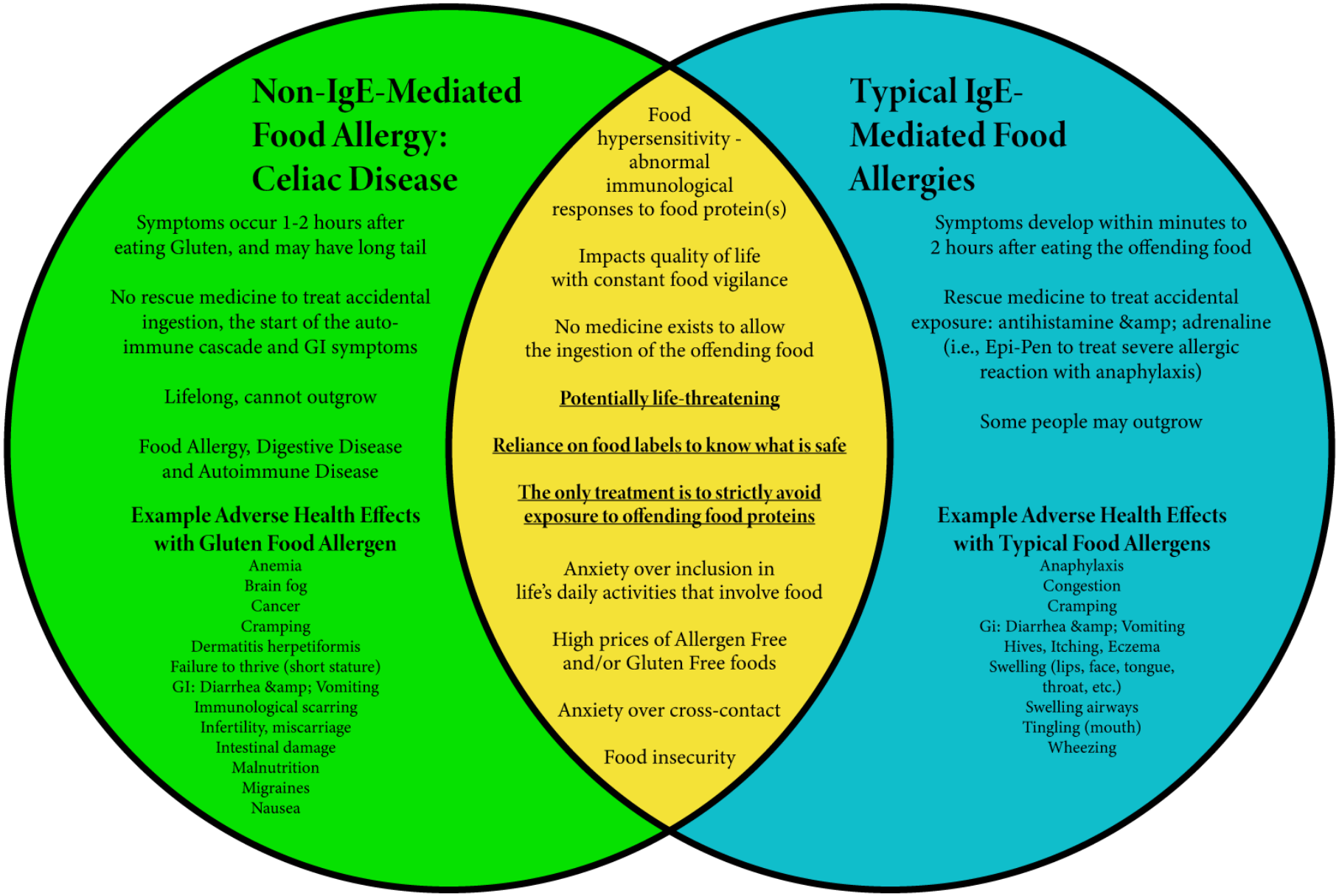
Celiac Disease Sits at the Intersection of Food Allergies, Auto-immune Diseases & Digestive Diseases



- Potentially life-threatening food allergy & auto-immune disease.
- **3.3 million Americans**, greater than 1.0% of the general population.
- **44% who follow a strict Gluten Free diet still get glutened once a month**.
- Gluten, which is found in Wheat, Barley, Rye and most Oats, triggers an immune response in Celiacs leading the body to attack itself.
- Gluten ingestion can cause anemia, cancer, GI issues: diarrhea & vomiting, heart disease, immunological scarring, intestinal damage, malnutrition, etc.
- The only available treatment is strict adherence to a lifelong, Gluten Free diet. There's no rescue medication in the event of accidental ingestion and one cannot outgrow Celiac.

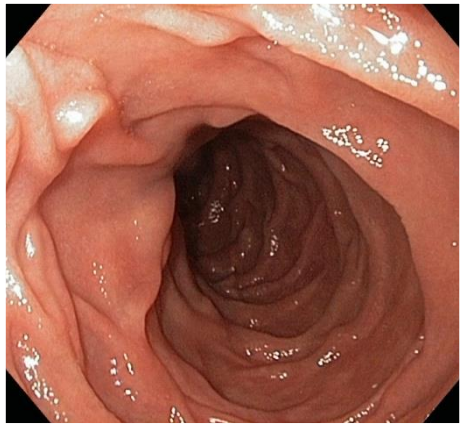
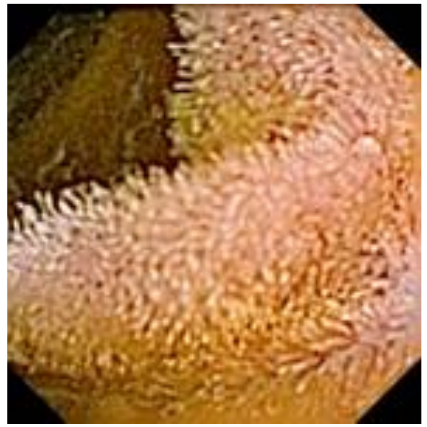
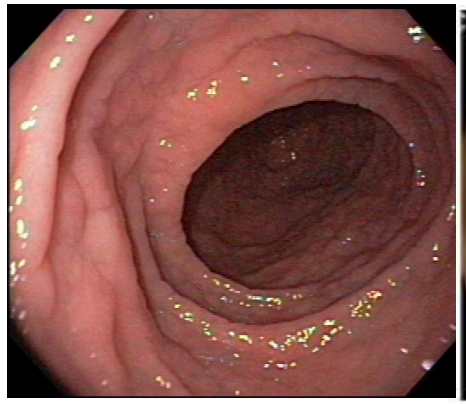
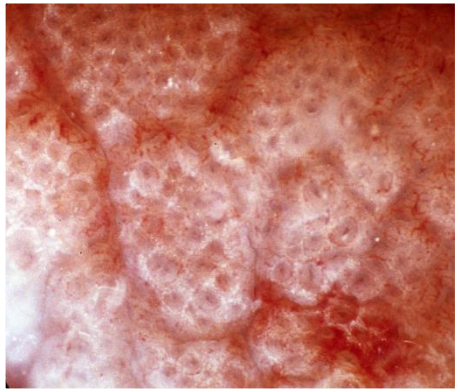
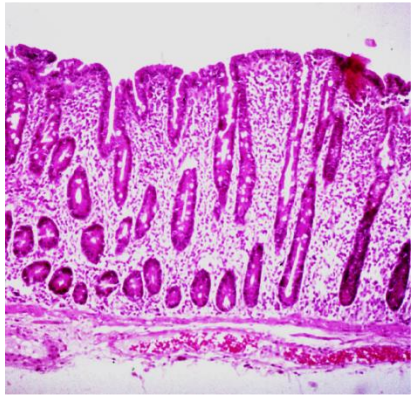
Sources: https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html
Public Witness Testimony submitted by Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago, U.S. Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Related Agencies, Department of Health and Human Services, June 3, 2019. Beyond Celiac, https://www.beyondceliac.org/ and https://twitter.com/abast/status/1551780196243603457

What is Food Allergy? The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms



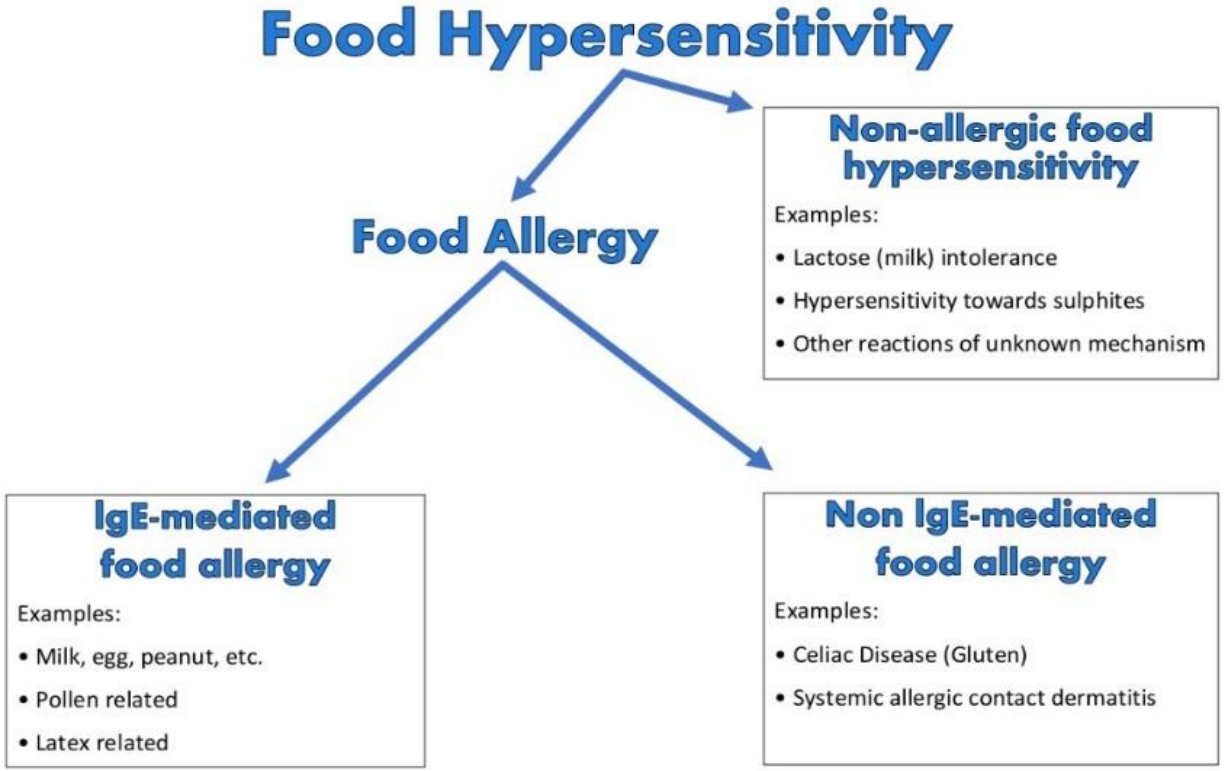
What getting Glutened looks like...
Gluten should be labeled on all packaged foods in the United States, just like it is in more than 85 countries around the world.

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

	Standard Endoscopy	Capsule Endoscopy	Dissecting Microscope	Standard Histology
Normal				
Celiac				

Source: Ciaran Kelly, MD, Medical Director, Celiac Center, BIDMC, Boston, Professor of Medicine & Co-founder, Celiac Research Program, Harvard Medical School, Used with Permission

Food Hypersensitivities Range from Intolerances to Allergies: Food Allergies Are Much More Serious Than Food Intolerances, But Too Often Incorrectly Get Conflated with Food Intolerances or Voluntary Food Preferences (i.e., Gluten Free Lifestyle, Vegan, Vegetarian)



Source: Food Allergies, International Food Safety Authorities Network, Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, INFOSAN Information Note No. 3, June 9, 2006.

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.

The Celiac Disease Treatment Burden

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**. [1]

Diagnosed patients report that they miss, on average, **23 days of work and school annually**, resulting in excess utilization of our healthcare resources. [2]

It's Personal – 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.

Sources:
[1] "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://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/ .
[2] 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/?.

“We are the United States of America. There is nothing beyond our capacity!” -- President Joe Biden

The Time Has Come to End the Gluten Guessing Game with Voluntary Labeling & Require that Gluten Be Labeled as a Major Food Allergen, Including on POTUS M&Ms

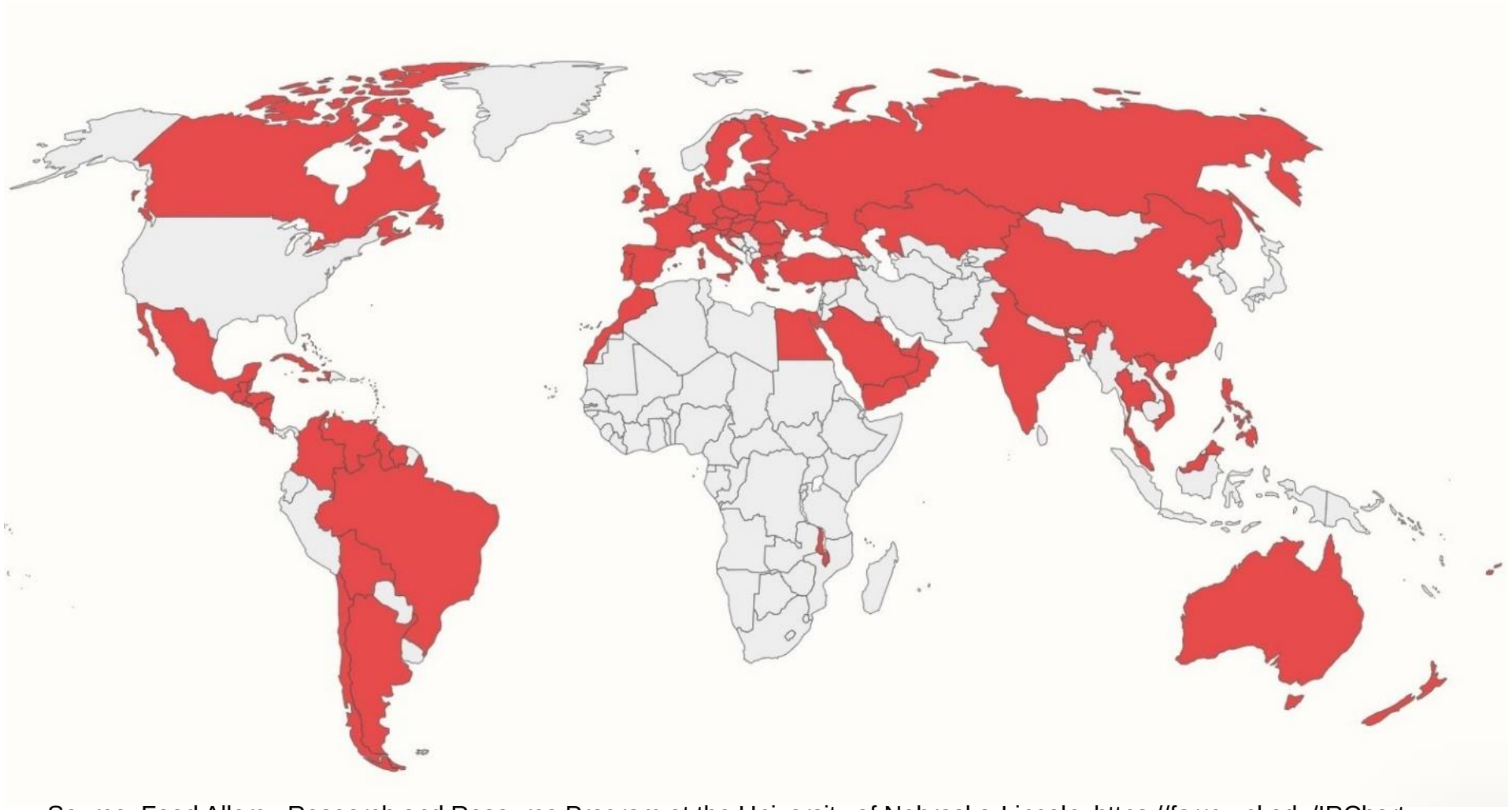
ON THE LABEL

“M&M's Milk Chocolate Candies INGREDIENTS:
Milk Chocolate (Sugar, Chocolate, Skim Milk, Cocoa Butter, Lactose, Milkfat, Soy Lecithin, Salt, Natural Flavor), Sugar, Cornstarch; Less Than 1% of: Corn Syrup, Dextrin, Colors (Includes Red 40 Lake, Blue 2 Lake, Blue 1 Lake, Yellow 6 Lake, Blue 1, Red 40, Blue 2, Yellow 6, Yellow 5, Yellow 5 Lake), Carnauba Wax, Gum Acacia.
ALLERGY INFORMATION: CONTAINS MILK AND SOY.
MAY CONTAIN PEANUTS.”

IN THE LAB

Tested by Gluten Free Watchdog, March 5, 2021, Less than 5 parts per million of Gluten

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, https://farrp.unl.edu/IRChart

Food and Agriculture Organization of the United Nations

World Health Organization

Conclusions of FAO-WHO Expert Consultation on Risk Assessment of Food Allergens – May 2021

"The Expert Committee determined that **only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac [Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods]**", and that the **GSLPF list includes Gluten**.

Source: "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", May 21, 2021.

Food and Agriculture Organization of the United Nations

World Health Organization

Conclusions of FAO-WHO Expert Consultation on Risk Assessment of Food Allergens – May 2021

"**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: <u>Cereals containing gluten</u> (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains)**, crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut)."* (emphasis added)

* "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."

Source: "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", May 21, 2021.

Food and Agriculture Organization of the United Nations

World Health Organization

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

Food and Agriculture Organization of the United Nations

World Health Organization

The 2021 FAO/WHO Expert Consultation was Comprised of 20 (twenty) "Experts" Including:

- Dr. Lauren Jackson, Chief, Process Engineering Branch, FDA, Division of Processing Science & Technology, Institute for Food Safety & Health, who served as Chairperson of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens (FDA Ref. 45); (Pictured in top row of photograph, 1st person on left).
- Dr. Joseph Baumert, Professor and Director of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln; (Pictured in top row of photograph, 3rd from left).
- Dr. Stefano Luccioli, Medical Officer and Allergy Specialist at the Center for Food Safety and Applied Nutrition of the FDA, and Board-certified doctor in allergy/immunology who sees patients at the General Internal Medicine clinic at MedStar Georgetown University Hospital in Washington, D.C. (Pictured 2nd row of photograph, 4th person from left).
- Dr. Stephen Taylor, Professor and Founding Director (Retired) of the Food Allergy Research and Resource Program (FARRP), Department of Food Science and Technology at the University of Nebraska-Lincoln. (Pictured in bottom row of photograph, 2nd person from left).

Food and Agriculture Organization of the United Nations

World Health Organization

Just like the 2021 FAO/WHO Expert Consultation including Dr. Lauren Jackson, Dr. Stefano Luccioli, Dr. Joseph Baumert, and Dr. Stephen Taylor did not distinguish between IgE-Mediated and Non-IgE-Mediated food allergies in their systematic and thorough assessments which used all three criteria (prevalence, severity and potency) to determine the Risk Assessment of Food Allergens, the FDA must not distinguish between IgE-Mediated and Non-IgE-Mediated food allergies when it comes to evaluating the labeling Gluten as a Major Food Allergen to protect 3.3 million American Celiacs.

Children's Hospital of Philadelphia℠

NATIONAL ACADEMIES Sciences Engineering Medicine

Dr. Virginia Stallings Has Called for Gluten to Be Labeled

Dr. Virginia Stallings:

- Board-certified nutrition pediatrician
- Professor of Pediatrics
- Director of the Nutrition Center at the Children's Hospital of Philadelphia (CHOP)

Dr. Stallings served as the Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies: "Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy."

Children's Hospital of Philadelphia℠

Dr. Virginia Stallings Has Called for Gluten to Be Labeled

"A gluten free diet is not all that is needed to treat Celiac Disease; rather a gluten free diet is all that has ever been historically available to treat Celiac Disease. Additionally, with respect to labeling food products in the United States, the voluntary gluten free labeling scheme does not sufficiently protect consumers who are on medically required and very restrictive gluten free diets.

My strong recommendation is that gluten be labeled on all packaged foods in the United States, in accordance with the 2021 FAO/WHO Expert Consultation, just like it is in more than 85 countries around the world." (emphasis added)

Food Insecurity

"Food insecurity is the limited or uncertain availability of nutritionally adequate and safe foods, or limited or uncertain ability to acquire acceptable foods in socially acceptable ways." **-- USDA** [1]

"Eating without fear is our hope! Food insecurity happens everyday 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 packaged foods in the U.S." **-- Jax Bari (as told to David Muir) [2]**

[1] https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/measurement/#insecurity , and Definitions are from the Life Sciences Research Office, S.A. Andersen, ed., "Core Indicators of Nutritional State for Difficult to Sample Populations," The Journal of Nutrition 120:1557S-1600S, 1990.
[2] www.celiacjourney.com/abcnews

President Joe Biden's Executive Order 13985 On "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

Section 2(a) of Executive Order 13985 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." (emphasis added)

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

Celiac Disease Community Has Been Historically Underserved by the Federal Government

- Underfunding NIH biomedical research for Celiac Disease over many years, on average $3.4 million annually from NIH
- Labeling Gluten only with a voluntary scheme since 2014 (including a delay of over 6 years from August 2008, in spite of FALCPA deadline)
- Disqualifying Celiacs from service in the U.S. Military
- Excluding Celiac from the CDC's Index of Diseases & Conditions
- 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
- Excluding Celiac Disease (through June 2022) from NIH's "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" that provides research and funding data on how NIH allocates its financial resources.
- 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.
- Missing on average 23 days or work or school per year due to being sick from Glutenings.
- Inhibiting Celiacs from the dating world.
- Excluding Celiacs from life's daily activities that involve food, etc.

https://www.celiacjourney.com/briefing
https://www.celiacjourney.com/falcpa
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/
https://www.cdc.gov/az/f.html
https://www.dropbox.com/s/2qxco3pc1i5xg49/Tufts_WhiteHouseReport_R16_IP22_082122.pdf?dl=0
https://web.archive.org/web/20200713010533/https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee
https://celiac.org/april-2019-congressional-testimony-by-ceo-marilyn-g-geller/?
https://www.beyondceliac.org/research-news/dating-doesnt-read-like-romantic-novel/

FDA's Draft Guidance Presents an Inequitable Framework for the Evaluation of the Public Health Importance of Food Allergens Other Than the Major Food Allergens , as well as Perpetuates Flawed 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 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 that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

FDA Docket Number: FDA-2021-N-0553

NIH/NIAID Celiac Disease-Focused Autoimmune Disease Coordinating Committee (“ADCC”) Meeting on May 29, 2020 – “This is Just Step 1”

“I’m just going to ask the question because I think maybe for this audience [ADCC], it might be surprising to them that the Gluten Free diet is not the be all and end all, its 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**.”
-- Dr. Annette Rothermel, Section Chief, Autoimmune and Primary Immunodeficiency Diseases Section, Division of Allergy Immunology and Transplantation at the NIH; Comments following presentation by Marilyn Geller of the Celiac Disease Foundation

Dr. Rothermel added, “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. (emphasis added)

Note: on 5/29/20, the ADCC had 52 members including 35 members from the Federal government (primarily from the NIH, but also the FDA, https://web.archive.org/web/20200713010533/https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee
https://www.dropbox.com/s/lb8ztfpyw1or2q1/ADCC%2005292020%20Zoom%20Meeting%20Recording%205-29-20.mp4?dl=0 ; 32:10-33:57 mark; email to Jon Bari, July 20, 2020.

A Tale of Two Evaluation Frameworks Whereby FDA's Draft Guidance is Inequitable

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 of food is IgE-mediated** (Factor #1)" (emphasis added)	"**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 [Non IgE-Mediated] since these diseases are well documented to cause serious adverse public health outcomes**. https://www.fao.org/3/cb9070en/cb9070en.pdf , page 7.

President Joe Biden's Executive Order 13985 On "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

The Celiac community represents an **underserved community which shares particular characteristic including a chronic disability 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 all aspects of economic, social and civil life, including in life's daily activities that involve food**. This can lead to anxiety, social isolation, depression, etc.

For someone with Celiac Disease, **eating, sleeping, thinking and learning 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.

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, 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 https://www.celiacjourney.com/williamsburg and https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf

A Mom's Poetic Plea: "What getting Glutened looks like... Gluten must be labeled on all packaged foods in the United States, just like it is in more than 85 countries around the world."

"This.
This right here.
This is celiac.
Celiac Disease.
Two simple words.
One complex disease.

No gluten.
Simple?
It should be.
It isn't.

No gluten.
Label reading.
Constant questioning.
Cross contamination.
Can we eat here?
Do we trust them?
Is this labeled correctly?

No gluten.
Ever.
Not even a crumb.

This is
This is celiac disease.
Accidents.
Accidental glutening.

Source: Britney Asbell, FDA-2021-N-0553, FDA Tracking Number l6c-exmk-ywis.
As posted on Facebook, June 17, 2021
https://www.facebook.com/photo/?fbid=10161476598607289&set=a.10150292089997289
used with permission by Ms. Asbell of her son Tucker

Glutening.
Belly pain.
Nausea.
Vomiting.
Heaving.
Over and over again.
For hours.

Laying on the bathroom floor.
Falling asleep between episodes.
Dark circles under the eyes.
Pale skin.
Distended abdomen.
And more.

For us.
It's a 5 year old warrior.
It's a 5 year old who lives to the fullest.
It's a 5 year old who takes these accidental glutenings like a champ.
It's a 5 year old who's a super celiac kid.

Fight on…"

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:
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

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
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.

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.

Oats - https://downloads.regulations.gov/FDA-2021-N-0553-1584/attachment_1.pdf (footnote 10)

What is Food Allergy 1934 Congressional Testimony: FDA Commissioner Walter Campbell, Senator Felix Hebert (R, RI) and Senator Royal Samuel Copeland, MD (D, NY).

"Mr. Campbell: I do not think you heard, and I am sorry that you and the entire committee did not hear Dr. Brown, of Washington, an expert on hypersensitivity, testify yesterday afternoon. He pointed out this, that he had a child in his office who was suffering from allergy. I don't know whether the cause was eggs or milk.

Senator Hebert: What was that word, allergy?

Mr. Campbell: Yes; allergy.

Senator Hebert: How do you spell it?

Mr. Campbell: A-l-l-e-r-g-y.

Senator Hebert: What is the definition of it? I heard the term a number of times and I admit my ignorance. Now, I ask you to explain it to me.

Mr. Campbell: You need not feel humiliated, because it is not in the dictionary, or at least it is not in those that I have consulted. It is a medical term. It means the hypersensitivity of certain individuals to certain protein products. It may manifest itself in the form of asthma or hives or other forms of physical distress.

Senator Copeland: What is food for one is poison for another.

Mr. Campbell: That is right.

Senator Hebert: I would like to look up the derivation of that word.

Senator Copeland: Here is a book on the subject.

Senator Hebert: All right. I suppose it is one of those $14 words that physicians coin."

Source: "Hearing Before the Senate Comm. on Commerce, 73d Cong. (1934) (statement of Walter G Campbell, Chief of FDA), reprinted in Dunn, supra note 170 [Hearing Before the S. Comm. on Commerce, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), reprinted in Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record 1176 (1987).], at 1176."

Perplexing Paradigm of Consumer Protection for Celiacs

- With the mitigation of the burden of chronic disease in mind, it is instructive to understand the following current perplexing paradigm. Unlike the Food Allergen Labeling and Consumer Protection Act ("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 (not mandatory) in the U.S.
- 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.

FALCPA Negotiations Were Scientifically Flawed From the Start with Celiac Being Incorrectly Othered as Gluten Intolerance and Not a Food Allergy: No One From FDA or HHS Spoke Up

On August 9, 2002, Inside Washington's (Health Policy'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] 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),

> "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)

https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf
https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf

Food Labels Are Critical, But Voluntary Labeling for Gluten Free is Insufficient, Inaccurate & Dangerous

- Today, 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 gap does exist with voluntary Gluten labeling for 3.3 million American Celiacs like Jax.
- That's not very safe and it doesn’t provide equal protection under the law.

HHS/FDA Can Declare Gluten as a Major Food Allergen Without Congress, Actionable and Attainable Now

WHITE HOUSE CONFERENCE ON HUNGER, NUTRITION, & HEALTH

According to the Food & Drug Law Journal's seminal article in 2006 that was entitled, "When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004,"[1] **FALCPA "does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme**."[2] **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**."[3]

"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, 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.

HHS/FDA Can Declare Gluten as a Major Food Allergen Without Congress, Actionable and Attainable Now

Sources for the previous page:

[1] 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. 65165. *JSTOR*, http://www.jstor.org/stable/26660870. Accessed 30 Sep. 2022.

[2] 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.” “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

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

Economics and Availability of Nutritionally Adequate and Safe Gluten Free Food Products

If the labeling of Gluten was mandatory on all packaged food products, our research and lived experience strongly suggest that the number of Gluten Free food products available to those who have Celiac Disease or Non-Celiac Gluten Sensitivity would greatly expand just by virtue of food products that do not contain Gluten being labeled as such.

This would help to decrease food costs.

Note: Additional research would be worthwhile to analyze this in more detail.

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

Kraft Mac & Cheese Original, 7.25oz

$1.29 ($0.17/oz)

Target
Philadelphia, PA 19131
10/31/22

Kraft Gluten Free Mac & Cheese Original, 6.0oz

$4.79 ($0.80/oz)

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

King Arthur Flour Unbleached All-Purpose Flour, 5lbs

$5.59 ($0.07/oz)

All-Purpose

5 lbs

Target
Philadelphia, PA 19131
10/31/22

King Arthur Gluten Free Measure for Measure Flour, 48oz

$9.99 ($0.21/oz)

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

Wonder Round Top White Sliced Bread, 20oz

$3.19 ($0.16/oz)

Canyon Bakehouse Gluten Free Mountain White Bread, 18oz

$6.79 ($0.38/oz)

Target
Philadelphia, PA 19131
10/31/22

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

Freschetta Natural Rising Signature Pepperoni Frozen Pizza, 27.35oz

$7.49 ($0.27/oz)

Target
Philadelphia, PA 19131
10/31/22

Freschetta Gluten Free Pepperoni Frozen Pizza, 17.78oz

$10.99 ($0.62/oz)

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

Pillsbury Funfetti Premium Cake & Cupcake Mix, 15.25oz

$1.99 ($0.13/oz)

Target
Philadelphia, PA 19131
10/31/22

Pillsbury Gluten Free Funfetti Cake & Cupcake Mix, 17oz

$4.79 ($0.28/oz)

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

Krusteaz Honey Cornbread & Muffin Mix, 15oz

$2.69 ($0.18/oz)

Target
Philadelphia, PA 19131
10/31/22

Krusteaz Gluten Free Honey Cornbread & Muffin Mix, 15oz

$5.59 ($0.37/oz)

Gluten Free Food Premium Marketplace: Inflation Worsens Inequality

M&M's Milk Chocolate Candy Theater Box, 3.1 oz

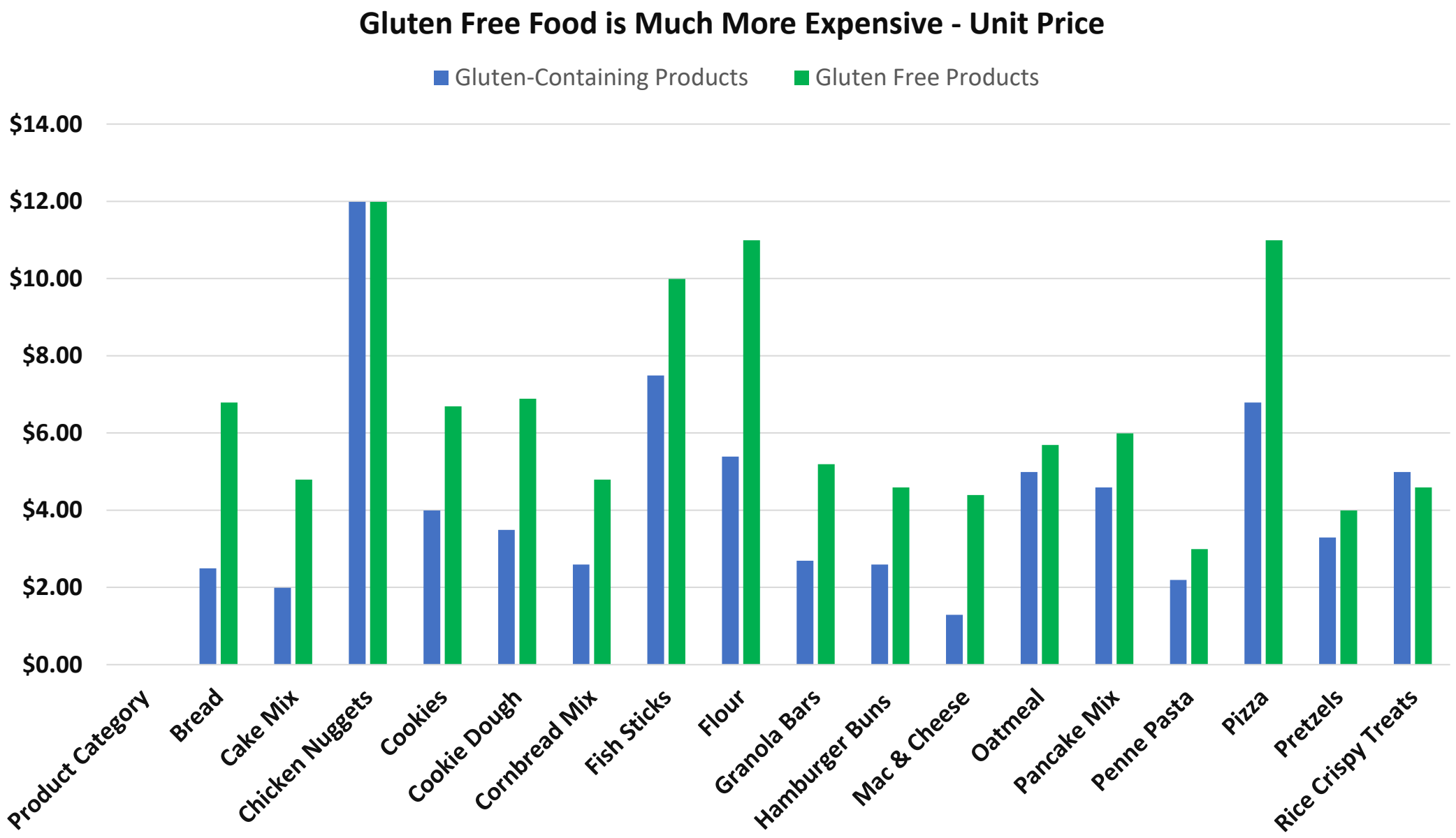
$1.39 ($0.45/oz)

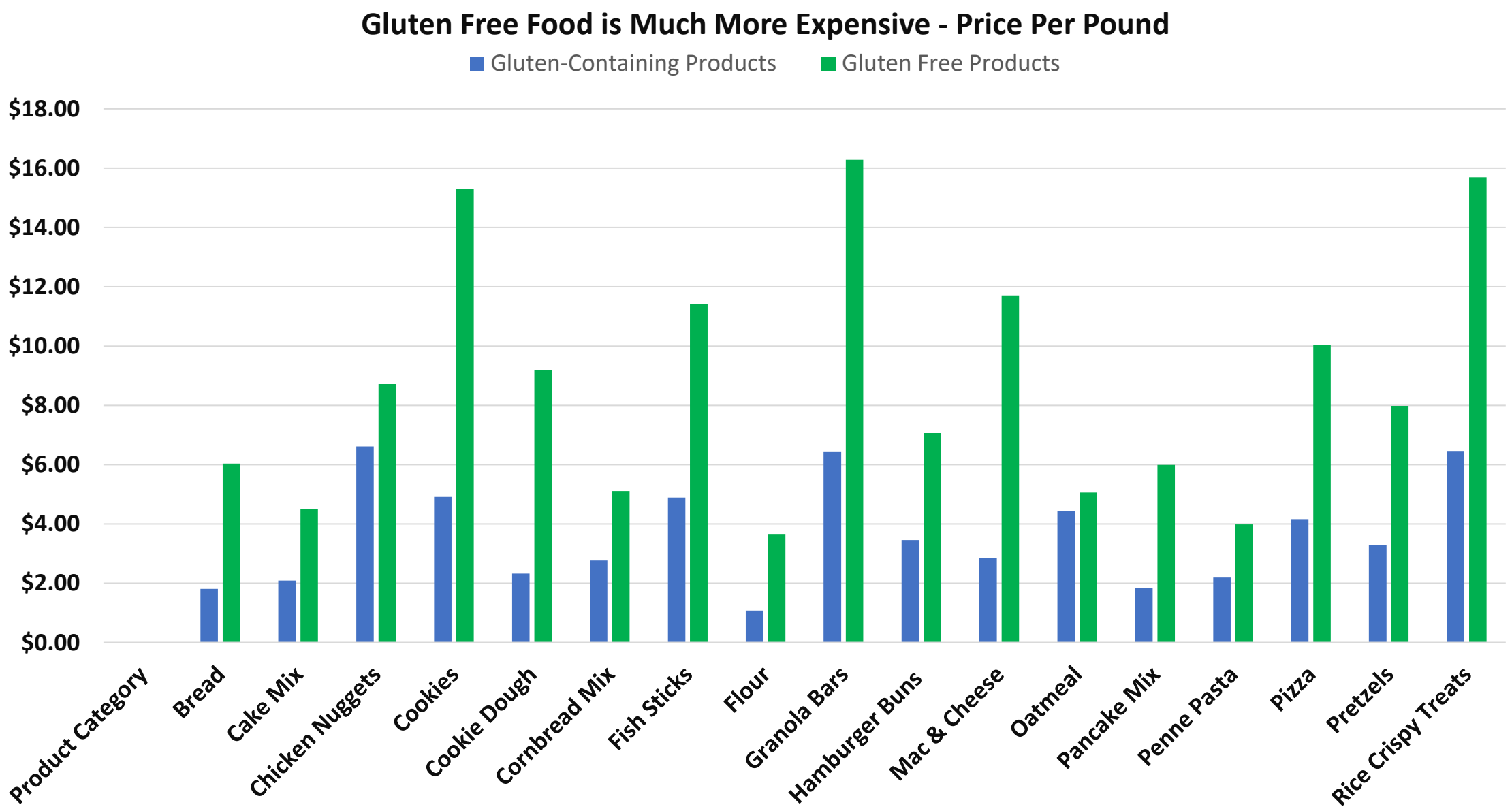
No Whey Foods, Choco No No's, 1.6 oz

$3.48 ($2.18/oz)

amazon.com

Amazon
10/31/22


Gluten Free Food is Much More Expensive - Unit Price
Gluten-Containing Products
Gluten Free Products
$14.00
$12.00
$10.00
$8.00
$6.00
$4.00
$2.00
$0.00
Product Category
Bread
Cake Mix
Chicken Nuggets
Cookies
Cookie Dough
Cornbread Mix
Fish Sticks
Flour
Granola Bars
Hamburger Buns
Mac & Cheese
Oatmeal
Pancake Mix
Penne Pasta
Pizza
Pretzels
Rice Crispy Treats


Gluten Free Food is Much More Expensive - Price Per Pound
Gluten-Containing Products
Gluten Free Products
$18.00
$16.00
$14.00
$12.00
$10.00
$8.00
$6.00
$4.00
$2.00
$0.00
Product Category
Bread
Cake Mix
Chicken Nuggets
Cookies
Cookie Dough
Cornbread Mix
Fish Sticks
Flour
Granola Bars
Hamburger Buns
Mac & Cheese
Oatmeal
Pancake Mix
Penne Pasta
Pizza
Pretzels
Rice Crispy Treats

Celiac is Just as Grave and Deadly as IgE-Mediated Food Allergies

On July 20, 2004, Representative Nita Lowey, the primary House sponsor of FALCPA, spoke on the House floor and urged her colleagues to pass the Food Allergen Labeling and Consumer Protection Act (FALCPA),

> "Navigating insufficient labels is much more than an irritation for the millions with food allergies. **It is a matter of life and death. Unfortunately, the situation is the same for those with Celiac Disease**, a lifelong digestive disorder that damages the small intestine and interferes with absorption of nutrients from food. **Although Celiac sufferers do not go into anaphylactic shock if they consume Gluten, the consequences of leaving the disease undiagnosed or untreated can be just as grave and deadly**, potentially leading to additional autoimmune disorders, infertility, osteoporosis or cancer."

Source: https://www.congress.gov/congressional-record/2004/7/20/house-section/article/h6093-1?

The “Modern” History

The year was 1887…

- Grover Cleveland was President of the United States
- Gustave Eiffel began work on the Eiffel Tower in Paris
- Americans celebrated the 100th Anniversary of the Constitution of the United States (1787)
- The Eisenhower Executive Office Building was one year away from completion in 1888
- The NIH was established
- Dr. Samuel Gee presented the first modern definition of Celiac Disease at a lecture at the Hospital for Sick Children in London. Dr. Gee first established the connection between Celiac Disease and diet, and theorized, “**if the patient can be cured at all, it must be by means of diet**.” [1]

That was 135 years ago!!!

[1] https://www.beyondceliac.org/celiac-news/from-mussels-to-bananas-to-gluten-celebrating-samuel-gee-advances-in-celiac-disease-research/

The “Modern” History (Continued)

The year was 1952…

- Harry S. Truman was President of the United States
- The Korean War was being fought
- Dr. Jonas Salk was poised to develop and test a Polio vaccine ((1953-1954) which led to the Polio vaccine being licensed in 1955)
- First discovered that Gluten was the trigger of Celiac Disease [1]

That was 70 years ago!!!

Fast forward to 2022, and the only known treatment option for Celiac Disease is a medically required, strict Gluten Free diet, with no exceptions!

[1] https://www.beyondceliac.org/celiac-news/from-mussels-to-bananas-to-gluten-celebrating-samuel-gee-advances-in-celiac-disease-research/

Permanent State of Food & Nutritional Insecurity

The Universal Declaration of Human Rights expressly and directly links “health and well-being” with adequate food – **The Human Right to Adequate Food**.

However, for Celiac patients and their caretakers, the issue of food being cross contaminated with Gluten, inadequate voluntary labeling and the high price of Gluten Free food contributes to a **permanent state food and nutritional insecurity** to holders of this potentially life-threatening and life-debilitating food allergy and auto-immune disease who medically require a lifelong special diet.

This can cause loss of quality of life, socialization, and health of the individual, both in the short and long term.

Sources:
"The Only Available Treatment for Celiac Disease Gluten Free Food Should Be Viewed in the Context of a Human Rights Issue: The Right to Adequate Food", by Jon Bari, December 19, 2019, www.celiacjourney.com/humanrights
“The Principle of Human Right to Adequate Food and Celiac Disease: Advancements and Challenges”, by Juliana Nadal (Department of Nutrition. Food Quality and Nutrition Area. Federal University of Parana, Curitiba, PR, Brazil), Sila Mary Rodrigues Ferreira, Islandia Bezerra Da Costa, Suely Teresinha Schmidt (Post-graduation Program in Food and Nutrition Security. Federal University of Parana, Curitiba, PR, Brazil), 2013.
“Going Gluten Free as a Human Rights Issue”, By Yvonne Vissing Ph.D. and Christopher Moore-Vissing, Journal of Gluten Sensitivity, Summer 2016 Issue, July 11, 2016.

A Guiding Framework – "The Best Interests of the Child"

According to the **United Nations** **Convention on the Rights of the Child**:

- "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 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, HHS, FDA, 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**."

Source: https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf

The NIH Has Historically Underfunded Celiac Disease Research

Out of various Gastrointestinal Disorders, from 2011-2015:

A. "**Celiac disease consistently received the lowest amount of NIH funding over the 5-year period, at approximately $3 million per year**."

B. "**Celiac disease consistently received the lowest amount of NIH grants, at approximately eight grants per year**."

C. "**In conclusion, NIH funding of GI diseases is not proportional to disease prevalence or mortality**. These data further suggest that a few diseases, including IBS and celiac disease, are underfunded in comparison with other diseases, especially when the prevalence, burden, and available treatment options are considered."

Source: "Disparities Among Gastrointestinal Disorders in Research Funding From the National Institutes of Health," The American Gastroenterological Association, By: Emma Clerx, Harvard University; Sonia Kupfer, Celiac Disease Center at University of Chicago; and Daniel Leffler, North American Society for the Study of Celiac Disease, Beth Israel Deaconess Medical Center; September 4, 2017, https://www.gastrojournal.org/article/S0016-5085(17)36084-5/pdf

About the Presenters

Leslie and Jon Bari are the Pennsylvania parents of Jax (9) and Lexi (17). In August 2018, Jax was diagnosed with Celiac Disease.

Up until August 2018, we took our food freedom for granted. We enjoyed our food privilege of being able to eat whatever and wherever we wanted.

We are working to require that Gluten be labeled as a Major Food Allergen on all packaged foods since a strict Gluten Free diet is the only available treatment option for Celiac Disease. We are also working to foster greater understanding and inclusion of those who suffer from Celiac Disease. To that end, we want to drive change in the research ecosystem so that hopefully in the short run, treatment options and a cure can be found, and we can return to our pre-Celiac life.

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