



## **Sharing Our Lived Experience with Celiac Disease**

### **Comments on “Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance”**

**Docket Number: FDA-2021-N-0553**

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**“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**

**August 16, 2022 (updated August 19, 2023)**

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## I. Executive Summary

**“When you see something that is not right, not fair, not just, you have to speak up.  
You have to say something; you have to do something!”**

-- Congressman John Lewis, The Conscience of the Congress

On April 19, 2022, the FDA published “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the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders – Draft Guidance”, April 19, 2022, Docket number: FDA-2021-N-0553 (“FDA’s Draft Guidance”).<sup>1</sup> We appreciate the opportunity to share our lived experience and provide our Comments on the FDA’s Draft Guidance” (“Comments”).

According to the FDA’s News Release about the FDA’s Draft Guidance,

“Currently, the major food allergens [in the U.S.] are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans, though more than 160 foods are known to cause food allergic reactions. Sesame becomes the ninth major food allergen, effective Jan. 1, 2023.

‘The nine major food allergens don’t currently represent all foods nationwide that people are allergic to or that cause food hypersensitivities,’ said Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition. ‘This draft guidance is part of the FDA’s efforts to evaluate emerging evidence about other non-listed food allergens that can cause serious reactions in a consistent and transparent manner, which can inform potential future actions to better help protect the health of consumers.’...

The draft guidance focuses on immunoglobulin E antibody (IgE)-mediated food allergies, which are capable of triggering anaphylaxis and are considered the most severe and immediately life-threatening food allergies.”<sup>2</sup>

Therefore, with respect to the Celiac Disease community, which has been historically underserved and marginalized by our Federal government (i.e., underfunding medical research for Celiac Disease,<sup>3</sup> labeling Gluten only with a voluntary scheme,<sup>4</sup> disqualifying Celiacs from service in the military,<sup>5</sup> excluding Celiac Disease from the CDC’s Index of Diseases &

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<sup>1</sup> <https://www.fda.gov/media/157637/download> ; Note that throughout the FDA Draft Guidance, there are citations to FDA “VIII. References” that are cited as “Ref. [X]” and those citations correspond to references in <https://www.regulations.gov/document/FDA-2021-N-0553-0007> . Throughout these Comments, I refer to “FDA Ref. [‘X’]” to refer to the documents cited in the FDA Draft Guidance

<sup>2</sup> FDA News Release, “FDA Takes New Steps Regarding Evaluating Public Health Importance of Additional Food Allergens,” April 18, 2022, <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-regarding-evaluating-public-health-importance-additional-food-allergens>

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

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

<sup>5</sup> 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

Conditions,<sup>6</sup> etc.), the FDA's Draft Guidance presents an inequitable evaluation framework, 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<sup>7</sup> 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<sup>8</sup> that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

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[https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003\\_vol1.PDF?ver=7fhqacc0jGX\\_R9\\_1iexudA%3d%3d](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/613003_vol1.PDF?ver=7fhqacc0jGX_R9_1iexudA%3d%3d)

<sup>6</sup> <https://www.cdc.gov/az/f.html>

<sup>7</sup> The FDA's final rule defining Gluten Free 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#>

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

**Figure 1 - What is Food Allergy? The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms**

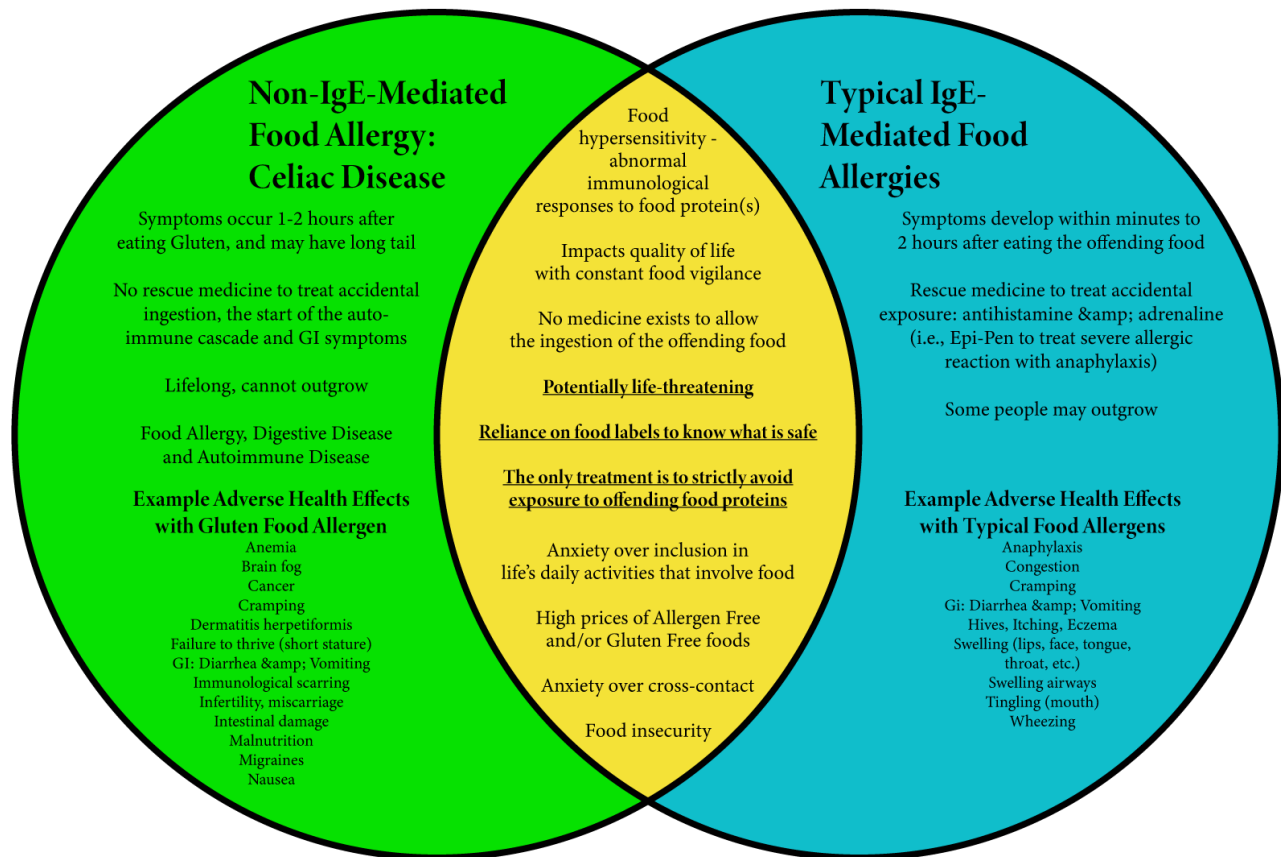


Figure 1 above illustrates the key near-peer similarities between food allergies that are Non-IgE-Mediated mechanisms with Celiac Disease (Gluten as a food allergen) and typical IgE-Mediated Mechanisms: potentially life-threatening, the only treatment is to strictly avoid the food allergen(s), and consumers' reliance on food labels to know what is safe to eat.

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).<sup>9</sup>

While U.S. consumers' reactions to the top 9 major food allergens (Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, and Soybeans (plus Sesame as of January 1, 2023), collectively "Major Food Allergens") and Gluten vary, their consumer habits are the same -- they

<sup>9</sup> This diagram graphic is intended to convey that Non-IgE-Mediated food allergy with Celiac Disease and typical IgE-Mediated food allergies are both really dangerous and deserve equal treatment with respect to consumer protection with food labeling. The adverse health effects are listed in alphabetical order, and these health dangers are an illustrative, but not exhaustive list. This diagram will be discussed in greater detail herein, but it should be noted that this expands and updates information as was included in Table 2-1 in FDA's Draft Guidance Ref. 2.

avoid purchasing foods that contain the allergen(s) that cause a potentially life-threatening immunological adverse reaction. Notwithstanding the foregoing, the key difference from a consumer protection standpoint is that under the Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”), the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is permissive. Wheat is required to be labeled, but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats.<sup>10</sup> Just because something is Wheat free does not mean its Gluten Free. In other words, whereas sufferers of the current top 9 Major Food Allergens in the U.S. rely on what ingredients are expressly included in required labeling disclosures of packaged foods, the Celiac community must rely only on what ingredients are excluded in voluntary Gluten Free labeling disclosures on packaged foods.

The FDA’s Draft Guidance also suggests cognitive dissonance and confirmation bias by preemptively excluding Gluten containing grains from being considered in the context of evaluating the public health importance of food allergens other than the Major Food Allergens listed in the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). This is because in part both the Food Allergen Labeling and Consumer Protection Act of 2004 and the FDA’s Draft

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<sup>10</sup> Gluten containing grains are Wheat, Barley, Rye and most Oats. Wheat is already codified as a Major Food Allergen in the US. 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) 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](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). 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> . It is also 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](https://s22.q4cdn.com/584207745/files/doc_financials/2021/ar/Final-GMI-2021-Annual-Report.pdf)

Guidance are incongruent 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”).<sup>11</sup>
- 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 FDA’s Draft Guidance).<sup>12</sup>

The 1999 FAO/WHO Expert Consultation included 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.<sup>13</sup> Dr. Taylor served as one of six esteemed scientists on the Ad Hoc Panel on Food Allergens in February 1999 to provide advice to the Joint FAO/WHO Expert Committee on Food Additives about criteria for labelling food allergens. The 1999 FAO/WHO Expert Consultation determined:

“The revised list of those foods and ingredients known to cause food allergies and intolerance and **whose presence should always be declared** was identified as the following: **cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products**; Crustacea and products of these; Egg and egg products; Fish and fish products; Peanuts, soybeans, and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulfites in concentrations of 10 mg/kg or more.”<sup>14</sup> (emphasis added)

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

**“Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”**<sup>15 16</sup> (emphasis added)

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<sup>11</sup> [https://apps.who.int/iris/bitstream/handle/10665/42378/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf)

<sup>12</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>13</sup> <https://farrp.unl.edu/fss/staylor>

<sup>14</sup> [https://apps.who.int/iris/bitstream/handle/10665/42378/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf)

<sup>15</sup> “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ...

The 2021 FAO/WHO Expert Consultation also included several other expert scientists and physicians from the United States, including esteemed public servants from the FDA and the United States Department of Agriculture. See section herein entitled “2021 FAO/WHO Expert Consultation The Scientists Have Spoken”.

It is ironic and troubling that while the FDA Ref. 25 and FDA Ref. 45 are cited as sources in the FDA’s Draft Guidance, the FDA’s Draft Guidance excludes salient findings in those treatises by the “scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry”<sup>17</sup>, 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 tantamount to eating poison and potentially life-threatening and life-debilitating.

The global adherence to and implementation of FDA Ref. 25 and FDA Ref. 45 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.<sup>18</sup>

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should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.”

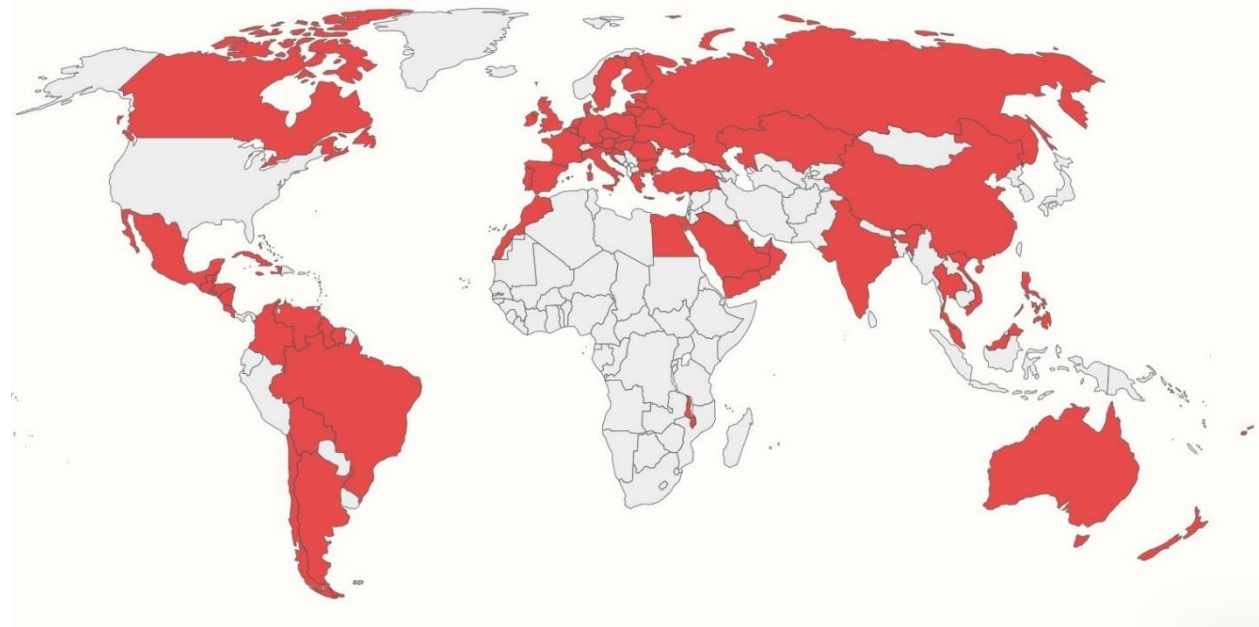
<sup>16</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>17</sup> It is estimated that a large number of multinational companies in the food industry, including American firms which sell their food products abroad, already label Gluten on their products sold in countries outside of the US that require Gluten to be labeled on all packaged foods. In other words, the food industry has been helping to protect consumers for many years in labeling Gluten on their products which are sold in any one of the more than 85 countries around the world which require Gluten to be labeled on all packaged foods, in accordance with the 1999 Codex Criteria and more recently with the 2021 FAO/WHO Expert Consultation.

<sup>18</sup> According to the University of Nebraska-Lincoln, the following countries require that Gluten be labeled on packaged foods: Anguilla, Antigua and Barbados, Argentina, Australia, Austria, Bahamas, Barbados, Belarus, Belgium, Belize, Bermuda, Bolivia, Brazil, British Virgin Islands, Bulgaria, Canada, Cayman Island, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominica, Egypt, El Salvador, Estonia, Fiji, Finland, France, Germany, Greece, Grenada, Guatemala, Guyana, Haiti, Honduras, Hong Kong, Hungary, India, Ireland, Italy, Jamaica, Kazakhstan, Kuwait, Latvia, Lithuania, Luxembourg, Malawi, Malaysia, Malta, Mexico, Montserrat, Morocco, Netherlands, New Zealand, Nicaragua, Oman, Philippines, Poland, Portugal, Qatar, Romania, Russia, Saint Lucia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, Sweden, Thailand, Trinidad and Tobago, Turkey, Turks and Caicos Island, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam, and Yemen. Source: <https://farrrp.unl.edu/IRChart>

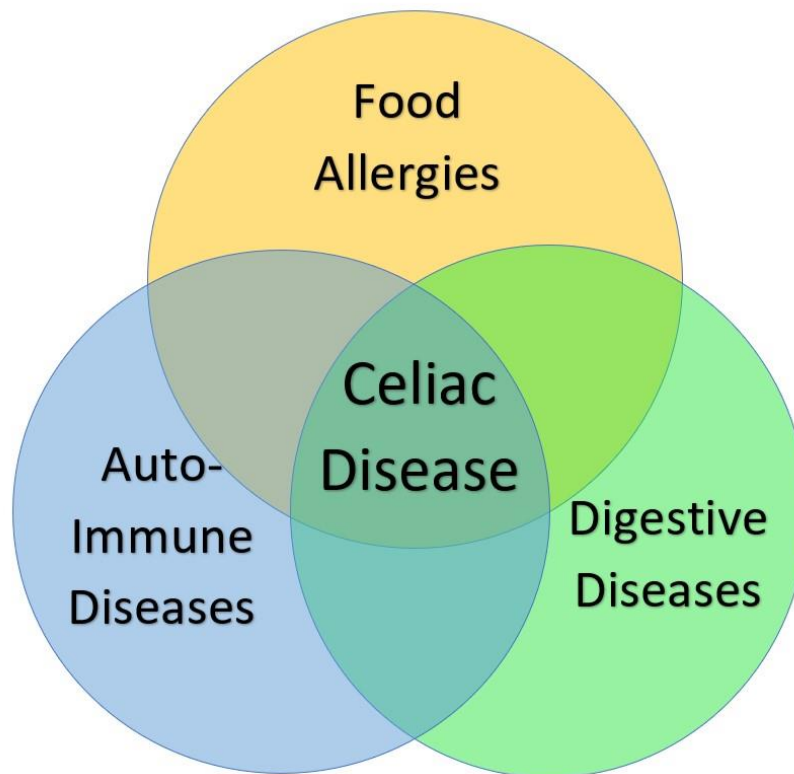


**Figure 2 - Gluten Is Required to Be Labeled as a Major Food Allergen on Packaged Foods In More than 85 Countries Worldwide (shaded in red), Not Including the United States**



In terms of consumer protection, the Celiac community would benefit greatly if the FDA and scientists would consistently refer to Celiac as a food allergy and Gluten as a food allergen. See section herein, “What’s In A Name? Celiac is a Food Allergy!”. Additionally, it is important to note that a classification for Celiac Disease is not binary. In other words, if someone refers to Celiac as a digestive disease and/or an auto-immune disease, that is not mutually exclusive from Celiac also being a food allergy. A review of various written descriptions about Celiac Disease, and programs related thereto, from various Federal government agencies (i.e., FDA, National Institutes of Health (“NIH”), Centers for Disease Control (“CDC”)) suggests that this complexity has also enabled the ingrained othering by various government officials of a food allergy with Non-IgE-Mediated mechanism to be considered something else and something less serious than a typical food allergy, something else other than a digestive disease and/or something else other than an auto-immune disease.

**Figure 3 - Celiac Disease Sits At The Intersection of Food Allergies, Auto-immune Diseases and Digestive Diseases**



In accordance with President Joe Biden’s Executive Order 13985, advancing equity requires a systematic approach to embedding fairness in the decision-making processes that all FDA functions are routed through.<sup>19</sup> Using that lens and framework, the FDA’s Draft Guidance suggests systemic food privilege that contributes to food insecurity, and the FDA should work to redress historical inequities in various agencies’ policies and processes, including in the FDA’s Draft Guidance. To that end, it is instructive to look at how the USDA defines 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.”<sup>20</sup>

These inequities serve as barriers to the equal protection under the law and fair evaluation of the public health importance of adverse reactions to food due to a food hypersensitivity that is mediated by immune mechanisms, including for Gluten as a potentially life-threatening and life-debilitating food allergy with a Non-IgE-Mediated mechanism. By way of example, independent and peer-reviewed analysis has shown that NIH funding of Celiac Disease research is not

<sup>19</sup> <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government> and <https://www.hhs.gov/about/news/2022/04/14/hhs-statements-on-new-plan-advance-equity-delivery-health-human-services.html>

<sup>20</sup> <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.

proportional to its disease prevalence or mortality in terms of a cohort of digestive diseases.<sup>21</sup> In addition to digestive diseases, further analysis has shown that NIH funded research of Celiac has also lagged behind in the biomedical imagination of other much more well-funded areas including autoimmune diseases, food allergies and foodborne illnesses. See section herein entitled, “Disparities Among Gastrointestinal Disorders in Research Funding From the NIH”.

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. For example, the FDA’s Draft Guidance states,

“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)”<sup>22</sup> (emphasis added)

In other words, since Celiac research (Non-IgE-Mediated food allergy) has historically been underfunded, including from the NIH and Department of Defense (“DoD”), Celiac is not as very 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.

Unfortunately, in spite of our many precautions, our 9 year old son, Jax, has been “glutened” at times through accidental ingestion of Gluten and that has resulted in him experiencing GI issues commensurate with foodborne illness (food poisoning),<sup>23</sup> and in addition, potential long-term complications including damage to his small intestine. Last Summer, Jax got violently ill when the chef at a restaurant thought a packaged food product was Gluten Free since it did not have Wheat labeled on the package, but the food product did have unlabeled Gluten in it.<sup>24</sup> That’s one

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<sup>21</sup> “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](https://www.gastrojournal.org/article/S0016-5085(17)36084-5/pdf)

<sup>22</sup> <https://www.fda.gov/media/157637/download>

<sup>23</sup> <https://www.cdc.gov/foodsafety/symptoms.html>

<sup>24</sup> See “Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers”, Question 26, “What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic? FALCPA only applies to packaged FDA-regulated foods. However, FDA advises consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumer’s home.” <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents->

real world example of getting Glutened and why we need Gluten to be labeled on packaged foods!

As Jax says, eating without fear is our hope. Food insecurity happens every day because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the limited availability of Gluten Free food (especially eating out of home), and Gluten is not required to be labeled on packaged foods in the US, like it is in 85 countries around the world including in Canada and across Europe.

In terms of being historically underserved by the Federal government, our research has informed our findings that the Celiac community in the United States has been left to fend for ourselves, literally and figurately. As a consequence, the Celiac community has received “half a loaf at twice the price” (see section herein “The Economics of Celiac Disease The Financial Burden of the Gluten Free Diet” and Figure 9 herein for Market Shopping in the Philadelphia Area as of July 10, 2022). FALCPA’s voluntary labeling scheme has caused informational malnourishment and created a premium marketplace for Gluten Free food.

The bottom line is that until there is a cure for Celiac Disease, a treatment other than a strict Gluten Free diet for life, or even a rescue medicine that can be administered in the event of accidental ingestion of Gluten (i.e., epinephrine or antihistamine in the case of IgE-Mediated food allergy), the FDA can help save a life (or lives) or help someone (or some people) have a better life by protecting the Celiac community in an equitable and meaningful manner, and that includes starting with revising the FDA’s Draft Guidance and requiring that Gluten be labeled on all packaged foods.

## **II. Preliminary Statement on the Food Allergen Labeling and Consumer Protection Act**

**“I have the audacity to believe that peoples everywhere can have three meals a day for their bodies, education and culture for their minds, and dignity, equality, and freedom for their spirits.”**

-- Dr. Martin Luther King, Jr.

**“Did you know that 44% of people with celiac disease who follow a strict gluten-free diet still get glutened once a month?”<sup>25</sup>**

-- Alice Bast, CEO of Beyond Celiac

As a preliminary statement, it is instructive to note that the Food Allergen Labeling and Consumer Protection Act of 2004 (alternatively, FALCPA) expressly addressed both typical Immunoglobulin E (IgE)-Mediated food allergies<sup>26</sup> and Celiac Disease, a Non-IgE-Mediated

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regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#

<sup>25</sup> <https://twitter.com/abast/status/1551780196243603457?>

<sup>26</sup> According to the World Allergy Organization, “Typical food allergies are IgE-mediated, but several reactions involve different immunologic mechanisms. These food allergies are defined as nonIgE-mediated or mixed IgE- and nonIgE-mediated.” Source: <https://www.worldallergy.org/education-and-programs/education/allergic-disease-resource-center/professionals/food-allergy>

food allergy, because these two disorders pose particularly serious health and potentially life-threatening safety risks, such as anaphylaxis and intestinal damage, respectively, that are not associated with food intolerances (i.e., lactose intolerance).<sup>27 28</sup>

Moreover, the FALCPA does not preclude the FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme.<sup>29</sup> **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.”**<sup>30</sup>

In order to look forward, we must first look back at FALCPA's provenance. In undertaking various research, I have relied heavily on “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004” by Laura E. Derr, as published in the Food and Drug Law Journal in 2006 (“When Food Is Poison”).<sup>31</sup> According to When Food Is Poison:

“Unlike the EU Labeling Directive,<sup>32</sup> the international labeling standards promulgated in the Codex Alimentarius,<sup>33</sup> and an earlier proposed U.S. allergen labeling bill,<sup>34</sup> the

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<sup>27</sup> <https://www.jstor.org/stable/26660870>

<sup>28</sup> “Food intolerances can be defined as any form of food sensitivity that does not involve immunologic mechanisms.” Source: <https://www.fao.org/3/x2670e/x2670e.htm>

<sup>29</sup> “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>

<sup>30</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

<sup>31</sup> <https://www.jstor.org/stable/26660870>

<sup>32</sup> “EU Labeling Directive, supra note 346 at 23, Annex IIIa. [See generally EU Council Directive 2003/89. This Amending Directive principally added provisions to Article 6 of the 2000 Labeling Directive, 2000/13 2000 O.J. (L 109), available at [https://web.archive.org/web/20030810035215/http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en\\_2000L0013\\_do\\_001.pdf](https://web.archive.org/web/20030810035215/http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000L0013_do_001.pdf)

The Amending Directive revises previously-instituted labeling exemptions that allowed certain ingredients, such as those found in additives and processing aids, to not be included on labels.

‘In order to achieve a high level of health protection for consumers and to guarantee their right to information, it must be ensured that consumers are appropriately informed as regards foodstuffs, inter alia, through the listing of all ingredients on labels... When used in the production of foodstuffs and still present, certain ingredients or other substances are the cause of allergies or intolerances in consumers, and some of those allergies or

FALCPA does not require the labeling of grains containing gluten on food products. This is so, even though, according to some allergy experts as late as 2001, gluten-containing

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intolerances constitute a danger to the health of those concerned... Even if labelling [sic], which is intended for consumers in general, is not to be regarded as the only medium of information acting as substitute for the medical establishment, it is nevertheless advisable to assist consumers who have allergies or intolerances as much as possible by providing them with more comprehensive information on the composition of foodstuffs... in order to provide all consumers with better information and to protect the health of certain consumers, it should be made obligatory to include in the list of ingredients all ingredients and other substances present in the foodstuff.’

Council Directive supra note 291, at 1.” [“See generally European Union Council Directive 2003/89, 2003 (L 308), available at [europa.eu.int/eur-lex/lex](http://europa.eu.int/eur-lex/lex). These labeling regulations did not go into effect, however, until November 2005. See, e.g., Anthony Fletcher, EU Strengthens Allergen Labelling (Nov. 30, 2005), available

<http://www.foodnavigator.com/news/ng.asp?n=64224-eu>”]

<sup>33</sup> Joint FAO/WHO Food Standards Programme, supra note 289, at 4; [“The Codex Alimentarius is a set of international food standards established to protect health of consumers and facilitate fair international trade. See Joint FAO/WHO Food Standards Programme of the Codex Alimentarius Commission, Codex Alimentarius: Food Labelling Complete Texts (2001) [hereinafter Joint FAO/WHO Food Standards Programme].” See also FAO Consultation, supra note 290. “The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.” Source:

[https://web.archive.org/web/20110622081804/http://www.codexalimentarius.net/web/index\\_en.jsp](https://web.archive.org/web/20110622081804/http://www.codexalimentarius.net/web/index_en.jsp)

[See Allergen Labeling Policy Considered by Codex Committee, Food Labeling & Nutrition News, May 6, 1993, at 15-17; see also FAO, 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.”

<sup>34</sup> H.R. 4704 explicitly included “grains containing gluten” among the “allergens” within the scope of the legislation’s mandatory labeling scheme. H.R. 4704, 107th Cong. 3 (2d Sess. 2002). The bill listed oats among its examples of gluten-containing grains. *Id.*; see also 148 Cong. Rec. S4163-64 (May 9, 2002) (statement of Senator Kennedy).

grains -- not just wheat -- are included in lists of the Big Eight allergens.<sup>35</sup> Although the FALCPA mandates that wheat be disclosed on food labels, other grains toxic to individuals with celiac disease (e.g., rye and barley) need not be disclosed in plain English or when present in spices, flavorings, colors, or additives.<sup>36,37</sup>

Note: The footnotes from When Food Is Poison have been transcribed and attributed within quotes from When Food Is Poison throughout these Comments to the FDA's Draft Guidance.

Additionally, 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.

Since the FDA's Draft Guidance has been written for FDA Staff and Stakeholders, it is valuable to understand that Ms. Derr wrote the "When Food Is Poison" treatise when she was a student at Harvard Law School, under the supervision of Harvard Lecturer on Law, Peter Barton Hutt, Partner at Covington & Burling, Washington, D.C., for Harvard Law School's Winter 2005 Food and Drug Law course. 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.<sup>38</sup>

It was not until I read (and reread) When Food Is Poison that I gained meaningful insight into the history and impact of the Food Allergen Labeling and Consumer Protection Law. When Food Is Poison has provided a fascinating window back in time to the then contemporaneous origins of the FALCPA's timeline, narrative and nuances. The article memorialized FALCPA's legislative intent and dealmaking, including how Grains Containing Gluten (Wheat, Barley, Rye and Oats) were initially classified as a Major Food Allergen which would have required the labeling of Gluten on packaged foods in the U.S.

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<sup>35</sup> Susan L. Hefle & Steve L. Taylor, Food Allergies and Other Food Sensitivities, 55(9) Food Tech. 69, 75, at 71 tbl. 2. Sept. 2001).

<sup>36</sup> See, e.g., Steve L. Taylor, Prospects for the Future: Emerging Problems Food Allergens, in FAO, Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition (ALICOM 99 15) (1999), available at <https://www.fao.org/3/x2670e/x2670e.htm>

(**"As with IgE-mediated food allergies, the cereal grains involved in celiac disease can be 'hidden' in foods as a result of the lack of source labelling [sic] of certain ingredients ... and various inadvertent errors made by food manufacturers."**). **Moreover, the 2001 FDA Public Meeting regarding the labeling of food allergens was purposefully limited to a discussion of food allergies and not celiac disease.** See FDA, Transcript: Public Meeting On: The Challenge of Labeling Food Allergens 32 (August 13, 2001), Statement of Anne Munoz-Furlong, President and Founder, FAAN). (Dr. Christine Lewis, Director of the Office of Nutritional Products, Labeling, and Dietary Supplements, **FDA, stated that the meeting would not concern** latex allergies, **celiac sprue [Celiac Disease]**, or restaurant labeling.).

<sup>37</sup> 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.

<sup>38</sup> <https://www.fdpi.org/career/austern-writing-competition/>

When Food Is Poison has an in-depth discussion on Celiac Disease -- “Because the FALCPA addresses food allergies and celiac disease, this article focuses on these two ailments.” While the entire article is fascinating, I found the section “The FALCPA’s Impact on People with Celiac Disease” particularly informative (pages 142-145), and I would recommend that the FDA staff to carefully read Ms. Derr’s treatise in order to more meaningfully understand our Comments herein on the FDA’s Draft Guidance and how to move forward with the equitable evaluation of the public health importance of other food allergens including Gluten.

### **III. Preliminary Statement on Health Equity and President Biden’s Executive Order 13985**

**“We have been too quiet for too long. There comes a time when you have to say something. You have to make a little noise. You have to move your feet. This is the time.”**  
-- Congressman John Lewis (1940-2020), The “Conscience of the Congress”

As will be detailed throughout these Comments, including in the sections herein entitled, “About Celiac Disease and the Gluten Free Diet”, “FALCPA Fell Short in Safeguarding Celiacs”, “The FDA Fell Short for a Decade in Protecting the Celiac Community” and “Disparities Among Gastrointestinal Disorders in Research Funding From the NIH”, the Celiac community (including patients and their families/caregivers) has been historically underserved and marginalized for many years by the Federal government, including with funding medical research and labeling Gluten.<sup>39</sup>

The FDA’s Draft Guidance suggests apathy and othering to the chronic medical needs of the Celiac community. Additionally, unless the FDA’s Draft Guidance is significantly revised as requested herein, it has the potential to continue to adversely impact the quality of life, dignity, civil rights, human rights and social equity of at least 1% of Americans, including the way in which other government agencies and branches view Gluten as a food allergen that is potentially life-threatening, potentially life-debilitating and impacts the health and wellbeing of 3 million Americans with Celiac, including my son.

It is instructive to view these Comments as well as all comments received on the FDA’s Draft Guidance<sup>40</sup> 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,

“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

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<sup>39</sup> Testimony provided to the U.S. Senate Appropriations Committee by Jonathan and Leslie Bari, <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; and Congressional Briefing, January 14, 2020, [www.celiacjourney.com/briefing](http://www.celiacjourney.com/briefing)

<sup>40</sup> <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=gluten>



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.”<sup>41</sup>

We would also like to specifically note our support for the comments submitted to the FDA’s Draft Guidance by (in no order of importance):

- Dr. Virginia A. Stallings, Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine, Director Nutrition Center, Jean A. Cortner Endowed Chair in Gastroenterology and Nutrition at the Children’s Hospital of Philadelphia;<sup>42</sup>
- Dr. Amanda Muir, Pediatric Gastroenterologist in the Division of Gastroenterology, Hepatology and Nutrition at the Children’s Hospital of Philadelphia;<sup>43</sup>
- Beyond Celiac;<sup>44</sup>
- National Celiac Association;<sup>45</sup>
- Britney Asbell;<sup>46</sup>
- Brian Davis and family;<sup>47</sup>
- Galen Rydzik;<sup>48</sup>
- Catherine Baril; and
- Tricia Thompson, MS, RD<sup>49</sup>, Founder of Gluten Free Watchdog.<sup>50</sup>

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,

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<sup>41</sup> <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/>

<sup>42</sup> FDA Tracking Number: l6g-mawc-nbs8, [https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-0553-1169/attachment_1.pdf)

<sup>43</sup> 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. <https://www.chop.edu/doctors/muir-amanda>

<sup>44</sup> FDA Tracking Number: l6q-v6ic-9kfi, [https://downloads.regulations.gov/FDA-2021-N-0553-1353/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-0553-1353/attachment_1.pdf)

<sup>45</sup> FDA Tracking Number: l4e-cf9x-ka7n, [https://downloads.regulations.gov/FDA-2021-N-0553-0822/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-0553-0822/attachment_1.pdf)

<sup>46</sup> FDA Tracking Number l6c-exmk-ywis

<sup>47</sup> FDA Tracking Number l6v-04b4-4gs6, [https://downloads.regulations.gov/FDA-2021-N-0553-1385/attachment\\_1.docx](https://downloads.regulations.gov/FDA-2021-N-0553-1385/attachment_1.docx)

<sup>48</sup> FDA Tracking Number: l6n-ycm5-uamd

<sup>49</sup> <https://www.glutenfreewatchdog.org/news/wp-content/uploads/2021/05/CurriculumVitae2021.pdf>

<sup>50</sup> FDA Tracking Number l2u-t68j-qa01, and [https://downloads.regulations.gov/FDA-2021-N-0553-0208/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2021-N-0553-0208/attachment_1.pdf)

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.”<sup>51</sup> (emphasis added)

The Celiac community represents an underserved community which shares particular characteristic including a chronic disability<sup>52</sup> 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. 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 the digestive system, nervous system and integumentary system.

### **Executive Order 13985 & The White House Conference on Hunger, Nutrition, and Health**

With regard to the subject matter of these Comments, Executive Order 13985 aligns with the White House Conference on Hunger, Nutrition, and Health (White House Conference”) scheduled for September 2022, including,

“Conference “Pillar #2, 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”<sup>53</sup> (“Pillar2”).

We were inspired by the opening plenary remarks at the White House Conference Regional Listening by Robert Califf, M.D., Commissioner of the FDA and Laura Carroll, Senior Policy Advisor at FDA. Specifically, we provided input to the White House Conference on Hunger, Nutrition, and Health as follows:

- Our participation and spoken comments in the Breakout Room for Pillar 2 in the Listening Session on June 7, 2022;

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<sup>51</sup> <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

<sup>52</sup> 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 <https://www.celiacjourney.com/post/colonial-williamsburg-lessons-learned-about-the-civil-rights-of-the-celiac-community> and [https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7\\_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf](https://e283a7ed-372c-4d14-b65c-6fe40bfad779.usrfiles.com/ugd/e283a7_82b2da0c6e2d40ee9f55e3e57ef820a4.pdf)

<sup>53</sup> <https://health.gov/our-work/nutrition-physical-activity/white-house-conference-hunger-nutrition-and-health/conference-details>

- Our meeting on May 6, 2022 with Dr. Sandi Ford, Special Assistant to the President for Health and Science, in order to inform the White House about the unmet needs of the Celiac community, especially the pediatric community (labeling Gluten and funding Celiac research);
- Our written comments submitted via email to the White House Conference on July 15, 2022, entitled “Celiac Journey - White House Conference on Hunger, Nutrition, and Health”<sup>54</sup> (Note that these July 15, 2022 comments to the White House that we provided included an earlier version of the Executive Summary for our Comments on the FDA’s Draft Guidance); and
- Our complete Comments herein to the FDA’s Draft Guidance.

As it pertains to Executive Order 13985, it is also instructive to review the Health Equity Plan from the U.S. Department of Health and Human Services (“HHS”) since the FDA is an HHS agency.

“‘Extensive evidence tells us we have more work to do to ensure that all communities HHS serves have the opportunity to access and experience optimal health and wellbeing,’ said Assistant Secretary [Rebecca] Haffajee. ‘Our HHS Equity Action Plan demonstrates that we are committed, in collaboration with the public and our partners, to overcoming existing inequities through our research, policies, and programs.’”<sup>55</sup>

“‘At HHS, we are committed to an evidence-based approach to understanding barriers and advancing opportunity and equity. We are committed to using every tool in our toolbox to ensure that a healthier future includes eliminating health disparities and promoting health equity,’ said Assistant Secretary [Rachel] Levine. ‘The HHS Equity Action Plan is a vital step toward enabling everyone living in America to reach their dreams.’”<sup>56</sup>

It is important for all stakeholders to note that the HHS Health Equity Action Plan details “five areas as an example of HHS’s commitment to advance equity in all aspects of our work.” Therefore the HHS Health Equity Action Plan is not limited in scope and the framework thereof should also be applied to recognizing that the consumer protection needs of the underserved Celiac community have not been adequately met by current laws, practices and policies.<sup>57</sup>

By way of example, the FDA’s Draft Guidance could in principle follow the lead taken by the FDA’s Project Equity -- “Project Equity is a public health initiative established by the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence (OCE) to ensure that the data

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<sup>54</sup> Email from Jonathan Bari to WHHungerHealth@hhs.gov and Will McIntee william.t.mcintee@who.eop.gov, July 15, 2022. Note that there was an excerpt of the Comments to the FDA’s Draft Guidance

<sup>55</sup> <https://www.hhs.gov/about/news/2022/04/14/hhs-statements-on-new-plan-advance-equity-delivery-health-human-services.html>

<sup>56</sup> <https://www.hhs.gov/about/news/2022/04/14/hhs-statements-on-new-plan-advance-equity-delivery-health-human-services.html>

<sup>57</sup> <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>

submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended.”<sup>58</sup>

To that end, the principles of Project Equity should be applied to revising the FDA’s Draft Guidance to ensure that the FDA’s Draft Guidance provides a more inclusive framework that equitably and meaningfully enables the FDA to consider the public health importance of Gluten as a food allergen to adequately reflect the demographic representation and medical needs of patients for whom FALCPA was intended to protect, including consumers with a Non-IgE-Mediated food allergy to Gluten (i.e., Celiac Disease) as well as IgE-Mediated food allergies to Gluten.

Moreover, as Robert Califf, M.D., Commissioner of the FDA stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session on June 7, 2022,

“There is another important area that the FDA is engaged in -- helping to give Americans the tools that they need to make informed healthy dietary choices. This is especially important because so much of what people eat, and in too many cases what they are not able to eat, because of the scarcity of the food available to them, can have an enormous impact on their health. It can lead to debilitating illnesses and shorter life expectancy... One way we are working to reduce the burden of chronic disease is to make sure consumers have the information they need to make more healthy responsible choices and to be empowered to improve their health and the health of their families. In other words, by supporting the patterns of healthy eating, including ensuring the availability of healthy foods while mitigating the risks to exposure to toxic elements through investments in nutrition, we have a chance to make profound generational improvement in the nutrition health and well-being of the nation.”<sup>59</sup>

With the mitigation of the burden of chronic disease in mind, it is instructive to understand the following. 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 (not mandatory) 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.

To that end, getting information across to over 3 million people with Celiac and their caregivers is challenging because of the voluntary labeling scheme, and this is compounded by the different reading levels, different languages, different ages, etc. that Dr. Califf also spoke of in his plenary remarks. Mandatory labeling of Gluten would go a long way to help ameliorate food insecurity with the uncertainty surrounding what foods are safe to consume and may help to close the life expectancy gap that Dr. Califf also addressed:

“Recent studies have shown that life expectancy in the US has been improving much more slowly than our peer high income countries. It’s very important to realize that the

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<sup>58</sup> <https://www.fda.gov/about-fda/oncology-center-excellence/project-equity>

<sup>59</sup> Robert Califf, M.D., Commissioner of the FDA stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session, June 7, 2022.

latest analysis demonstrates that there is now a five year gap compared with our peer countries. That is the life expectancy of an American is on average five years shorter than other economically high income countries.

The driver of this difference is common chronic disease -- heart disease, lung disease, kidney disease, along with addiction and mental health problems. Good nutrition is a core essential element to reduce these alarming trends. In other words, **by supporting the patterns of healthy eating, including ensuring the availability of healthy foods, while mitigating the risks to exposure to toxic elements** through investments in nutrition, we have a chance to make profound generational improvement in the nutrition, health and well-being of the nation. I'm proud of the hard-working people of the FDA working on this and really excited that so many of you want to join in."<sup>60</sup> (emphasis added)

As will be discussed, Celiac Disease is a disqualifying condition from service in the U.S. Military.<sup>61</sup> Historically, it is instructive to reflect that there were other relatively recent exclusionary practices in the U.S. Military which were embodied in the Don't Ask, Don't Tell "set of policies, laws, and regulations governing how the U.S. Military dealt with gay, lesbian, and bisexual service members... In 2011, the 'Don't Ask, Don't Tell' policy was formally repealed by the Obama Administration under Pub. L. 111-321."<sup>62</sup>

We suggest that FALCPA's voluntary Gluten Free labeling scheme is as convoluted and ill-conceived as Don't Ask, Don't Tell. In addition to it being time for the Federal government to allow Celiacs to serve in the U.S. Military by accommodating their medically required Gluten Free diet, it is also time for the FDA to require that Gluten be labeled on all packaged foods to protect more than 3.3 million Americans with Celiac who have a potentially life-threatening and life-debilitating food allergy to Gluten.

#### **IV. Preliminary Statement on Human Rights**

**"Where, after all, do universal human rights begin? In small places, close to home — so close and so small that they cannot be seen on any maps of the world. [...] Unless these rights have meaning there, they have little meaning anywhere. Without concerted citizen action to uphold them close to home, we shall look in vain for progress in the larger world."**

-- Eleanor Roosevelt, Chair of the United Nations Human Rights Commission

It is instructive to view these Comments (and all comments received) on the FDA's Draft Guidance<sup>63</sup> through the lens that the only available treatment for Celiac -- Gluten Free food -- must also be viewed as a human rights issue. See section herein – "The Only Available Treatment for Celiac Gluten Free Food Must Be Viewed as a Human Right."

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<sup>60</sup> Robert Califf, M.D., Commissioner of the FDA stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session, June 7, 2022.

<sup>61</sup> 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/>

<sup>62</sup> [https://www.law.cornell.edu/wex/don%27t\\_ask\\_don%27t\\_tell](https://www.law.cornell.edu/wex/don%27t_ask_don%27t_tell)

<sup>63</sup> <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=gluten>

According to the United Nations, “Human rights are rights inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status. Human rights include the right to life and liberty, freedom from slavery and torture, freedom of opinion and expression, the right to work and education, and many more. Everyone is entitled to these rights, without discrimination.”<sup>64</sup>

For a frame of reference, it is helpful to distinguish human rights from civil rights, even though there is overlap between the two types of rights. Human rights are existential, or in other words arise simply by the state of being a human being. Civil rights, on the other hand, are those rights that a person is entitled to by virtue of citizenship in a particular nation or state. For example, in the United States, Civil rights are enshrined for American citizens by the Constitution of the United States.

The Universal Declaration of Human Rights expressly and directly links “health and well-being” with adequate food.<sup>65</sup> According to the United Nations Office of the Commissioner for Human Rights (“UN Human Rights Commissioner”), “The right to [adequate] food is recognized in the 1948 Universal Declaration of Human Rights as part of the right to an adequate standard of living and is enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights.”<sup>66</sup> According to the UN Human Rights Commissioner, “Human rights are interdependent, indivisible and interrelated. This means that violating the right to [adequate] food may impair the enjoyment of other human rights, such as the right to health, education or life, and vice versa.”<sup>67</sup>

The United Nations Convention on the Rights of the Child expressly and directly links the importance of “combating [pediatric] disease and malnutrition, including within the framework of primary health care... through the provision of adequate nutritious foods.” The Convention on the Rights of the Child also addresses “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.”<sup>68</sup>

According to the United Nations Office of the Commissioner for Human Rights, the Right to Adequate Food means that “the food must satisfy dietary needs, taking into account the individual’s... health... Food should be safe for human consumption and free from adverse substances...”<sup>69</sup>

With respect to the FDA’s Draft Guidance and food labeling in the U.S., the Right to Adequate Food encompasses that the Celiac community has the right to adequate, complete and truthful information in terms of mandatory labeling of Gluten in the food and medicine that they consume.

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<sup>64</sup> “Human Rights.” United Nations. <https://www.un.org/en/global-issues/human-rights>

<sup>65</sup> Universal Declaration of Human Rights, Article 25, <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

<sup>66</sup> <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

<sup>67</sup> <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

<sup>68</sup> “Convention on the Rights of the Child.” United Nations. 20 November 1989.

<https://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf>

<sup>69</sup> <https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

## V. About the Commenters – What is Our Why?

**“For me, an area of moral clarity is: you’re in front of someone who’s suffering and you have the tools at your disposal to alleviate that suffering or even eradicate it, and you act.”**

-- Dr. Paul Farmer

**“Do not be daunted by the enormity of the world’s grief. Do justly, now. Love mercy, now. Walk humbly now. You are not obligated to complete the work, but neither are you free to abandon it.”**

-- The Talmud

My wife, Leslie, and I are the parents of two children, Lexi (age 17) and Jax (age 9), and we live in Philadelphia. Lexi is a rising senior in high school, and she helped research and edit these Comments.<sup>70</sup> <sup>71</sup> Jax is a rising 4<sup>th</sup> grader who has Celiac Disease.

In August 2018, Jax, at age 5, was diagnosed through serology tests and an endoscopy at Children’s Hospital of Philadelphia. Jax’s endoscopy revealed Marsh 3 level (significant) damage to his small intestine which caused anemia and inhibited him from absorbing proper nutrients for growth and development. Serology was initially conducted because of failure to thrive.

Jax is intelligent, compassionate, athletic and mature beyond his years (which often times happens to kids who have chronic diseases). In September 2018, Jax started Kindergarten, and as he learned to read, he started with fairy tales and food labels.

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. Now, as parents of a child with Celiac Disease, our family has embraced its new normal. We are working to foster greater understanding of, accommodation for, and inclusion of those who suffer from Celiac Disease in life’s daily activities that involve food. The required labeling of Gluten and referring to Gluten as a food allergen would be very helpful in terms of protecting Jax and 3 million Americans with Celiac.<sup>72</sup>

After a few months of transitioning Jax to a Gluten Free diet, my wife created an Instagram account (@glutenfreefinds\_pa) where she has been publishing content related to Jax trying to safely navigate a Gluten-filled world on a Gluten Free diet in life’s daily activities that involve food. After seeing so many of the unmet needs of the Celiac community and how we have been historically underserved by the Federal government, I started a patient advocacy platform, Celiac Journey (www.CeliacJourney.com), which conducts research and publishes articles pertaining to Celiac Disease and our two primary goals to (in no order of importance):

1. Increase Federal funding to find a cure and more treatment options, other than a strict Gluten Free diet for life (over the past decade, only about \$3 million has been annually appropriated

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<sup>70</sup> <https://www.bariconsulting.com/sites/bariconsulting.com/files/Bari%2C%20Jonathan%20-%20CV%2C%20Case%20Listings%20and%20Case%20Studies%20Taught%2C%2012-1-21.pdf>

<sup>71</sup> <https://www.linkedin.com/in/lbari/>

<sup>72</sup> <https://www.celiacjourney.com/about>

by the NIH to Celiac research -- only about \$1 per American, per year, with Celiac and that is not nearly enough)<sup>73</sup>; and

2. Designate Gluten as a top 10 Major Food Allergen and require that Gluten be labeled on all packaged foods in the U.S., just like it is 85+ countries worldwide including across Europe and in Canada.<sup>74</sup>

### **Eating Ethos**

Our patient advocacy goals are important to us because some day we want to be able to (in no order of importance):

- enjoy a worry-free meal with our family and eat without fear,
- have our family never have to worry about cross contact with Gluten, which is poison to our son's body,
- have our son not get violently ill if he gets Glutened (as has unfortunately happened on previous occasions),
- have our son enjoy the spontaneity of food in life's daily activities and special occasions that involve food,
- have our son always feel socially included at meal time with his friends and family by not having to eat special foods,
- have our son never experience food insecurity,
- have us be able to rely on packaged food labels which are required to inform us if Gluten is in a product.

We want to attain these goals so that our son can grow and develop fully, normally and in a healthy manner, physically and emotionally.

Without the mandatory labeling of Gluten legislation, our family (and 3 million Americans) continue to be at risk of unknowingly eating foods that contain Gluten. With the mandatory labeling of Gluten, it will help to ensure that food that our family purchases will be safe to eat for our son.

Until such time as other treatments and a cure are found, we hope others, including the FDA, will check their food privilege and understand that reasonable, common sense and low impact accommodations foster a sense of diversity and inclusion to help those with allergic reactions to Gluten, especially children, safely and successfully navigate a Gluten filled world.

When Jax was diagnosed with Celiac, we were informed that the only available treatment was a strict Gluten Free diet for life, and that if he ate Gluten, he would get sick and continue to damage his small intestine. We intuitively thought of it in the context of a food allergy as most consumers and lay people do. As the Boston Globe reported about Dr. Alessio Fasano in 2015, "Fasano now gives his celiac patients *permission* to use the word allergy to describe their disease, since that will probably be taken more seriously."<sup>75</sup> I loved that, but fast forward 7 years, and I think that we need much more than permission. In terms of consumer protection, the Celiac community would benefit greatly if the FDA and scientists would consistently refer to Celiac as a food allergy and Gluten as a food allergen. See section herein, "What's In A Name? Celiac is a Food Allergy!"

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<sup>73</sup> [www.celiacjourney.com/briefing](http://www.celiacjourney.com/briefing)

<sup>74</sup> [www.celiacjourney.com/labels](http://www.celiacjourney.com/labels)

<sup>75</sup> <https://www.bostonglobe.com/magazine/2015/10/14/why-food-allergy-fakers-need-stop/PB6uN8NF3eLWFjXnKF5A9K/story.html>



When someone is buying food for Jax, preparing food for Jax, and/or serving food to Jax, we need to be able to clearly communicate to that person that Jax must avoid eating Gluten, since if he does eat Gluten, he will likely have an adverse health reaction. The simplest and most effective way to communicate this in Plain English is to say that Jax has a Food Allergy. This is the way that people organically talk about food when it can cause an adverse immunological reaction.

Unfortunately, in spite of our many precautions, Jax has been “glutened” at times through accidental ingestion of Gluten and that has resulted in him experiencing severe GI adverse reactions commensurate with foodborne illness (food poisoning),<sup>76</sup> and in addition, potential long-term complications including damage to his small intestine. Last Summer, Jax got violently ill when the chef at a restaurant thought a packaged food product was Gluten Free since it did not have Wheat labeled on it, but the food product did have unlabeled Gluten in it.<sup>77 78</sup> That’s one real world example of getting Glutened and why we need Gluten to be labeled on packaged foods!

Anecdotally, we can attest to the treatment burden of chronic disease, including the constant anxiety over cross contamination and inclusion of our son in life’s numerous daily activities that involve food at home, at school and away from home (i.e., soccer practice, camp, celebrations, special events, vacation). We worry about every bite, every day! Period. Full stop.

It took over 24 months of Jax being on a strict Gluten Free diet for his serology tests to normalize including his Tissue Transglutaminase IgA (TTG-IgA). That said, on February 2, 2022, after having been on a strict Gluten Free diet for more than 3 years, Jax still needed to receive an iron infusion because he was still iron deficient anemic, and after doing multiple diagnostic and serologic tests, including hematology consults, the only reason that his team of physicians could provide was that this was as a result of his Celiac Disease and malabsorption issues.

I have written extensively on Celiac Disease including:

- “The Only Available Treatment for Celiac – Gluten Free Food – Must Be Viewed as a Human Rights Issue”, December 19, 2019.<sup>79</sup>

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<sup>76</sup> <https://www.cdc.gov/foodsafety/symptoms.html>

<sup>77</sup> See “Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers”, Question 26, “What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic? FALCPA only applies to packaged FDA-regulated foods. However, FDA advises consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumer’s home.” <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#>

<sup>78</sup> The CDC has estimated that fewer than half of the members of the restaurant staffs surveyed in 278 restaurants had received training on food allergies. Source: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm> Taking that into account, it is suggested that even less understand about Celiac as a food allergy and Gluten as a food allergen, in part since Celiac often gets conflated with a voluntary Gluten Free diet.

<sup>79</sup> [www.celiacjourney.com/humanrights](http://www.celiacjourney.com/humanrights)

- “Gluten Should Be Labeled as a Top Food Allergen in the U.S., Just Like In Canada & Across Europe”, July 7, 2021.<sup>80</sup>
- “Food Insecurity in the Context of Celiac Disease”, October 2, 2019.<sup>81</sup>
- “Celebrating the 30th Anniversary of the Americans with Disabilities Act”, July 30, 2020.<sup>82</sup>

I encourage FDA staff to review these articles, especially in also evaluating the context of these Comments on the FDA’s Draft Guidance through the lens of a human rights issue – the Human Right to Adequate Food.

Leslie, Jax, Lexi and I have engaged in patient advocacy on behalf of our family and others; created community with fellow Celiacs, parents and caretakers; spoken at various events and conferences; submitted testimony to Congress; held a bi-partisan Congressional Briefing on Capitol Hill; met with Members of Congress; recruited 9 Members of Congress to the bipartisan Congressional Celiac Disease Caucus that stands at 27 Members now; participated in the listening session for the White House Conference on Hunger, Nutrition, and Health and submitted written comments (our comments including in this document fit squarely into Conference “Pillar #2, 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”<sup>83</sup>); interfaced with NIH staff including from NIAID’s Autoimmune Disease Coordinating Committee; communicated and met with senior members of the Executive Branch of the Trump and Biden Administrations; participated in industry and advocacy events; met with many leading scientists, physicians and advocates; and met many wonderful involuntary members of our Celiac community with whom we have fellowship as we strive to improve the quality of life of Celiacs.

The lived experience of those with Celiac who must avoid Gluten in their diet is the same as those who must avoid the top 9 major allergens, but for the fact that there is no comparable rescue medicine treatment available (i.e., antihistamine or adrenaline) to reverse the effects in the event of the ingestion of Gluten and the beginning of the autoimmune cascade that can cause a myriad of life-threatening conditions (cancer) as well as GI symptoms (similar to typical food allergies) and damage to the small intestine.

We stand for Jax, and as his voice, we demand action. We demand change. We seek progress. We seek more agency. We seek the labeling of Gluten on all packaged foods in the U.S., just like it is done in 85 countries around the world.

## **VI. Eating Without Fear – Jax’s Story**

**“I admire your courage and the incredible work you’ve done to help the millions of Americans like you who live with Celiac disease. The story about you on the news was terrific, and I am so impressed that you met with Members of the United States Congress to talk about ways to further improve the lives of people with Celiac**

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<sup>80</sup> [www.celiacjourney.com/falcpa](http://www.celiacjourney.com/falcpa)

<sup>81</sup> [www.celiacjourney.com/foodinsecurity](http://www.celiacjourney.com/foodinsecurity)

<sup>82</sup> <https://www.celiacjourney.com/ada>

<sup>83</sup> <https://health.gov/our-work/nutrition-physical-activity/white-house-conference-hunger-nutrition-and-health/conference-details>

**disease... Young Americans like you are the future of our Nation. When you make your voice heard, adults listen. I look forward to seeing where your future takes you and the positive changes you inspire for people with Celiac disease.”<sup>84</sup>**

-- Letter from President Joe Biden to Jax Bari, August 17, 2021

On May 19, 2021, Jax’s Celiac journey was featured on ABC News’ World News Tonight with David Muir. As Jax told Mr. Muir, **“Eating without fear is our hope. Food insecurity for Celiacs happens every day”** because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the limited availability of Gluten Free food (especially eating out of home), and Gluten is not required to be labeled on packaged foods in the US, like it is in 85 countries around the world including in Canada and across Europe.<sup>85</sup> Out of the mouths of babes.



Jax Bari from Philadelphia, Pennsylvania (source: World News Tonight)

Please watch this amazing story featuring some of Jax’s friends from around the country who also have Celiac and bravely shared their pediatric perspectives.<sup>86</sup> See [www.CeliacJourney.com/abcnews](http://www.CeliacJourney.com/abcnews) .

Our family’s story represents just one story from the millions of Americans who live with and/or care for someone with Celiac Disease who requires a strict Gluten Free diet with every bite, every day.

Jax is one of the many faces of Celiac Disease who can speak to the public health importance of food allergens other than the Major Food Allergens, and to that end, why we need Gluten to be named a Major Food Allergen and labeled on all packaged foods in the US in order to adequately protect him and millions of others similarly situated.

As Mr. Muir reported in 2021, “Matthias Brockington, [a then] 10<sup>th</sup> grader from Norristown, Pennsylvania, and Ava, [a then] 6<sup>th</sup> grader from Maryland, said that the Gluten Free diet can be

<sup>84</sup> [www.celiacjourney.com/biden](http://www.celiacjourney.com/biden)

<sup>85</sup> [www.celiacjourney.com/abcnews](http://www.celiacjourney.com/abcnews)

<sup>86</sup> [www.celiacjourney.com/abcnews](http://www.celiacjourney.com/abcnews)

hard to follow -- especially with limited gluten-free options. ‘The only treatment for Celiac is a strict gluten-free diet which is pretty tough,’ said Brockington.”<sup>87</sup>



Matthias Brockington from Norristown, Pennsylvania (source: World News Tonight)

“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.<sup>88</sup>



Ava, Maryland (source: World News Tonight)

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<sup>87</sup> <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

<sup>88</sup> <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

“Maggy Beck, a third grader [in 2021] in Richmond, Virginia, said she struggles with being cautious around food. ‘I wish when I went to parties, I didn’t have to bring my own food and I didn’t have to worry about cross-contamination,’ said Maggy.”<sup>89</sup>



Maggy Beck, Richmond, Virginia (source: World News Tonight)

Gianna Carlino commented on food labeling, “Hey David, I’m Gianna Carlino, I’m in seventh [in 2021], and I live in Wyomissing Pennsylvania. My mom and I both have Celiac Disease and just staying on a gluten-free diet is not enough we need to have gluten labeled as an allergen on processed foods in the United States just like it is in Europe and Canada.”<sup>90</sup>

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<sup>89</sup> <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

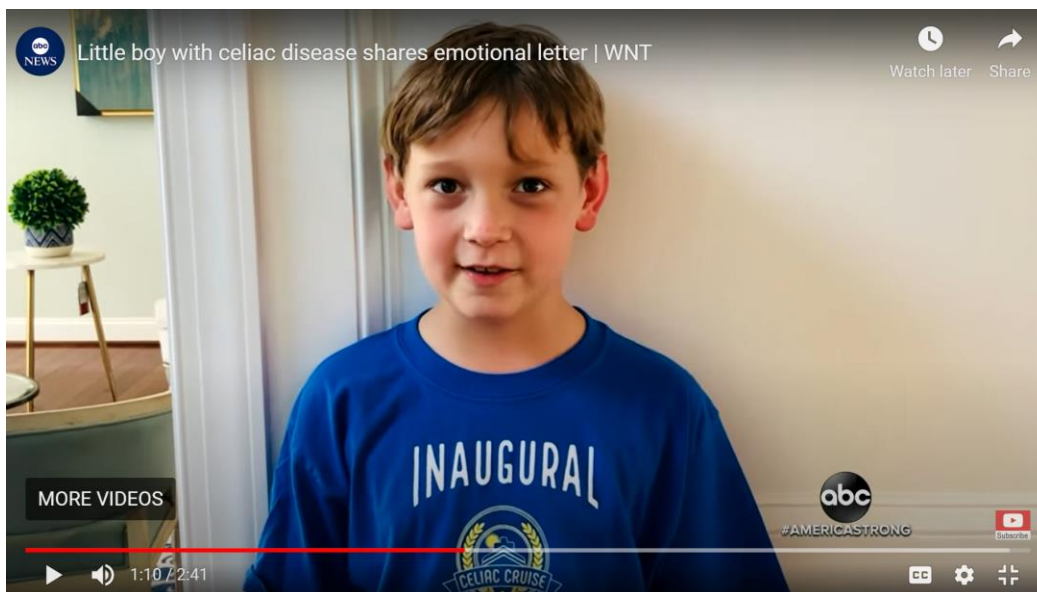
<sup>90</sup> <https://www.dropbox.com/s/jrmq4p14rhj4pmf/kitchen%20%281%29.MOV?dl=0> ; and <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>





Gianna Carlino from Wyomissing, Pennsylvania (source: World News Tonight)

Peter B. from Herndon, Virginia commented, “My dad and I both have Celiac Disease. Just staying on a Gluten Free diet is not enough.”<sup>91</sup>



Peter B. from Herndon, Virginia (source: World News Tonight)

“Solving Celiac could be the gateway to understanding so many other diseases. But we need a treatment that’s better than the gluten free diet,” said Vanessa Weisbrod,<sup>92</sup> Director of the Celiac Disease Program at Boston Children’s Hospital.<sup>93</sup>

<sup>91</sup> <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

<sup>92</sup> <https://abcnews.go.com/US/children-country-share-experiences-celiac-disease/story?id=77791565>

<sup>93</sup> <https://www.childrenshospital.org/directory/vanessa-weisbrod>



Brandon and Vanessa Weisbrod from Massachusetts (source: World News Tonight)

Everyone's experience is unique. 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.

## VII. 2021 FAO/WHO Expert Consultation – The Scientists Have Spoken

**“The idea that you can get up here and talk about what you know – what the evidence, what the science is -- and know that's it, let the science speak.”<sup>94</sup>**

-- Dr. Anthony Fauci

According to the FDA's Dr. Mayne, “This draft guidance is part of the FDA's efforts to evaluate emerging evidence about other non-listed food allergens that can cause serious reactions in a consistent and transparent manner, which can inform potential future actions to better help protect the health of consumers.”<sup>95</sup>

We appreciate the spirit of the FDA's Draft Guidance to evaluate the public health importance of food allergens other than the Major Food Allergens. However, the fact is that this work has already been completed, including from senior FDA and USDA public servants, whereby evidence and conclusions on the Big 8 food allergens in Codex from 1999, including Gluten, was just re-evaluated and reaffirmed by the 2021 FAO/WHO Expert Consultation.

On October 5, 2021, the Food and Agriculture Organization (“FAO”) of the United Nations published the article entitled, “Experts convene to re-evaluate ‘The big 8’ food allergens in Codex” which stated,

<sup>94</sup> <https://www.nytimes.com/2021/01/21/us/politics/fauci-trump-biden-coronavirus.html>

<sup>95</sup> <https://www.fda.gov/media/157637/download>

**“Food allergies are a significant public health concern. With no cure, consumers must avoid the foods to which they are allergic by making informed food choices that include diligently reading food packaging labels and asking questions when making menu selections.**

**The list of 8 major foods and ingredients (cereals containing gluten, crustacea, egg, fish, peanut and soybeans, milk, tree nuts)** known to cause hypersensitivity was included into the Codex General Standard for the Labelling of Packaged Foods (GSLPF)<sup>96</sup> in 1999.

Since then, there have been many scientific developments in the understanding of food allergens and their management. As such, the Codex Alimentarius Commission endorsed new work aimed at providing food business operators and competent authorities with updated guidance on the managing food allergens in food production and labelling.

#### **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**



To support this work, the Joint FAO-WHO Scientific Advice Programme, which is carried out to support the development of Codex international food standards through the provision of scientific advice related to food safety and nutrition, was tasked with validating and updating ‘The big 8’ list of food allergens based on risk assessment. In December 2020 with the first in a series of meetings of the ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens evaluated ‘The big 8’ and other food allergens based on **prevalence, severity of reaction and potency.**

More details on key discussions and outcomes of the expert meeting, **chaired by Dr Lauren Jackson [Chief, Process Engineering Branch, Food and Drug Administration, Division of Processing Science & Technology, Institute for Food Safety & Health]**, have been captured in this summary report.

<sup>96</sup> [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS\\_001e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS_001e.pdf)



Another two parts of this meeting are foreseen. This meeting, Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens Part 1, focused on the review and validation of Codex priority allergen list through risk assessment.”<sup>97</sup>

The joint 2021 FAO/WHO’s Expert Consultation included a committee comprised of “scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry,” and they reviewed a list of allergens in existence since 1999 and “determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac<sup>98</sup> [Celiac] disease should be included on the list of foods and ingredients...” The Expert Committee then retained “cereals containing Gluten” on the 1999 list of food allergens whose presence should always be declared in the list of ingredients on a food label.

The 2021 FAO/WHO Expert Consultation (FDA Ref. 45, Annex 1) was comprised of 20 (twenty) “experts” from around the world including four experts from the United States, two of whom work for the FDA:

- **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;<sup>99</sup> (Pictured in top row of photograph, 3<sup>rd</sup> from left)
- **Dr. Lauren Jackson**, Chief, Process Engineering Branch, Food and Drug Administration. 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);<sup>100</sup> (Pictured in top row of photograph, 1<sup>st</sup> person on left)
- **Dr. Stefano Luccioli**, Medical Officer and Allergy Specialist at the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, and Board-certified doctor in allergy/immunology -- sees patients at the General Internal Medicine clinic at MedStar Georgetown University Hospital in Washington, D.C.;<sup>101</sup> and Chairperson of Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens Part 3: Review and establish precautionary labelling in foods of the priority allergens<sup>102</sup> (Pictured 2<sup>nd</sup> row of photograph, 4<sup>th</sup> 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.<sup>103</sup> Dr. Taylor was also one of six scientists who served on the Ad Hoc Panel on Food Allergens met in Geneva, Switzerland in February 1999 to provide advice to the Joint FAO/WHO Expert Committee on Food Additives about criteria for labelling food allergens. Their treatise was memorialized in the 1999 FAO/WHO Expert Consultation; also referred to as the “1999 Codex criteria” as detailed in the FDA’s Draft

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<sup>97</sup> <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/>

<sup>98</sup> “Coeliac” is the Greek spelling of Celiac which is used in some parts of the world.

<sup>99</sup> <https://farrp.unl.edu/fss/joe-baumert>

<sup>100</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>101</sup> <https://www.medstarhealth.org/doctors/stefano-luccioli-md>

<sup>102</sup> <https://cdn.who.int/media/docs/default-source/food-safety/jemra/3rd-allergen-summary-report-13dec2021.pdf>

<sup>103</sup> <https://farrp.unl.edu/fss/staylor>

Guidance and cited as “FDA Ref. 25”.<sup>104</sup> (Pictured in bottom row of photograph, 2<sup>nd</sup> person from left).

In addition to these experts, the 2021 FAO/WHO Expert Consultation was comprised of 10 (ten) “resource persons” including two from the United States who work for the USDA and FDA:

- **Dr. J. Emilio Esteban**, Chief Scientist of the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), who serves as the Codex Committee Chairperson from the United States;<sup>105</sup> and
- **Dr. Douglas Balentine**, Senior Science Advisor, Global Nutrition Policy Center for Food Safety and Applied Nutrition, FDA, who serves as the U.S. Delegate on Food Labeling on the Codex Committee.<sup>106</sup>

### **The Scientists Have Spoken**

The Conclusions of the Expert Committee, which was chaired by Dr. Jackson of the FDA, should be adopted by the FDA pertaining to the mandatory labeling of Gluten.

**“The Expert Committee determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF.”**<sup>107</sup> Thus, it was recommended that foods or ingredients such as lactose, sulphite, and food additives which cause food intolerances rather than immune-mediated responses, should be excluded from this list.

**The Committee identified prevalence of the immune-mediated hypersensitivity to a specific food, severity (i.e. proportion of severe objective reactions to a food/ingredient such as anaphylaxis), and the potency of food/ingredient (i.e. the amount of the food/ingredient required to cause objective symptoms) as the three key criteria that should be used to establish the priority allergen list. Subgroups of the Expert Committee were established to review the literature on the prevalence, severity and potency of immune-mediated hypersensitivity of each food currently on the GSLPF list (cereals containing gluten and products of these; crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products; tree nuts and nut products;), as well as other foods found on priority allergen lists established in individual countries or regions (e.g. mollusks, mustard, celery, sesame, buckwheat, lupin, and others).**

**Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame,**

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<sup>104</sup> <https://apps.who.int/iris/handle/10665/42378>

<sup>105</sup> <https://www.fsis.usda.gov/contactus/j-emilio-esteban>

<sup>106</sup> <https://www.usda.gov/sites/default/files/documents/us-codex-program-officials.pdf> ; and <https://www.fsis.usda.gov/contactus/j-emilio-esteban>

<sup>107</sup> [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS\\_001e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS_001e.pdf)

specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut). 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, such as buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts), should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries. Since current dietary trends include an increased consumption of plant-based foods and diets consisting of alternative protein sources, it was recommended that pulses, insects and other foods such as kiwi fruits be included in a watch list and evaluated for the priority allergen list when data on prevalence, severity and potency become available. Finally, the Expert Committee recommended that foods and ingredients derived from the list of foods known to cause immune-mediated hypersensitivities should be evaluated on a case-by-case basis for exclusion from declaration on ingredient lists and/or on food packaging.”<sup>108</sup>

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<sup>108</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

**Figure 4 - Summary of the “Big 8” Food Allergens from the 1999 Codex Criteria, FALCPA and the 2021 Ad Hoc Joint FAO/WHO Expert Consultation**

	<b>Food Allergen</b>	<b>Prevalence of Food Allergy<sup>109</sup></b>	<b>“The Big 8” - 1999 Codex Criteria<sup>110</sup></b>	<b>Top 8 Major Food Allergens - FALCPA 2004<sup>111</sup></b>	<b>2021 FAO/WHO Expert Consultation, May 2021<sup>112</sup></b>
1	<b>Gluten Containing Grains</b>	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	<b>Crustacea (Shellfish)</b>	8.2 million	X	X	X
3	<b>Egg</b>	2.6 million	X	X	X
4	<b>Fish (fin)</b>	2.6 million	X	X	X
5	<b>Milk</b>	6.1 million	X	X	X
6	<b>Peanuts</b>	6.1 million	X	X	X
7	<b>Sesame</b>	0.7 million		X (as of 1/1/23)	X
8	<b>Soybeans</b>	1.9 million	X	X	
9	<b>Tree Nuts</b>	3.9 million	X	X	X (Almond, Cashew, Hazelnut, Pecan, Pistachio and Walnut)
10	<b>Wheat</b>	2.4 million		X	

<sup>109</sup> Gluten containing grains: <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> (see: 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.

<sup>110</sup> <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/> , and [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS\\_001e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS_001e.pdf)

<sup>111</sup> <https://www.fda.gov/media/77570/download>

<sup>112</sup> <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/> and <http://www.fao.org/3/cb4653en/cb4653en.pdf>

The FALCPA does not preclude the FDA from expanding via regulation the list of major allergens to include Gluten containing grains requiring identification under the FALCPA’s labeling scheme.<sup>113</sup> 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.”<sup>114</sup> In other words, the voluntary labeling of Gluten is not so sacrosanct that it cannot be changed to mandatory, and FALCPA enables the FDA to do so now.

It is instructive to understand to note the following on Oats and Soybeans from the 2021 Ad hoc Joint FAO/WHO Expert Consultation. “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, such as **buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts)**, should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.”<sup>115</sup> (emphasis added)

According to the FDA’s Draft Guidance, the “estimated prevalence of IgE-mediated food allergy in the U.S. population for the already identified major food allergens based on probable food allergy rates” appear in Table 3 (page 24) as reproduced below and with Gluten added in:

Population	Milk	Soy	Peanut	Tree Nuts	Fish	Shellfish	Egg	Wheat	Sesame	Gluten
“All ages, self-reported symptoms *% total) (Ref. 1)” <sup>116</sup>	3.0	0-0.6	0.6	0-4.1	0.6	1.2	1.0	0.2-1.3	N/A	>1.0 <sup>117</sup>

The bottom line is that according to the FDA, “There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten. Without a standardized definition of ‘gluten-

<sup>113</sup> “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>

<sup>114</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

<sup>115</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>116</sup> <https://www.fda.gov/media/157637/download>

<sup>117</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

free,’ these consumers could never really be sure if their body would tolerate a food with that label.”<sup>118</sup>

By limiting the above statement to just a standardized definition of Gluten Free, the FDA’s flawed logic marginalizes the needs of the Celiac community of having a right to know when Gluten is in all packaged foods. In the spirit of equity, the FDA must change its labeling scheme with FALCPA to require that Gluten be labeled on all packaged foods in the US, in accordance with the findings of the authoritative bodies of the 1999 FAO/WHO Expert Consultation with the 1999 Codex Criteria as well as the 2021 FAO/WHO Expert Consultation.

By requiring the labeling of Gluten, this will enable 3 million Americans with Celiac to have a more equitable quality of life similar to those who suffer from any of the 8 Major Food Allergens (9 as of 1/1/23 with Sesame) whereby they know that if Gluten is not on the label, they can be sure “for the most part” that Gluten is not in the food product. This Q&A with Dr. Luccioli informs that position,

**“Q: But when it comes to the eight major food allergens, can you be sure that it’s not in the food if it’s not on the label?”**

**For the most part, yes,** but there are instances when there may be inadvertent introduction of a major food allergen into a food product not intended to contain it. This is known as allergen cross-contact. Allergen cross-contact can happen in cases when there is shared food-processing equipment that may transfer an allergen to a product that shouldn’t contain it. For example, a manufacturer may use the same equipment to make both milk chocolate and dark chocolate, and the facility’s cleaning practices may not be adequate to remove all the milk protein on their equipment between the different batches.

There may also be instances of labeling or manufacturing errors that result in the presence of an allergen in product that is not properly labeled. Recalls due to undeclared food allergens are a leading cause of all food product recalls.

To address allergen cross-contact and other potential labeling or manufacturing errors leading to undeclared allergen hazards, FDA enforces laws and regulations applicable to food allergens. For example, under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule, food manufacturers are required to implement controls to ensure accurate labeling of finished foods with respect to the major food allergens and controls to significantly minimize or prevent allergen cross-contact.”<sup>119</sup> (emphasis added)

The research is done, the world is watching, and moreover our kids are watching. The United States is not in a leadership position when it comes to consumer protection for the Celiac community. Instead, the United States is in a laggard position among our peer countries, many of which are our peer high income countries. History is calling, and it is time for the FDA to take action on the unfinished business of FALCPA to correct the historical inequities associated with the voluntary labeling of Gluten Free foods. It is time for common sense consumer protection with the mandatory labeling of Gluten on all packaged foods.

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<sup>118</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

<sup>119</sup> <https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape>

## VIII. About Celiac Disease and the Gluten Free Diet

**“What is food for one is poison for another.”**

Senator Royal S. Copeland, MD (D, NY, who served from 1923-1938)

Since it was first theorized in 1887 that treating Celiac Disease patients “must be by means of diet”<sup>120</sup> (1887 was ironically the same year that the NIH was founded), and it was discovered in 1952 that Gluten was the trigger of Celiac Disease, the one and only treatment is still the same. For all intents and purposes, the status quo from 1952 remains — strict adherence to a Gluten Free diet has been the only available treatment!<sup>121</sup> For an historical point of reference, in 1952, Harry S. Truman was President of the United States, the Korean War was being fought, and Dr. Jonas Salk was poised to develop and test a Polio vaccine (1953-1954) which led to the Polio vaccine being licensed in 1955.<sup>122</sup>

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

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

Clinical manifestations are multifaceted and include gastrointestinal (ranging from **severe malabsorption to subclinical damage of the gastrointestinal tract**) as well as extraintestinal (e.g., skin) expressions of disease. Additional manifestations may vary from subclinical damage of the gastrointestinal tract to refractory celiac disease that is non-responsive to a gluten-free diet. Although rare, celiac disease is associated with increased risk of gastrointestinal tract **cancers and lymphomas.**”<sup>123</sup> (emphasis added)

According to the FDA, people with Celiac Disease “**face potentially life-threatening illnesses if they eat gluten,** typically found in breads, cakes, cereals, pastas, and many other foods... **There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.**”<sup>124</sup> (emphasis added)

In 2019, Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago Celiac Disease Center provided testimony to the U.S. Senate Appropriations Committee,

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<sup>120</sup> <https://pubmed.ncbi.nlm.nih.gov/30860740/#>

<sup>121</sup> <https://www.celiacjourney.com/post/national-celiac-disease-awareness-day-presents-a-call-to-action>

<sup>122</sup> <https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year>

<sup>123</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

<sup>124</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

“Celiac disease is a serious autoimmune disease that is not being taken seriously enough by our government... In Celiac disease patients, gluten, a protein found in wheat, barley and rye, triggers an immune response leading the body to attack the small intestine. This intestinal damage causes more than 200 debilitating symptoms. Moreover, gluten ingestion for people with celiac disease causes permanent immunological scarring, doubles the risk of heart disease, and acts as a carcinogen, quadrupling the risk of small intestinal cancers.

Strict adherence to a gluten-free diet is the *only* available treatment. But, as our celiac disease researchers agree, **‘There is no such thing as a truly gluten-FREE diet’ because of the constant risk of cross-contact with gluten, and gluten is in 80% of our foodstuffs.**

**It is imperative that celiac disease be recognized as an important threat to the health of our citizens by the US government, including and especially by the NIH, the FDA, the CDC, and CMS.** Celiac disease research receives virtually no investment from the private sector, and little to no resources from NIH, especially when compared to diseases with similar impact.

Celiac disease is very serious:

- **“The lifetime 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.**
- Our diagnosed **patients report that they miss, on average, 23 days of work and school annually,** resulting in excess utilization of our healthcare resources.”<sup>125</sup> (emphasis added)

It is instructive for the FDA to meaningfully appreciate quantitative and qualitative research such as this that focuses on experiences that we simply cannot just count. It is underpinned by an understanding that the experience of Celiac, a food allergy, auto-immune disease and a digestive disease, is much more than just biomedical findings. Qualitative research aims to help us to understand what it is like to stand in someone else’s shoes and can allow the FDA to sit alongside patients and caretakers, without necessarily finding other treatment options or a cure. In this manner, qualitative research can contribute to a collaborative patient–clinician-regulator partnership with regard to why the labeling of Gluten on all packaged foods is necessary, equitable and long-overdue especially as long as a strict lifetime Gluten Free remains the only available treatment.

Eating Gluten Free is not a choice for Celiacs. There is no medicine or surgery available to treat Celiac Disease. To date, Celiac Disease research has produced only a single approved treatment -

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<sup>125</sup> <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. Dig Dis Sci 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>



- strict adherence to a lifelong Gluten Free diet with no exceptions! There is no break from Celiac, and there is no cheating on the strict Gluten Free diet for life. Celiac is a constant, and food insecurity happens every day with every bite. Diabetes, hypertension and congestive heart failure patients ranked their overall treatment burden below that of patients with Celiac Disease.<sup>126</sup>

According to 2019 U.S. Senate Appropriations Committee testimony from Children's Hospital of Philadelphia's David Piccoli, MD, Chief, Division of Gastroenterology, Arunjot Singh, MD, MPH, Co-Director, CHOP Celiac Center and Lisa Fahey, MD, Director, CHOP Celiac Center,

“Currently, there are no pharmacotherapy options available for celiac disease and the only therapy remains a strict gluten elimination diet. Dietary changes may seem simple, but the need for 100% elimination of gluten from the diet is challenging and isolating. There is a real risk of cross-contamination from packaged foods, restaurants and school cafeterias that families struggle [with] daily. Even eating a few crumbs of gluten can cause intestinal damage and setback disease healing. Hence, families and children avoid eating out and feel an increased anxiety about food that can impact a child's normal development. Nearly half of children with celiac disease exhibit anxiety and physical symptoms from a heightened fear of gluten. Even when they attempt strict adherence to a gluten-free diet, 70% of children continue to be accidentally exposed to gluten, putting their long-term health at risk.”<sup>127</sup>

In U.S. Senate testimony provided by Howard and Gail Morris of Naples, Florida,<sup>128</sup>

“For all intents and purposes, Gluten is poison to our grandson's body, and it is analogous to the serious danger that peanuts pose to those who are afflicted with nut allergies. Eating Gluten does not initiate an anaphylactic cascade reaction in Celiac Disease patients. However, the ingestion of Gluten, even accidental ingestion of a trace amount of Gluten, can sicken and endanger (set back) the healing of a patient's small intestine enabled through his/her strict adherence to a Gluten Free diet, and/or trigger new damage to the small intestine that could take additional years to heal. There is no medicine available (i.e., epinephrine pen for nut allergies) to take to treat any accidental ingestion of Gluten... Until our grandson was diagnosed, we had no clue or awareness of the condition and its effects.”<sup>129</sup>

According to Dr. Benjamin Lebwohl, the Director of Clinical Research, Celiac Disease Center at Columbia University, November 11, 2021,

“The NIH is really the Gold Standard and major funder of the top medical, biomedical research, in the United States! Getting NIH funding is notoriously difficult. The competition is very fierce, and **Celiac Disease has historically been underrepresented in the diseases that the NIH funds. It's particularly underrepresented given how**

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<sup>126</sup> Shah, S.; Akbari, M.; Vanga, R.; Kelly, C.P.; Hansen, J.; Theethira, T.; Tariq, S.; Dennis, M.; Leffler, D.A. Patient perception of treatment burden is high in celiac disease compared to other common conditions. *Am. J. Gastroenterol.* 2014, 109, 1304–1311.

<sup>127</sup> <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=74>

<sup>128</sup> Jax Bari's grandparents

<sup>129</sup> <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=74>

**common Celiac Disease is, and this is for a number of reasons, including the notion, misguided, that Celiac Disease is a solved problem, that the Gluten Free diet is all we need for Celiac Disease.**<sup>130</sup> (emphasis added)

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.<sup>131</sup>

According to the National Academy of Sciences' report, Enhancing NIH Research on Autoimmune Disease (2022) ("Enhancing NIH Research on Autoimmune Disease"):

- **"The gluten-free diet is very restrictive and not all 'gluten-free' labels are accurate. Inadvertent gluten ingestion can cause severe symptoms."**<sup>132</sup>
- "Another major research gap is that there is currently no treatment for the gastrointestinal symptoms of a person with celiac disease who has inadvertently ingested gluten."<sup>133</sup>

According to Beyond Celiac,

- "1 in 5 children with celiac disease isn't healing on the gluten-free diet
- 44% who follow a strict gluten-free diet still get glutened once a month
- Many with celiac disease pay over 40% more [than the average American] in annual healthcare costs"<sup>134</sup>

"It can be tough to completely cut out gluten post-diagnosis, but to be clear, someone with celiac disease can not 'safely cheat' on the gluten-free diet. For those of us with CD, gluten is dangerous. You wouldn't encourage someone with a peanut allergy to have a peanut butter sandwich "just this one time," right?

Myth: It's okay to have cheat days and eat gluten every now and again, like on holidays.

Fact: A crumb is enough to set off your immune system and cause damage to the small intestine, whether or not you experience symptoms."<sup>135</sup>

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<sup>130</sup> <https://vimeo.com/653234173#t=382s>

<sup>131</sup> "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](mailto:cbaker@beyondceliac.org)."

<sup>132</sup> National Academies of Sciences, Engineering, and Medicine 2022. "Enhancing NIH Research on Autoimmune Disease." Washington, DC: The National Academies Press. <https://doi.org/10.17226/26554>.

<sup>133</sup> National Academies of Sciences, Engineering, and Medicine 2022. "Enhancing NIH Research on Autoimmune Disease." Washington, DC: The National Academies Press. <https://doi.org/10.17226/26554>.

<sup>134</sup> <https://www.beyondceliac.org/> and <https://twitter.com/abast/status/1551780196243603457>

<sup>135</sup> <https://www.facebook.com/photo?fbid=425540332936139&set=a.359755692847937>

According to Drs. Jocelyn Silvester (Faculty of Health Sciences, College of Medicine, University of Manitoba, Winnipeg and Celiac Research Program, Harvard Medical School), Dayna Weiten (Nutrition Services, Grace General Hospital, Winnipeg, Manitoba), Lesley Graff (Faculty of Health Sciences, College of Medicine, University of Manitoba, Winnipeg, MB, and Department of Clinical Health Psychology, University of Manitoba), John R Walker (Faculty of Health Sciences, College of Medicine, University of Manitoba, Winnipeg, MB, and Department of Clinical Health Psychology, University of Manitoba), and Donald Duerksen (Faculty of Health Sciences, College of Medicine, University of Manitoba, Winnipeg, MB and Department of Internal Medicine, University of Manitoba),

“Gluten ingestion due to lack of awareness of the gluten content of foods may be a significant issue for many individuals, but has the potential to be modified. Determining whether a food contains gluten is challenging. Gluten is a component of many ingredients, thus it is often not explicitly listed on product labels. Within specific food categories (e.g., potato chips), certain brands may be gluten-free while others may contain trace amounts of gluten and thus should be avoided.<sup>136</sup> Even within a brand, some flavors may contain gluten while others are gluten-free. The products available and the composition of particular products also changes. For example, some companies have adjusted the recipe for popular breakfast cereals to offer gluten-free versions.<sup>137</sup> For these reasons, following a gluten-free diet is a dynamic process that requires continuous review and reassessment.”<sup>138</sup>

According to Dr. Peter H.R. Green, Director of the Celiac Disease Center at Columbia University and Rory Jones, Adjunct Professor of Narrative Medicine at Barnard College,

“‘We bake our own pastry, gluten is now Satan’ reads a knowing sign in San Francisco. The gluten-free diet has now surpassed all others searched for on Google in the United States, beating the South Beach, Atkins and Paleolithic diets along with veganism, low-carb, low-calorie and organic food in terms of Internet interest. Best-selling books tout gluten as the main source of health problems affecting everything from the brain to the belly. It’s the topic of cartoons in the New Yorker and fodder for late-night comedy shows. Movie stars, television personalities and major sports figures all sing the praises of a gluten-free diet. They say it makes them feel healthier, stronger and even happier.

And yet, there is little scientific evidence to support these claims. **People seem to be drawing wild conclusions from the fact that those who suffer from celiac disease must cut every trace of gluten out of their diet, deciding illogically that if cereal grains such as wheat, rye and barley are harmful to a small slice of the population,**

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<sup>136</sup> Case, S. Gluten-Free Diet: a comprehensive resource guide. 8. Regina, SK: Case Nutrition Consulting Inc; 2008.

<sup>137</sup> General Mills. General Mills 2015 Annual Report: Making food people love. Minneapolis, MN: 2015, [https://s22.q4cdn.com/584207745/files/doc\\_financials/2015/annual/Gen-Mills-AR-2015a-FINAL.pdf](https://s22.q4cdn.com/584207745/files/doc_financials/2015/annual/Gen-Mills-AR-2015a-FINAL.pdf)

<sup>138</sup> Silvester, J. A., Weiten, D., Graff, L. A., Walker, J. R., & Duerksen, D. R. (2016). Is it gluten-free? Relationship between self-reported gluten-free diet adherence and knowledge of gluten content of foods. *Nutrition*, 32(7-8), 777783. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457910/pdf/nihms860117.pdf>

**then they must be harmful to everyone. The association with celiac disease seems to give the gluten-free diet more medical legitimacy than other diets.**<sup>139</sup> (emphasis added)

On the one hand, our research suggests that the medical requirement for a strict Gluten Free diet coupled with the voluntary labeling of Gluten under FALCPA have converged to provide “medical legitimacy” to those who choose to eat Gluten Free. On the other hand, the voluntary labeling of Gluten coupled with authorities including the Federal government not referring to a Celiac as a food allergy, has led to undermining the medical legitimacy of the only treatment available for Celiac – a strict Gluten Free diet. See section herein, “The Economics of Celiac Disease The Financial Burden of the Gluten Free Diet”.

According to the National Academies of Sciences,

“The commonalities across autoimmune diseases,<sup>140</sup> such as mechanistic pathways, genetics, and effects of environmental factors, may provide significant insights that can further the development of patient care and therapies, and offer the greatest opportunity for advancing the field, the report says... 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.**”<sup>141</sup> (emphasis added)

### **Gluten Free Food is to Celiacs as What Insulin is to Diabetics**

According to Dr. Alessio Fasano, Director of the Center for Celiac Research and Treatment at Massachusetts General Hospital “[f]or people with celiac disease, the gluten-free diet is like insulin for diabetics.”<sup>142</sup> In the context of the analogy that Diabetes is to Celiac as insulin is to Gluten Free foods, it is instructive to view President Biden’s remarks at the 2022 State of the Union on the struggles that many families have to make on insulin and how that impacts one’s family and dignity.

“I spoke with Joshua’s [Davis] mom [Shannon Davis]. Imagine what it’s like to look at your child who needs insulin to stay healthy and have no idea how in God’s name you’re going to be able to pay for it -- what it does to your family, but what it does to your dignity, your ability to look your child in the eye, to be the parent you expect yourself to

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<sup>139</sup> <https://www.latimes.com/opinion/op-ed/la-oe-green-jones-gluten-free-diet-20160609-snap-story.html>

<sup>140</sup> The Enhancing NIH Research on Autoimmune Disease report specified 11 autoimmune diseases for special focus including Celiac Disease, Sjögren’s disease, systemic lupus erythematosus, antiphospholipid syndrome, rheumatoid arthritis, psoriasis, inflammatory bowel disease (Crohn’s disease and ulcerative colitis), primary biliary cholangitis, multiple sclerosis, type 1 diabetes, and autoimmune thyroid disease (Graves’ disease and Hashimoto’s thyroiditis).

<sup>141</sup> <https://www.nationalacademies.org/news/2022/05/nih-should-create-an-office-of-autoimmune-disease-research-says-new-report>

<sup>142</sup> <https://amp.cnn.com/cnn/2017/03/01/health/gluten-free-diet-history-explainer/index.html>

be. I really mean it. Think about that.”<sup>143</sup>

Also see the comments of Brian Davis and family to the FDA’s Draft Guidance.<sup>144</sup>

Regardless of socioeconomic position, Celiacs face food insecurity every day because of the constant threat of cross contact with Gluten, 80% of foods have Gluten in them, the limited availability of Gluten Free food (especially out of home), the high price of Gluten Free food, and that Gluten is not required to be labeled on all packaged foods in the United States. 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.

On October 3, 2011, Andrea Levorio, Executive Director, American Celiac Disease Alliance, captured the essence of the needs of the Celiac community in a letter to the FDA,

“There is no medical intervention for the treatment of celiac disease, no drug, no ongoing therapy. The treatment, while medically prescribed, is self-administered and in many instances without medical oversight. Gluten-free foods, in all forms, are the equivalent of a prescription medication used to manage another lifelong, chronic condition.”<sup>145</sup>

According to the University of Chicago,

“Living healthily with Celiac Disease requires skill in negotiating the everyday environment -- especially for children and teens, where most positive social encounters, from school lunches to prom, is organized around food.”<sup>146</sup>

According to the U.S. Department of Defense, Celiac Disease is so serious that it is a disqualifying condition from service in the U.S. Military.<sup>147 148</sup>

According to testimony from Marilyn Geller, CEO of the Celiac Disease Foundation to the House Appropriations Committee on April 9, 2019,

“If I leave you with one message today, it is that Celiac Disease is, in fact, a serious autoimmune disease that is not being taken seriously enough by our government... And despite what you might see in popular media, celiac disease is not a fad. It is not a

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<sup>143</sup> <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-joe-biden-state-of-the-union-address-as-delivered/>

<sup>144</sup> FDA Tracking Number 16v-04b4-4gs6, [https://downloads.regulations.gov/FDA-2021-N-0553-1385/attachment\\_1.docx](https://downloads.regulations.gov/FDA-2021-N-0553-1385/attachment_1.docx)

<sup>145</sup> <https://web.archive.org/web/20130511074749/http://americanceliac.org/comments-to-fda/#Comments>

<sup>146</sup> University of Chicago Celiac Disease Center, 2018 Year End Report, [https://www.cureceliacdisease.org/wp-content/uploads/CdC\\_YearEnd\\_Report\\_18\\_WEB.pdf](https://www.cureceliacdisease.org/wp-content/uploads/CdC_YearEnd_Report_18_WEB.pdf)

<sup>147</sup> 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/>

<sup>148</sup> <https://www.militarytimes.com/2016/01/14/medical-mix-up-sidelines-army-sergeant-s-career/>

punchline. Americans are dying because we are not paying enough attention to this disease.”<sup>149</sup>

When Ms. Geller concluded her testimony, House Appropriations Chair Rosa DeLauro seemed visibly and audibly moved, and she concurred that the Federal government has not been taking Celiac Disease seriously enough,

“Thank so much. I think I will take your last comment and say, you know, look, I have a colleague here who has celiac disease, and I watch how carefully she eats and what she can or what she can’t do. But I think you said something, and I will concur. I don’t think it is taken as seriously. It is, you know, okay, so you read to avoid things and you avoid this, you avoid that, or so forth, but I think you have laid out how serious it is, what it can lead to, and that it is not on the radar screen.”<sup>150</sup>

According to Comments by the Celiac Disease Foundation, the Society for the Study of Celiac Disease (SSCD), and Boston Children’s Hospital on the U.S. Preventive Services Task Force’s Draft Research Plan: Preventive Services for Food Insecurity in 2022,

“Failure or inability to adhere to a gluten-free diet, including accidental exposure to gluten, triggers the autoimmune response which can have devastating and debilitating consequences for patients by increasing the mortality risks for other diseases, including cancer, cardiovascular disease, and respiratory disease. Beyond mortality risk, celiac disease is also associated with an increased risk of a variety of chronic illnesses, including additional autoimmune disease and cancers such as intestinal malignancy and lymphoma.”<sup>151</sup>

On July 20, 2004, Representative Nita Lowey, the primary House sponsor of FALCPA, spoke on the House floor and urged her colleagues to pass 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.**”<sup>152</sup>  
(emphasis added)

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<sup>149</sup> <https://www.congress.gov/event/116th-congress/house-event/LC64261/text?s=1&r=14> , and <https://youtu.be/KGRHg-840KE?t=11228>

<sup>150</sup> <https://www.congress.gov/event/116th-congress/house-event/LC64261/text?s=1&r=14> , and <https://youtu.be/KGRHg-840KE?t=11499>

<sup>151</sup> [https://celiac.org/main/wp-content/uploads/2022/03/Celiac-Disease-Foundation.SSCD\\_.Boston-Childrens-Hospital-Comments-Draft-Reseach-Plan.Preventive-Services-for-Food-Insecurity.pdf](https://celiac.org/main/wp-content/uploads/2022/03/Celiac-Disease-Foundation.SSCD_.Boston-Childrens-Hospital-Comments-Draft-Reseach-Plan.Preventive-Services-for-Food-Insecurity.pdf)

<sup>152</sup> <https://www.congress.gov/congressional-record/2004/7/20/house-section/article/h6093-1?>

In testimony of Lisa Murphy on behalf of the American Celiac Task Force Before the Subcommittee on Labor, HHS, and Education on the Committee of Appropriations, U.S. House of Representatives on April 17, 2004, Ms. Murphy testified to how underserved the Celiac community was from the Federal government, including with food labeling. This exchange is between Ms. Murphy, Rep. Ralph Regula (R, OH-16) who served as Chair of the Subcommittee on Labor HHS, and Rep. Patrick Kennedy (D, RI-1).

“Mr. REGULA. Question. Do most foods that you have an identification; that is, there is gluten in them?

Ms. MURPHY. No.

Mr. REGULA. And that is one of the real dangers, isn't it, that you don't know?

Ms. MURPHY. Yes, it is.

Mr. KENNEDY. Big problem, Mr. Chairman.

Ms. MURPHY. The food labeling is the biggest problem as far as modified food starch, flavorings, all sorts of, a lot of processed [foods].”<sup>153</sup>

In contrast to the years of advocacy by the Food Allergy & Anaphylaxis Network (“FAAN”),<sup>154</sup> it was not until April 27, 2004 that individuals with Celiac Disease testified for the first time before a Congressional Committee. According to Allison Herwitt, former Co-Chair, Legislative Project, American Celiac Task Force (ACTF),

“Lisa Murphy, and her son, Colin, represented the ACTF before the House Appropriations Subcommittee on Labor, HHS, and Education... The Labor-HHS Subcommittee determines how much money NIH receives each year. Having individuals with Celiac Disease provide information about the disease is critical to securing funding for research. After hearing the testimony, Subcommittee Chairman, Ralph Regula (R-OH), asked if food labels were a problem for Celiacs. Not missing a beat, Lisa offered an emphatic, Yes, then highlighted problems she has encountered. Rep. Nita Lowey (D-NY), sponsor of H.R.

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<https://books.google.com/books?id=Dp2XSbZD0HUC&pg=PA968&lpg=PA968&dq=%22Question.+Do+most+foods+that+you+have+an+identification;+that+is,+there+is+gluten+in+them?+Ms.+MURPHY.+No.%22>

<sup>154</sup> “In 2012, Food Allergy Research & Education (FARE) was formed as the result of a merger between the Food Allergy & Anaphylaxis Network (FAAN) and the Food Allergy Initiative (FAI). The new organization combined FAAN’s expertise as the most trusted source of food allergy information, programs and resources with FAI’s leadership as the world’s largest private source of funding for food allergy research... FAAN was established in 1991 by Anne Munoz - Furlong, at a time when information about food allergies was difficult to find. The pioneering organization soon was widely recognized for the high quality of its educational initiatives, which offered expert advice to individuals and families who needed help in managing food allergies, as well as those working to support and care for them... FAI was founded in 1998 by concerned parents and grandparents who were committed to advancing food allergy research a field that received little federal or private support at the time. By the time of the merger, FAI was the largest private source of funding in the world for food allergy research, investing in clinical trials of new therapies, basic research, and epidemiological studies in the U.S. and overseas.” Source: <https://www.foodallergy.org/about-us/history-fare>

3684, the Food Allergen Labeling and Consumer Protection Act, and member of the Subcommittee, explained the bill was drafted to help individuals like Lisa, and Colin.”<sup>155</sup>

In April 2004, some of the world’s leading experts in Celiac Disease, including Dr. Alessio Fasano, Dr. Peter H.R. Green, Dr. Stefano Guandalini, Dr. Joseph A. Murray, M.D., and Dr. Michelle Pietzak testified to the U.S. House Appropriations Committee about how the Celiac community has been underserved including with “the lack of scientific attention and funding celiac disease has received” and the need for “better labeling of all foods”,

“The gluten-free diet is an effective treatment for the majority of patients and results in resolution of the damage to the intestine and the many consequences of the malabsorption. **In many countries of the world, celiac disease is regarded as a national health issue with gluten free foods provided by prescription. Many, if not most, patients find this an onerous diet that affects their quality of life. There are many ways to improve the quality of life including**, better education, better access to appropriate foods, **better labeling of all foods** and advances in biotechnology...

The association between cancer and celiac disease is well known. Individuals with a delayed diagnosis of celiac disease are substantially more likely to develop certain types of lymphoma, specifically non-Hodgkin’s lymphoma, and carcinoma both of the small intestine, the esophagus, colon and skin. Many of these cancers are deadly with fewer than 10 to 15% of patients surviving beyond five years. Little is known about the specific risk factors or mechanisms, for which cancers can develop from celiac disease. In addition, we do not know what percent of individuals in the United States with these cancers actually have celiac disease as the cause.

**Considering the lack of scientific attention and funding celiac disease has received in the United States**, we respectfully urge the Subcommittee to include celiac disease research as a priority when developing the funding levels for NIDDK and NIH for fiscal year 2005. The potential for major advances in this area by the United States can lead the world, and lead to commercially viable alternatives for the treatment of celiac disease. We believe money invested in this area will be money well spent. It will significantly improve the quality of life for many Americans and potentially save the lives of those who would otherwise suffer the effects of undiagnosed and untreated celiac disease.” (emphasis added)<sup>156</sup>

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<sup>155</sup> <https://www.celiac.com/articles.html/congress-hears-first-ever-testimony-on-celiac-disease-r775/>

<sup>156</sup> Written Statement of Alessio Fasano, M.D., Director Center for Celiac Research, University of Maryland; Peter H.R. Green, M.D., Director, Celiac Disease Center, Columbia University; Stefano Guandalini, M.D., Director, Celiac Disease Program, University of Chicago; Joseph A. Murray, M.D., Mayo GI Clinic; Michelle Pietzak, M.D., Director, Center for Celiac Research - West, University of Southern California, Keck School of Medicine, Children's Hospital Los Angeles, For the Subcommittee on Labor, HHS, and Education of the Committee on Appropriations, U.S. House of Representatives, April 27, 2014, Page 1709, [https://books.google.com/books?id=Udt\\_ZhImvLkC&lpg=RA3-PA960&dq=%22Colin%20Murphy%22%20%22Lisa%20Murphy%22%20%20to%20the%20Ho use%20Appropriations%20Subcommittee%20on%20Labor%2C%20HHS%2C%20and%20Education%2C%20April%2027%2C%202004&pg=PA1709#v=onepage&q=pietzak&f=false](https://books.google.com/books?id=Udt_ZhImvLkC&lpg=RA3-PA960&dq=%22Colin%20Murphy%22%20%22Lisa%20Murphy%22%20%20to%20the%20Ho use%20Appropriations%20Subcommittee%20on%20Labor%2C%20HHS%2C%20and%20Education%2C%20April%2027%2C%202004&pg=PA1709#v=onepage&q=pietzak&f=false)



More recently in October 2021, Beyond Celiac called out another example of the Celiac community being historically underserved by the Federal government, in this case by the CDC,

“Dear CDC: Why is celiac disease not listed in your online Index of Diseases & Conditions? Celiac disease is a serious autoimmune disease that affects at least 1% of the population. It can have long-term and devastating effects on physical and mental health. Please add this important condition to your list that already includes autoimmune disorders such as Lupus and RA [Rheumatoid Arthritis].”<sup>157</sup>

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),

“Avoiding one or more food allergens for years or for life to protect one’s health is no easy task. It takes an incredible amount of dedication, time and research by food allergy patients and their care providers to ensure they are making the right food choices when they shop, as well as when they eat away from home. The hurdles are even greater for socioeconomically disadvantaged households.”<sup>158</sup>

### **New Research on Non-IgE-Mediated Mechanisms to Ingestion of Gluten in Celiac Patients Suggests That The Term Delayed Hypersensitivity Should Be Considered as Hypersensitivity With Long Tail**

At the time when FALCPA was introduced in 2002, research from Steve Taylor, Ph.D. and Susan Hefle, Ph.D. on the acuteness of Non-IgE Cell-Mediated Reactions with Celiac Disease indicated “cell-mediated allergic reactions, also known as delayed hypersensitivity reactions, have an onset time of 6-24 hours after ingestion of the offending food.” Dr. Taylor and Dr. Hefle also reported that “[t]he reactions develop slowly, reaching a peak at approximately 48 hours and then slowly subsiding over 72-96 hours.”<sup>159</sup> In FDA Ref. 2 which was published in 2017, Table 2-1 indicates that a Non-IgE-Mediated food allergy has a “Time to onset of reaction” as “Delayed Often >4-6 hours”.<sup>160</sup>

However, research from 2016 has shown that “[m]edian time to symptom onset [following Gluten exposure] was 1 hour (range 10 min to 48 h), and median symptom duration was 24h (range 1 h to 8 days).”<sup>161</sup>

According to even more recent research published by Sciences Advances on the acuteness of symptom onset in Non-IgE Cell-Mediated Reactions with Celiac Disease in 2019, “Cytokine release and gastrointestinal symptoms after gluten challenge in celiac disease”, if Celiac Disease patients who are following a strict Gluten Free diet “**are exposed to gluten-containing food,**

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<sup>157</sup> <https://www.facebook.com/beyondceliac/photos/a.138794643705/10160023628828706>

<sup>158</sup> <https://www.foodallergy.org/media/1059/download>

<sup>159</sup> Susan L. Hefle & Steve L. Taylor, Food Allergies and Other Food Sensitivities, 55(9) Food Tech. 69, 75, at 71 tbl. 2. Sept. 2001), <https://www.ift.org/news-and-publications/food-technology-magazine/issues/2001/september/features/food-allergies-and-other-food-sensitivities>

<sup>160</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>161</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5283559/>

**they typically suffer from gastrointestinal reactions occurring 1 to 2 hours after the gluten exposure.**<sup>162</sup>

Given that, the term “delayed hypersensitivity” as it has previously been applied by some to Celiac Disease and used in comparison to IgE-Mediated food allergies (with reaction time ranging from a few minutes to 2 hours after ingestion of food allergen) now appears to be a misnomer. Moreover, the term “delayed hypersensitivity” has also connoted a less serious immune-mediated adverse reaction to a food protein (Gluten), when more recent evidence-based scientific research indicates that symptoms can start as soon as one hour after Gluten exposure, and also can be life-threatening. Regardless of how soon symptoms start with a Non-IgE-Mediated Gluten food allergy, that is a red herring when it comes to consumer protection with food labeling in the U.S. The reason is because there is no rescue medicine to take to reverse the effects of the ingestion of Gluten and the beginning of the potentially life-threatening autoimmune cascade that can cause a myriad of GI symptoms, similar to IgE-Mediated food allergies, but also in the case of Celiac, for example, anemia, cancer, heart disease, immunological scarring, infertility, intestinal damage, malabsorption, malnutrition, migraines, etc.

It is instructive as an anecdotal example of the real-world comorbidities with Celiac to note that on June 20, 2022, the Southwest Times Record of Fort Smith, Arizona published an obituary of Carolyn Sue Parks who passed away on June 20, 2022 at the age of 87. The obituary memorialized that her son Michael Morrison “helped her in every way” and “cared for her throughout her battle with celiac disease, lupus, and heart disease.”<sup>163</sup>

Accordingly, given that ingestion of Gluten can also cause symptoms to persist for days or weeks in some cases, and that the long-term consequences can have devastating and debilitating consequences, it is my opinion that a more accurate term for a Non-IgE-Mediated food allergy mechanism with Gluten should be hypersensitivity with long-tail.

## **IX. What’s In A Name? Celiac is a Food Allergy!**

**“What’s in a name?**

**That which we call a rose by any other name would smell just as sweet.”**

**-- William Shakespeare**

Shakespeare used this famous line in Romeo and Juliet to convey that the naming of things is irrelevant. However, I disagree with that when it comes to the terms “Food Allergy” and moreover “Food Allergen”. Is Celiac Disease a food allergy,<sup>164</sup> autoimmune disease<sup>165</sup> and/or

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<sup>162</sup> Goel et al., Sci. Adv. 2019; 5: eaaw7756 7 August 2019, <https://celiac.org/main/wp-content/uploads/2020/03/NexVax2-Study.pdf>

<sup>163</sup> <https://www.swtimes.com/obituaries/10026781>

<sup>164</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf) (page 4); <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> (pages 5. 11); and <https://www.fda.gov/media/157637/download> (page 10)

<sup>165</sup> <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#>

digestive disease<sup>166</sup>? With respect to the consumer protection needs of the Celiac community with food labeling, Celiac Disease is a food allergy and Gluten a food allergen. Words matter!

Anecdotally, in conversations I have had with some Congressional staffers on Capitol Hill in 2022 about naming Gluten as the 10<sup>th</sup> Major Food Allergen, I received feedback that in looking at Gluten ingestion from a “biological perspective with some type of biological identifier,” they said that the FDA does not consider Gluten as a food allergen since it does not cause anaphylaxis in people with Celiac. As such, and in spite of FALCPA’s Findings about Celiac Disease, I also heard feedback that FALCPA was not the “right vehicle” to address our request for Gluten to be codified as the 10<sup>th</sup> Major Allergen and to be labeled on all packaged foods.

It is no wonder that there is ingrained consumer and Congressional confusion. According to the FDA’s Web site page entitled, “‘Gluten-Free’ Means What It Says”, the FDA states that people with Celiac Disease “face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.”<sup>167</sup> However, there is no mention that Celiac is a food allergy, digestive disease and/or auto-immune disease. There is also no mention that Gluten is a food allergen, and that Gluten causes an allergic reaction in people with Celiac Disease.

On the FDA’s “Food Allergen Labeling And Consumer Protection Act of 2004 Questions and Answers”, dated December 12, 2005; Updated July 18, 2006 (“FDA’s FALCPA FAQs”), the questions and answers suggest that Celiac Disease is an after-thought. The FDA’s FALCPA FAQs also do not refer to Gluten as a food allergen, that Gluten causes an allergic reaction in people with Celiac Disease, or even mention the FALCPA’s Section 2, Findings (“FALCPA’s Findings”) that expressly discuss Celiac Disease as one of its six key findings.<sup>168</sup> 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.

The FDA’s FAQs suggest that Gluten is something other than a food allergen, “The following questions and answers will be useful in answering questions about FALCPA, food allergen labeling, gluten, and advice for consumers.”<sup>169</sup>

In FDA’s FAQ 21, the FDA seemingly goes out of its way to refer to a “concern” about Gluten (suggesting less serious than a food allergen) because Celiac is a “chronic digestive disease,” Celiac is not a food allergy and Gluten is not a food allergen.

“Why is there a concern about gluten?

Gluten describes a group of proteins found in certain grains (wheat, barley, and rye.) It is of concern because people with celiac disease cannot tolerate it. Celiac disease (also known as celiac sprue) is a chronic digestive disease that damages the small intestine and

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<sup>166</sup> <https://www.niddk.nih.gov/health-information/digestive-diseases>

<sup>167</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

<sup>168</sup> <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers>

<sup>169</sup> <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#q2>

interferes with absorption of nutrients from food. Recent findings estimate that 2 million people in the U.S. have celiac disease or about 1 in 133 people.”<sup>170</sup> [Note that the most current estimate from the NIH is that Celiac “affects greater than 1% of the US population, and incidence appears to have been increasing over the last several decades.”<sup>171</sup>]

On the FDA’s “Gluten-Free Labeling of Foods” page, there is no mention that Celiac is a food allergy, digestive disease and/or auto-immune disease and that Gluten is a food allergen. There is also no mention that Gluten is a food allergen.<sup>172</sup>

In the FDA’s “Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines Guidance for Industry May 2020”, the FDA once again othered Gluten as something else other than a food allergen,

“SAFETY: the ingredient being substituted for the labeled ingredient does not cause any adverse health effect (including food allergens, gluten, sulfites, or other ingredients known to cause sensitivities (see section C.2.a) in some people, for example, glutamates);”<sup>173</sup>

In the FDA’s “Small Entity Compliance Guide: Gluten-Free Labeling of Foods”, there is no mention that Celiac is a food allergy, digestive disease and/or auto-immune disease. There is also no mention that Gluten is a food allergen.<sup>174</sup>

The National Institutes of Health also do not refer to Celiac Disease as a food allergy or Gluten as a food allergen.

According to the NIH’s NIDDK, “Celiac disease is a **chronic digestive and immune disorder** that damages the small intestine. The disease is triggered by eating foods containing gluten. The disease can cause long-lasting digestive problems and keep your body from getting all the nutrients it needs.”<sup>175</sup> (emphasis added)

According to the NIH’s NIAID, “Celiac disease is an **autoimmune disease** that occurs in genetically susceptible individuals who develop an immune response to ingested gluten.”<sup>176</sup> (emphasis added)

## **Gaslighting Gluten as a Second Class Food Allergen**

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<sup>170</sup> FAQ 21, <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#>

<sup>171</sup> <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

<sup>172</sup> <https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods>

<sup>173</sup> <https://www.fda.gov/media/138315/download>

<sup>174</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-gluten-free-labeling-foods>

<sup>175</sup> <https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease#>

<sup>176</sup> <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html>

In addition to the FDA and NIH, there even appear to be various voices in the Celiac and IgE-Mediated food allergy communities who also seemingly go out of their way to say that Celiac is not a food allergy (or a “true” food allergy or a “typical” food allergy).<sup>177</sup> I think that not calling Celiac a food allergy and moreover not referring to Gluten as a food allergen has unintentionally hurt the Celiac community in myriad ways. I also believe that this gaslighting of Gluten not being a food allergen and Celiac not being a food allergy because the immune response is a Non-IgE Mediated mechanism stands in contrast to evidence based science, including as detailed in the FDA’s Draft Guidance “Section III.A. Background, What is Food Allergy?” (as will be discussed in herein).

As a parent of a child with Celiac Disease and as a Columbia University alumnus, I have great respect for the work of Dr. Peter Green, Director of the Celiac Disease Center at Columbia University. However, I respectfully believe that Dr. Green and other thought leaders in the Celiac community need to reimagine how these thoughts leaders communicate about Celiac Disease. According to Dr. Green, “Celiac disease is a delayed type of immune reaction – it is not a food allergy.”<sup>178</sup>

As previously mentioned herein, the Boston Globe reported that Dr. “Fasano now gives his celiac patients *permission* to use the word allergy to describe their disease, since that will probably be taken more seriously.”<sup>179</sup> I loved that, but fast forward 7 years, I think that we need much more than permission. In terms of consumer protection, the Celiac community would benefit greatly if the FDA and scientists would consistently refer to Celiac as a food allergy and Gluten as a food allergen.

FARE (Food Allergy Research & Education) does not refer to Celiac as a food allergy and Gluten as a food allergen. FARE also does not discuss that Celiac can be life-threatening.

“Celiac disease is an autoimmune disease. Antibodies are produced in response to the presence of gluten resulting in inflammation and damage to the lining of the small intestine. Many symptoms involve the gastrointestinal tract (e.g., diarrhea, constipation, weight loss, abdominal pain and bloating). Other symptoms can include skin rashes and disorders that result from nutrient deficiencies. The estimated global prevalence of celiac disease is 1%, similar to wheat allergy.”<sup>180</sup>

While FARE has done amazing advocacy and education work to protect those with IgE-Mediated food allergies, FARE has not embarked on advocating for the labeling of Gluten as a Major Food Allergen. This appears to be because FARE’s concentration follows the “orthodox” allergists who focus exclusively on IgE-Mediated food allergies that are potentially immediately life-threatening and can cause anaphylactic reactions, notwithstanding that a Gluten allergy with

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<sup>177</sup> By way of example and not limitation, <https://www.futureofpersonalhealth.com/asthma-and-allergies/understanding-the-differences-between-celiac-disease-and-gluten-allergy/#>

<sup>178</sup> “Celiac Disease (Newly Revised and Updated): A Hidden Epidemic”, Peter H.R. Green, M.D. and Rory Jones, Updated-4th Edition, New York : William Morrow, an imprint of HarperCollins Publishers, 2020

<sup>179</sup> <https://www.bostonglobe.com/magazine/2015/10/14/why-food-allergy-fakers-need-stop/PB6uN8NF3eLWFjXnKF5A9K/story.html>

<sup>180</sup> <https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/common-allergens/wheat>

Celiac is potentially life-threatening (coupled with many other adverse health outcomes including intestinal damage), and the Celiac community needs the same consumer protections as the IgE-Mediated food allergy communities in terms of the required labeling of Gluten on all packaged foods.

As it pertains to the Celiac community, we need to reduce Gluten allergy stigma and disparities in consumer protection, along the lines of what HHS is working on with the HIV Challenge: Innovative Community Engagement Strategies to Reduce HIV-Related Stigma and Disparities.<sup>181</sup>

### **American Academy of Allergy, Asthma & Immunology**

The American Academy of Allergy, Asthma & Immunology (“AAAAI”),

“Gluten is a protein found in grains, such as wheat, barley and rye. Some people are allergic to wheat, but that is not the same as a gluten allergy. **Gluten allergy is a misleading term commonly confused with wheat allergy, or sometimes celiac disease.** There is no such thing as a gluten allergy, but there is a condition called Celiac Disease.”<sup>182</sup> (emphasis added)

During discussions on Capitol Hill in 2022 about the required labeling of Gluten, it was shared with me that the article “Celiac Disease, Non-Celiac Gluten Sensitivity, and Food Allergy: How are they different?” by the American Academy of Allergy, Asthma & Immunology (“AAAAI”) had been relied upon by some policy makers’ staff in trying to understand the differences and similarities between typical IgE-Mediated food allergies and Non-IgE-Mediated food allergy with Celiac (“AAAAI Article”).<sup>183</sup> Those staffers were left with the conclusion that Non-IgE-Mediated food allergy were less serious, and therefore did not require the same consumer protections with labeling.

When I read the original AAAAI Article,<sup>184</sup> I reached out to AAAAI in March 2022 and informed them that I thought their original article was insensitive, incomplete and biased, and that it had the potential to misinform public policy decisions designed to protect consumers and fund research.

“Dear Dr. Khan,

While I suffer from food allergies and [occasional sports] asthma, I am writing to you as the father of a 9 year old child with Celiac Disease. To that end, I want to share some

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<sup>181</sup> <https://www.minorityhealth.hhs.gov/omh/Content.aspx?ID=22538&lvl=1&lvlid=1>

<sup>182</sup> <https://acaaai.org/allergies/allergic-conditions/food/wheat-gluten/>

<sup>183</sup> The FDA’s Dr. Stefano Luccioli was listed at the AAAAI’s 2014 Annual Meeting as a Fellow of AAAAI in the Scientific Abstract Sessions, page 131 – “Prevalence and Characteristics of Consumer-Reported Food Allergic and Anaphylactic Events in CAERS, 2007-2011 Ms. Taiye M Oladipo, MPH and Dr. Stefano Luccioli, MD, FAAAAI, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD”, Source: [http://www.aaaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/VAM/am14-final-prog\\_EDU-Content.pdf](http://www.aaaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/VAM/am14-final-prog_EDU-Content.pdf)

<sup>184</sup> <https://web.archive.org/web/20210819210601/https://www.aaaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/celiac-disease>

feedback on an article posted on your site that I think is insensitive, incomplete and biased, and has the potential to misinform public policy decisions designed to protect consumers and fund research.

The article in question is entitled, ‘Celiac Disease, Non-Celiac Gluten Sensitivity, and Food Allergy: How are they different?’<sup>185</sup>

**Feedback on AAAAI's article (in no order of importance)**

1) Rather than starting off with a discussion of what Celiac Disease is, the article starts off with an economic issue – ‘Awareness of celiac disease and concerns over reactions to gluten products have contributed to a 2.6 billion dollar market for gluten free products.’

I think that the article should start off with describing Celiac Disease and the seriousness thereof. For example, in 2019, Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago Celiac Disease Center testified to the U.S. Senate Appropriations Committee, ‘In Celiac disease patients, gluten, a protein found in wheat, barley and rye, triggers an immune response leading the body to attack the small intestine. This intestinal damage causes more than 200 debilitating symptoms. Moreover, gluten ingestion for people with celiac disease causes permanent immunological scarring, doubles the risk of heart disease, and acts as a carcinogen, quadrupling the risk of small intestinal cancers.’

2) ‘*Left untreated*, celiac disease may lead to non-intestinal symptoms including anemia, chronic fatigue, osteoporosis, impaired spleen, infertility, neurologic disorders, skin rashes and cancer.’

The words ‘Left untreated’ are biased because it makes treating Celiac Disease sound so simple and dismissive. It is not just a binary choice to treat or not. There is no recognition that Celiac Disease is a chronic disease, and that there are everyday issues with cross contamination, food insecurity and food anxiety (all very similar to what the IgE-mediated food allergy community experiences daily). The only available treatment option is a strict Gluten Free diet for life, and that does not work for many people, even if they are able to eat Gluten Free with no cross contact. The reality that the complications can continue on a Gluten Free is totally missed in your article.

3) Why is it necessary to use the word ‘controversial’ with discussing Non-Celiac Gluten Sensitivity today? NCGS is real, and can potentially lump Celiac Disease into this purported controversy also. Tying back to the economics feedback that I provided on the article’s opening line, the AAAAI’s language suggests that Celiac is a dietary fad. As we often say, Celiac is a disease, not a diet.

4) And it is not an allergy – ‘It is important to note that Celiac disease and NCGS are different from having a food allergy. With a food allergy, the immune system overreacts to a particular food causing symptoms that are potentially serious or even life-threatening. In food allergic patients, symptoms begin shortly after ingestion of the food (a few minutes to an hour or so) and include hives, shortness of breath, lightheadedness or vomiting. A food allergy is an immune, but not an autoimmune, reaction.’...

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<sup>185</sup> <https://web.archive.org/web/20210819210601/https://www.aaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/celiac-disease>

This paragraph suggests that Celiac does not cause symptoms that are serious, and that Celiac is not life threatening. This is wrong. As discussed below, there are differences between and immediate hypersensitivity with food allergies and a delayed hypersensitivity with Celiac, but both are grave and potentially deadly and involve the immune system.

The common denominator between food allergies and Celiac Disease is that both involve abnormal immunological responses to proteins in food. In a practical sense, what is food for one is poison for another.

It is really important to understand the biology basics here for everyone. To that end, I was in discussions on Capitol Hill recently about the required labeling of Gluten, and I was told that your article had been relied upon by some policy makers in trying to understand the differences and similarities between food allergies and Celiac, both of which are very serious to those afflicted and their family loved ones

Thank you for all that you do for the allergy and asthma communities. Thank you also for your consideration of updating your article ‘Celiac Disease, Non-Celiac Gluten Sensitivity, and Food Allergy: How are they different?’ to make it more accurate, inclusive and respectful, with the recognition that the AAAAI is an authority.”<sup>186</sup>

I appreciate that the AAAAI responded quickly and voluntarily engaged AAAAI’s Committee on Adverse Reactions to Food to review my concerns and revise the article. In May 2022, AAAAI published a revised article in which it referred to Celiac as a “non-IgE-mediated food allergy”, I think that AAAAI could do a better job in describing the similarities, in addition to the differences between IgE-Mediated and Non-IgE-Mediated food allergies. I also think that the AAAAI’s article would be more informative if it expressly referred to Celiac as a food allergy and Gluten as a food allergen.<sup>187</sup>

- **Original AAAAI Article (as archived with the Wayback Machine)**  
<https://web.archive.org/web/20210819210601/https://www.aaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/celiac-disease>
- **Revised AAAAI Article**  
<https://www.aaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/celiac-disease>

I think that we need to call out these types of scientific biases in the food allergy community that make Celiac perceived as less dangerous and Gluten as less important when it comes to labeling and consumer protection.

### **History of Food Allergy Terminology**

To understand the importance of naming, “[t]he word allergy has been around only since 1906, when Austrian pediatrician Clemens von Pirquet coined it to describe altered biological reactivity. It didn’t gain traction until the mid-1920s, when it took on a big-tent definition describing reactions to everything from food and insect stings to mold and hay fever, says medical historian Dr. Matthew Smith, author of the book “Another Person’s Poison: A History of

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<sup>186</sup> Email from Jon Bari to AAAAI, March 22, 2022.

<sup>187</sup> <https://www.aaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/celiac-disease>



Food Allergy.” For most of the 20<sup>th</sup> century, research-focused orthodox allergists, who insisted on a definition requiring a measurable immune reaction, battled with more flexible food allergists, whose main focus was bringing relief to their patient’s hypersensitivities.”<sup>188</sup>

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 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.”<sup>189</sup>

As Dr. Smith continued,

“Of course it was not just any food allergy the AAAAI had in mind; it was IgE-mediated, anaphylactic reactions to peanuts and a small number of other foods [footnote 13 – ‘Some of these other foods will be discussed later in this chapter, but included in their number were milk, egg, wheat, seafood, soya, nuts, and wheat. [sic]’]... Much as orthodox allergists had heralded the emergence of IgE for giving allergy legitimacy, peanuts made food allergy respectable, thrusting it into the spotlight like never before. Peanut allergy made that matter.”<sup>190</sup>

This is a great example which shows how the American Academy of Allergy, Asthma & Immunology has othered the consumer protection needs of the Celiac community by saying that there is no such thing as a Gluten allergy.

“Gluten is a protein found in grains, such as wheat, barley and rye. Some people are allergic to wheat, but that is not the same as a gluten allergy. **Gluten allergy is a misleading term commonly confused with wheat allergy, or sometimes celiac disease. There is no such thing as a gluten allergy**, but there is a condition called Celiac Disease.”<sup>191</sup> (emphasis added)

It is important to understand how when Celiac is othered and not referred to as a food allergy and when Gluten is not referred to as a food allergen, then those who have Celiac and their caretakers are effectively excluded from the following ecological-developmental model for food allergies as

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<sup>188</sup> <https://longreads.com/2015/10/27/the-word-allergy-didnt-exist-until-1906/>

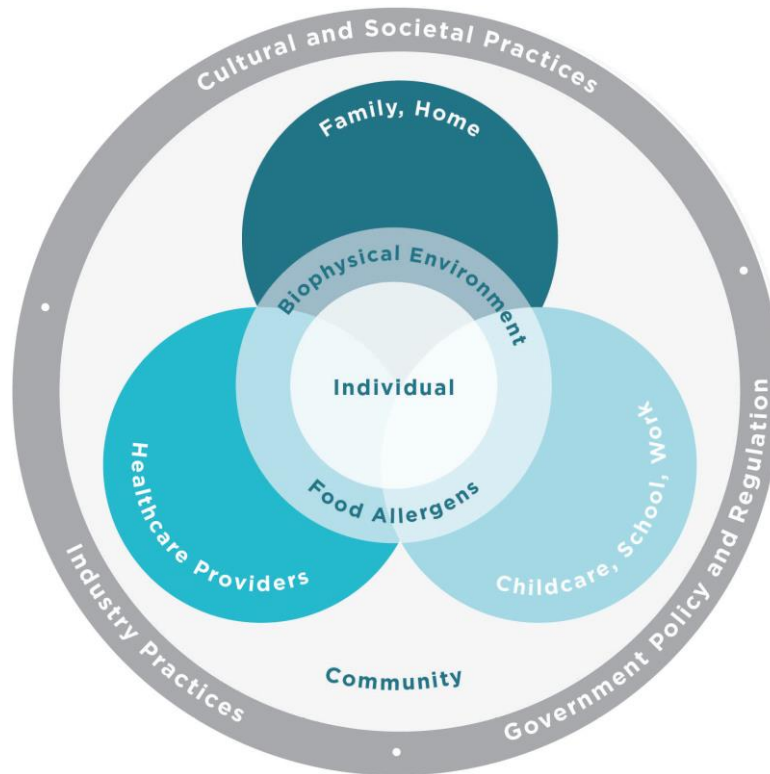
<sup>189</sup> Smith, Matthew. “Another Person’s Poison: A History of Food Allergy.” New York: Columbia University Press, 2015. Print, pages 155-156.

<sup>190</sup> Smith, Matthew. Another Person’s Poison: A History of Food Allergy. New York: Columbia University Press, 2015. Print, pages 155-156.

<sup>191</sup> <https://acaai.org/allergies/allergic-conditions/food/wheat-gluten/> . It should be noted that this article needs to be updated by the AAAAI as well, and the author will reach out to them in that regard, in a similar manner as I did with the AAAAI’s article, “Celiac Disease, Non-Celiac Gluten Sensitivity, and Food Allergy: How are they different?”

detailed below. Such exclusion negatively impacts quality of life, equity in participation in one of life's daily activities -- eating, consumer protections with labeling, medical research, etc.

**Figure 5 – “Ecological-developmental model for food allergies. Different systems that an individual interacts with are depicted as proximal (e.g., food, biophysical environment) and distal (e.g., industry, government).” [Reprinted from FDA Ref. 2, FIGURE S-1]<sup>192</sup>**



In Figure 5 above, “**Industry practices** refers to all the manufacturing processes and allergen control plans followed during food production, distribution, preparation or cooking, and serving. They also refer to mandatory and voluntary labeling of food allergens and to recall procedures followed when a product is contaminated with a food allergen. **Cultural and societal practices** refer to the particular diets and foods of regions and countries. **Biophysical environment** refers to the external proximal environment (e.g., air) while **Individual** refers to all systems internal to a developing human, including genome, epigenome, proteome, metabolome, central nervous system, immune system, microbiomes, and many other self-regulatory systems involved in adaptation and sustaining life. **Health care providers** include the persons (e.g., physicians, dieticians) and the institutions that protect individual and public health. **Child care, school, work** includes all proximal settings that interact with an individual at different life stages. Finally, **family, home** refers to the system of people, relationships, routines, and practices occurring at home. Interactions (e.g., communication, physical contact) occur between and among all those systems and the individual to support (or not) food safety.”<sup>193</sup> (emphasis in original)

### **Legislative History of Federal Food Drug and Cosmetic Act of 1938**

The legislative history of the FDCA [Federal Food Drug and Cosmetic Act of 1938] sheds light on the newness of the concept of “food allergy” in 1934. In some ways, what is old seems new again when it comes to naming conventions, consumer behavior and consumer protection for

<sup>192</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>193</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

food allergies. The following dialogue occurred between the Commissioner of FDA Mr. Walter Campbell, U.S. Senator Felix Hebert<sup>194</sup> who served from 1929-1935 (R, RI), and Senator Royal Samuel Copeland, MD<sup>195</sup> who served from 1923-1938 (D, NY) during a Congressional hearing in 1934 regarding proposed new food and drug legislation:<sup>196</sup>

“Mr. Walter Campbell [FDA Chief]: 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.”<sup>197</sup>  
(emphasis added)

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<sup>194</sup> <https://bioguide.congress.gov/search/bio/H000436>

<sup>195</sup> <https://bioguide.congress.gov/search/bio/C000769>

<sup>196</sup> 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 16 May 2022.

<sup>197</sup> “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.”

<https://biddle.on.worldcat.org/search/detail/577790092?queryString=no%3A577790092>

The term “food allergy” is generally understood as a term for any form of negative or adverse reaction. The use of the term “food allergy” has become a generic term by the public to describe any form of adverse reaction from food. This is just like when someone uses the word Kleenex to ask for a tissue, they are just using the word Kleenex in a generic manner, even though Kleenex is a registered trademark for a brand of tissue. Consumers (lay people) do not parse food allergen and food allergy terminology into IgE-Mediated and Non-IgE-Mediated mechanisms when it comes to understanding food labels and other consumer protections needed.

Let’s fast forward from FDA Commissioner Campbell’s Senate testimony in 1934 with the use of Plain English to describe allergy as a “medical term” that “means the hypersensitivity of certain individuals to certain protein products” to FDA Commissioner Califf’s opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session. Commissioner Califf spoke about getting information across to over 300 million people with all different reading levels, different languages, different ages, etc., including for the health of children like my son Jax who cannot eat Gluten and needs Gluten labeled on all packaged foods to keep him safe.

“A key revelation for me last time through as FDA Commissioner, this is my second stint, but last time through was the idea of getting information across to over 300 million people with all different reading levels, different languages, different age, really a difficult issue that we are working on very hard at the FDA, but we need to all work on it as a community. This is especially important when it comes to the health of children. For instance, we are focused on supporting the availability of foods that provide important nutrients essential for growth and development and reducing our exposure of young children to toxic elements like lead, arsenic, mercury, and cadmium in the foods they eat which can be harmful to their neurological development.”<sup>198</sup>

It is also instructive to understand the semantic context of allergy, food allergen and allergic reaction with regard to the way a reasonable person conversant with relevant social and linguistic practices have used the words and what those words mean in society.

When we use the term food allergy, we intend it to mean an immunological reaction (i.e., Celiac Disease) to normally tolerated food proteins defined as food allergens (i.e., Gluten). By way of example, when we eat out at a restaurant with my son, we inform the server that he has a “severe allergy to Gluten” since the average reasonable person understands that he cannot eat Gluten. As previously discussed, the simplest and most effective way to communicate this in Plain English is to say that Jax has a Food Allergy. Period. Full Stop.

If we had to explain in detail that he cannot eat Gluten because he has an autoimmune disease that attacks his small intestine when he eats Gluten, most people would say that he is allergic. However, it feels like every time we refer to it as a Gluten allergy, there is a societal bias that flows from the FDA and Federal government’s bias that Celiac is not a food allergy and/or an allergic reaction to Gluten is much less serious than a typical IgE-Mediated food allergy and that Gluten is not a food allergen.

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<sup>198</sup> Robert Califf, M.D., Commissioner of the FDA stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session, June 7, 2022.

## **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.<sup>199</sup> 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 fixated 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 focus also 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 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.”<sup>200</sup> 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.

## **Conflicting Definitions in the FDA’s Draft Guidance**

The FDA’s Draft Guidance contains conflicting definitions. In Section II.A, Food Allergen is defined as, “The food or component(s) of a food (often a protein) that elicits specific, IgE-mediated immunologic reactions (Ref. 1 and Ref. 2)”. However, on page 11 of the FDA’s Draft Guidance, Food Allergen is more inclusively defined as, “A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions (Ref. 1).”<sup>201</sup> This definition on page 11 should be the controlling language and comports with Section IIIA as detailed below.

According to “Section III.A. Background, What is Food Allergy?” of the FDA’s Draft Guidance,

“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) (Ref. 1). For example:

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<sup>199</sup> <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action>

<sup>200</sup> <https://www.foodallergy.org/fare-consumer-journey-infographic> ; and <https://www.foodallergy.org/food-allergy-consumer-journey>

<sup>201</sup> <https://www.fda.gov/media/157637/download>

- 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<sup>5</sup>); or
  - Cell-mediated mechanisms (e.g., contact dermatitis).
- Adverse reactions that are not immune-mediated can be caused by:
  - Metabolic mechanisms (e.g., lactose intolerance);
  - Pharmacologic mechanisms (e.g., reaction to caffeine);
  - Toxicological mechanisms (e.g., scombroid toxin poisoning); or
  - Other idiopathic (undefined) mechanisms (e.g., reactions to sulfites).

Food allergy can be broadly defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food (Ref. 1 and Ref. 2). A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions (Ref. 1).”<sup>202</sup>

So far so good. However, from this point forward, the FDA’s Draft Guidance lumps Celiac Disease in with lactose intolerance,<sup>203</sup> even though lactose intolerance is not life-threatening and does not lead to a plurality of short and long-term health effects as does Celiac Disease (i.e., anemia, cancer, failure to thrive, heart disease, immunological scarring, infertility, intestinal damage, malabsorption, malnutrition, migraines, etc.).

When the FDA labels Non-IgE-Mediated mechanisms as an intolerance or gives the impression that a Non-IgE-Mediated mechanism is an intolerance by conflating Celiac with an intolerance, the FDA endorses a false impression that people with Celiac, including children like my son Jax, can tolerate trace amounts of Gluten. Moreover, the FDA downplays the serious adverse health consequences, including for example, malabsorption and failure to thrive, in children, like in our son Jax.

Importantly, even though Celiac is a potentially life-threatening disease, the FDA’s Draft Guidance others Gluten into a category that the FDA wrongly suggests is not meritorious of the same consumer protections of the Top 9 Major Food Allergens in the US.

According to Dr. Matthew Smith, author of the 2015 book “Another Person’s Poison: A History of Food Allergy,”

“For those suffering from chronic allergies, peanut allergy does little more than to reinforce the notion that their non-anaphylactic symptoms are illegitimate, mere intolerance at best, and psychosomatic at worst. Terms such as ‘lactose intolerance’ and ‘gluten intolerant’ may provide some patients with more authoritative terminology to describe their ailments, and one can now find gluten-free breads, cookies, cereals, and cakes at many food stores and bakeries. Nonetheless such sufferers continue to be perceived somewhat suspiciously, as if their symptoms are somehow, indeed, all in their

<sup>202</sup> <https://www.fda.gov/media/157637/download>

<sup>203</sup> <https://www.niddk.nih.gov/health-information/digestive-diseases/lactose-intolerance>

minds. It is much easier to dismiss the gastrointestinal complaints of a middle-aged woman than it is to question a child with a severe anaphylactic allergy to peanuts or one of the seven other recognized major food allergies [in the U.S.]. **With peanut allergy, the long-stated desire of orthodox allergists [‘represented by AAAAI’] to restrict the definition of food allergy has finally become a reality.**”<sup>204</sup> (emphasis added)

Moreover, the FDA’s Draft Guidance again excludes salient findings in the FDA’s Ref. 25 and Ref. 45 treatises by scientists, regulators, physicians, clinicians, and risk managers from academia, government and the food industry, including from the FDA’s Dr. Lauren Jackson and the FDA’s Dr. Stefano Luccioli, 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 tantamount to eating poison and potentially life-threatening. To that end, the FDA’s Draft Guidance others Gluten as a less serious food allergy and Celiacs as having a less potentially life-threatening adverse reaction to Gluten since it is Non-IgE mediated. This language from the FDA’s Draft Guidance below must change.

**“While many different types of food allergies have been identified, food allergies that are recognized to be the most severe and immediately life-threatening are those that are mediated by immunoglobulin E antibodies (IgE) because IgE-mediated food allergic reactions are capable of triggering anaphylaxis, which can be fatal (Ref. 1 and Ref. 3). 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.**

IgE-mediated food allergic reactions can occur within a few minutes to hours after a sensitized individual consumes the applicable food allergen. Ref. 1 and Ref. 2). IgE-mediated food allergic reactions can involve a single organ system such as the skin (e.g., pruritis, erythema, urticaria, angioedema, eczema), eyes (e.g., conjunctivitis, periorbital swelling), nose (e.g., rhinitis, sneezing), oral cavity (e.g., swelling and itching of lips, tongue, or palate), or gastrointestinal tract (e.g., reflux, colic, abdominal pain, nausea, vomiting, diarrhea). The most severe IgE-mediated food allergic reactions (generally referred to as anaphylaxis) involve the shock organs of the respiratory tract or cardiovascular system and involve signs or symptoms<sup>6</sup> IgE-mediated food allergic reactions can have a wide range of clinical manifestations that, if untreated, can lead to serious adverse health consequences, including death <sup>7</sup> [Footnote 7 - See Table 1 for the definitions of “objective signs of food allergy” and “subjective symptoms of food allergy.”] In the remainder of this guidance, we generally refer to “signs or symptoms” without noting that “signs” are objective and “symptoms” are subjective.” such as cough, wheezing, difficulty breathing, swelling of the larynx or vocal cords, fainting, and low blood pressure. These anaphylactic reactions can lead to loss of consciousness, asphyxiation, shock, or death.

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<sup>204</sup> Smith, Matthew. “Another Person’s Poison: A History of Food Allergy.” New York: Columbia University Press, 2015. Print, pages 184-185. Note that Another Person’s Poison: A History of Food Allergy (Columbia University Press, 2015), was reviewed in The New York Times and given honourable mention in the Association of American Publishers’ Prose Awards for 2015.



The focus of this guidance is IgE-mediated food allergy, which is a type of food hypersensitivity that has been studied extensively and is associated with the most severe and immediately life-threatening allergic reactions, including anaphylaxis. Likewise, the discussions in this guidance of food allergens is limited to those foods that elicit IgE-mediated immune reactions.<sup>8</sup> [Footnote 8 - A food allergen may also be associated with reactions that are not IgE-mediated or not immune mediated.]”<sup>205</sup> (emphasis added)

### **International Food Safety Authorities Network**

It would be helpful if the description of “What is Food Allergy” in the FDA’s Draft Guidance and FDA’s Web site on pages about FALCPA and food allergens be augmented by including the following figure from the International Food Safety Authorities Network (INFOSAN), a global network of national authorities with a role in food safety, coordinated by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization

For example, on June 9, 2006, INFOSAN published Information Note No. 3/2006 Food Allergies,

“In 2003 the World Allergy Organization proposed a revised nomenclature for allergic and allergic-like reactions.<sup>206</sup> According to this proposal ([INFOSAN] figure 1), adverse non-toxic reactions to food should be termed food hypersensitivity. When an immunologic mechanism has been demonstrated the appropriate term is food allergy. Food allergy can further be characterized by whether the immunological mechanism involves IgE antibodies or not. Other reactions to food, previously referred to as “food intolerance”, should be called non-allergic food hypersensitivity.”<sup>207</sup>

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<sup>205</sup> <https://www.fda.gov/media/157637/download>

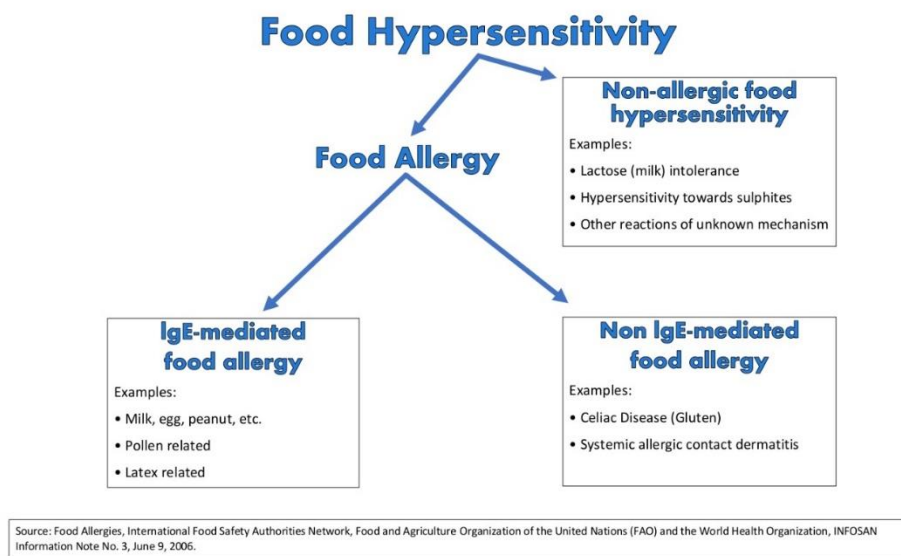
<sup>206</sup>

[https://web.archive.org/web/20060720104447/http://www.worldallergy.org/professional/allergic\\_diseases\\_center/nomenclature/nomenclaturesynopsis.shtml](https://web.archive.org/web/20060720104447/http://www.worldallergy.org/professional/allergic_diseases_center/nomenclature/nomenclaturesynopsis.shtml)

<sup>207</sup>

[https://web.archive.org/web/20170211164406/https://www.who.int/foodsafety/fs\\_management/No\\_03\\_allergy\\_June06\\_en.pdf](https://web.archive.org/web/20170211164406/https://www.who.int/foodsafety/fs_management/No_03_allergy_June06_en.pdf) (note that this is a recreation of INFOSAN Figure 1)

**Figure 6 - INFOSAN Figure 1**



The FDA’s Draft Guidance and the FDA’s Web site on food allergens should include some similar figures to INFOSAN Figure 1 and Figure 1 (with the Venn diagrams appearing earlier in these Comments) to help various stakeholders better visually understand how Celiac is a food allergy and Gluten is a food allergen.

As illustrated in Figure 1 in the Executive Summary of these Comments, there are several very important near-peer similarities between food allergies between a Celiac food allergy with Non-IgE-Mediated Mechanisms (Gluten) and typical IgE-Mediated Mechanisms: potentially life-threatening, the only treatment is to strictly avoid the food allergen(s), and consumers’ reliance on food labels to know what is safe to eat. Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE-Mediated mechanisms such as Celiac Disease. Additionally, those with a Non-IgE-Mediated food allergy to Gluten cannot outgrow their food allergy – Celiac is lifelong (until such time as a cure may be developed).<sup>208</sup>

While there are many similarities between food allergies with IgE-Mediated Mechanisms and Non-IgE-Mediated Mechanisms, including needing the same consumer protections with food labeling, it is also instructive to understand how Celiac Disease is uniquely complex since it sits at the intersection of food allergies,<sup>209</sup> auto-immune diseases<sup>210</sup> and digestive diseases.<sup>211</sup> Please

<sup>208</sup> This diagram graphic is intended to convey that Non-IgE-Mediated food allergy with Celiac Disease and typical IgE-Mediated food allergies are both really dangerous and deserve equal treatment with respect to consumer protection with food labeling. The adverse health effects are listed in alphabetical order, and these health dangers are an illustrative, but not exhaustive list. This diagram will be discussed in greater detail herein, but it should be noted that this expands and updates information as was included in Table 2-1 in FDA’s Draft Guidance Ref. 2.

<sup>209</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> (pages 5. 11); and <https://www.fda.gov/media/157637/download> (page 10)

see Figure 3 in the Executive Summary of these Comments. Figure 3 shows how Celiac can often be misunderstood. The complexity of this amalgam has seemingly made it more challenging for public servants, scientists and the Celiac community to address and protect the Celiac community's needs. A review of various descriptions of Celiac Disease and programs related thereto from Federal government agencies suggests that this complexity has also enabled the othering by various government officials of a food allergy with Non-IgE-Mediated mechanism for Celiac to be considered something other than/less serious than a food allergy and Gluten something other than/less serious than a food allergen.

### **Labeling Food Allergies**

When it comes to labeling food allergies, I agree in principle with Mun Cho, registered dietitian that the way we currently talk about food allergies minimizes the visibility of Non-IgE-Mediated food allergies, and the impact they have on families. For example, Cho wrote,

“Strict avoidance of the food trigger is a must, regardless of the type of food allergy. **Parents must be vigilant** with label reading and avoiding cross contact. The social, emotional and financial burden of food allergies are real, and they do not discriminate between the two types [IgE-Mediated and Non-IgE-Mediated].”<sup>212</sup> (emphasis in original)

“Celiac disease is not a food allergy per se, but rather an autoimmune disease where a lifelong avoidance of gluten is called for. If a patient consumes gluten, malabsorption (or the inability to absorb nutrients) occurs. In contrast, those with a gluten intolerance do not experience malabsorption, despite having disruptive gastrointestinal symptoms. Malabsorption can also occur in non-IgE allergies leading to failure to thrive.”<sup>213</sup>

“It’s time we talk about all allergies and better communicate the different types of symptoms for both types of allergies. I’m not trying to downplay the severity of IgE allergies. On the contrary, I strongly believe we need to talk about what anaphylaxis looks like, and how a reaction may or may not involve widespread hives. We also need to go over some of the less typical symptoms, such as vomiting and a sense of doom. Misconceptions around anaphylactic shock still abound.

So why does the language we use matter? It shapes the way we perceive and communicate. The way we currently talk about food allergies minimizes the visibility of non-IgE food allergies, and the impact they have on families. To the healthcare providers reading this, please do not take what I’m saying as a criticism. My hope is that we can change the way we talk about food allergies so that we do so in a more inclusive manner.”<sup>214</sup>

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<sup>210</sup> <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#>

<sup>211</sup> <https://www.niddk.nih.gov/health-information/digestive-diseases>

<sup>212</sup> <https://www.foodallergy.org/fare-blog/why-we-need-stop-referring-ige-mediated-allergies-true-food-allergies>

<sup>213</sup> <https://www.foodallergy.org/fare-blog/why-we-need-stop-referring-ige-mediated-allergies-true-food-allergies>

<sup>214</sup> <https://www.foodallergy.org/fare-blog/why-we-need-stop-referring-ige-mediated-allergies-true-food-allergies>

## **Labeling Gluten as Something Else Other than a Food Allergen Has Had Consequences in Terms of Undermining Perceptions of Public Health Importance of Consumer Protections for Celiacs**

The Boston Globe reported on how some servers in restaurants do not take the Gluten food allergy seriously and put people's lives at risk because they did not perceive Celiac as a true food allergy, but instead as a joke; they perceived a Gluten Free diet request as preference and not a medical requirement. It is my contention that the FDA and the Federal government's historical underserving of the Celiac community has helped perpetuate these governmental and societal biases by not using proper and consistent terminology to indicate the seriousness and life-threatening nature of Celiac Disease and the need for Gluten to be called a food allergen.

“Recall what a former cook at the Tavern on the Green in New York's Central Park copped to a few years back. Alleging that customers' gluten problems were all in their 'disturbed little heads,'<sup>215</sup> Damian Cardone boasted he had made a habit of secretly giving anyone ordering gluten free pasta the normal stuff with gluten and that they were no worse for it. (He seemed clueless that the most serious damage that celiac patients suffer takes place over time, not immediately.)

Then there was the waitress who posted an anonymous screed on Reddit<sup>216</sup> that went viral. It began: A server will never say this to your face but we all know your gluten allergy is fake.... You are just on a gluten-free diet and want attention. When I track down the author, Chelsea Welch, she admits she had written the post in frustration, after witnessing too much nonsense as a waitress in an Italian restaurant in St. Louis.”<sup>217</sup>

## **Foodborne Illness Provides an Analogy for Umbrella Terminology for “Food Allergy” and “Food Allergen”**

The FDA and the Federal government must view food allergy in a collective sense that does not exclude or other Gluten as a less serious food allergen than the Major Food Allergens. The FDA and the Federal government must also expressly communicate the terms “food allergy” and “food allergies” in a collective sense that does not exclude or other Celiac as a less serious food allergy or Gluten as a less serious food allergen.

Let's look at the terminology involving foodborne illness in the context of consumer protections. There are many different disease-causing germs that can contaminate foods, so there are many different foodborne infections (also called foodborne disease or food poisoning).<sup>218</sup> The key to understand here is that these are all referred to as foodborne illness, foodborne disease or food poisoning. The use of different terminology is not about creating a hierarchical level of importance or othering some forms of foodborne illness as less severe and therefore meritorious of less consumer protections.

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<sup>215</sup> <https://www.nydailynews.com/new-york/chef-damian-cordone-claims-ignores-gluten-free-requests-facebook-rant-article-1.114116>

<sup>216</sup>

[https://www.reddit.com/r/TalesFromYourServer/comments/1fl2y1/your\\_gluten\\_allergy\\_is\\_fake\\_and\\_i\\_hate\\_you/](https://www.reddit.com/r/TalesFromYourServer/comments/1fl2y1/your_gluten_allergy_is_fake_and_i_hate_you/)

<sup>217</sup> <https://www.bostonglobe.com/magazine/2015/10/14/why-food-allergy-fakers-need-stop/PB6uN8NF3eLWFjXnKF5A9K/story.html>

<sup>218</sup> <https://www.cdc.gov/foodsafety/foodborne-germs.html>

According to the CDC, “anyone can get food poisoning, but certain groups of people are more likely to get sick and to have a more serious illness. Their bodies’ ability to fight germs and sickness is not as effective for a variety of reasons. These groups of people are: Adults Aged 65 and Older, Children Younger Than 5 Years, People with Weakened Immune Systems, and Pregnant Women.”<sup>219</sup> Further, we do not offer foodborne illness protections because some people may be more likely to get foodborne illness. To the contrary, we strive to protect everyone against foodborne illness, but call out the special and incremental needs of those at-risk communities.

## **X. Comments on the “Food Allergen” Definition in the FDA’s Draft Guidance**

**“If they don’t give you a seat at the table, bring in a folding chair.”**

-- Representative Shirley Chisholm (D-12, NY), the first African-American Congresswoman<sup>220</sup>

I think that the crux of the problem with the FDA’s Draft Guidance is a definitional one whereby “Food Allergen” is described as:

“The food or component(s) of a food (often a protein) that elicits specific, IgE-mediated immunologic reactions” (Ref. 1 and Ref. 2).”

Based on that limiting definition, the FDA’s Draft Guidance seemingly excludes Gluten as a food allergen for consideration of mandatory labeling as a Major Food Allergen. In apparent justification of that exclusion, the FDA’s Draft Guidance also refers back to the Citizen Petition from 2008 for labeling Rye and Barley and its dismissive denial of the Petition (FDA Ref. 18 and FDA Ref. 22). See also section herein entitled, “The FDA Fell Short for a Decade in Protecting the Celiac Community (Example 2 September 10, 2008: Citizen Petition to Label Barley and Rye in 2008).

The FDA’s Draft Guidance excludes Gluten as a “Food Allergen” for consideration of mandatory labeling since the FDA in Table 1 defines Food Allergen as “The food or component(s) of a food (often a protein) that elicits specific, IgE-mediated immunologic reactions (Ref. 1 and Ref. 2).”

Accordingly, it is instructive to review Ref. 1 and Ref. 2. and see how Ref. 1 and Ref. 2 each expressly state that they do not discuss/cover Celiac Disease, a Non-IgE-Mediated mechanism with an adverse/allergic reaction to Gluten.

The bottom line is that the FDA’s decision making should not be a zero sum game for consumer protection with Major Food Allergens. In other words, it is not a binary choice meaning that only IGE-Mediated food allergies are meritorious of required labeling protection.

### **FDA’s Draft Guidance Ref. 1**

FDA’s Draft Guidance Ref. 1 refers to “Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-sponsored Expert Panel”, December 2010.

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<sup>219</sup> <https://www.cdc.gov/foodsafety/people-at-risk-food-poisoning.html>

<sup>220</sup> [https://history.house.gov/People/Listing/C/CHISHOLM,-Shirley-Anita-\(C000371\)/](https://history.house.gov/People/Listing/C/CHISHOLM,-Shirley-Anita-(C000371)/)

**“The Guidelines focus on diseases that are defined as FA (see section 2.1) and include both IgE-mediated reactions to food and some non-IgE-mediated reactions to food. The Guidelines do not discuss celiac disease, which is an immunologic non-IgE-mediated reaction to certain foods. Although this is an immune-based disease involving food, existing clinical guidelines for celiac disease will not be restated here.”**<sup>221</sup>

Ref. 1 was sponsored by the National Institute of Allergy and Infectious Disease (NIAID). It is instructive to review one key example of how the Federal government has historically underserved the Celiac community. As I often say, it’s tough to be fed, literally and figuratively, when you do not even have a seat at the table where decisions get made that impact the health and quality of life of 3 million Americans.

In addition to the historical underfunding of Celiac Disease research, it is illustrative to consider the following: Autoimmune Diseases Coordinating Committee (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. The ADCC meets once or twice yearly.”<sup>222</sup>

Up through at least May 2021, of the 52 members of the ADCC, there were 17 members representing specific diseases. A full one third of the ADCC members came from outside the NIH/NIAID. It appears that there through May 2021, 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).<sup>223</sup>

## **FDA’s Draft Guidance Ref. 2**

FDA’s Draft Guidance Ref 2. refers to the National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Food and Nutrition Board; Committee on Food Allergies. “Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy, Committee on Food Allergies: Global Burden, Causes, Treatment, Prevention, and Public Policy, Food and Nutrition Board, Health and Medicine Division, Virginia A. Stallings and Maria P. Oria, Editors” November 2016, which expressly states,

“Food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated. **The recommendations in this report focus on IgE mediated food allergies,** which have better defined underlying cellular mechanisms and physiological reactions. **Other food-related diseases, such as celiac disease, food intolerances (e.g., lactose intolerance) are not covered.**”<sup>224 225</sup>

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<sup>221</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf>

<sup>222</sup> <https://www.niaid.nih.gov/about/autoimmune-diseases-committee>

<sup>223</sup> <https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee>

<sup>224</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

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<sup>225</sup> Following are the other references to Celiac Disease in Ref. 2:

**“Other food-related diseases, such as celiac disease, or food intolerances, such as lactose intolerance, or toxicity of food additives, are not covered in this report because they were beyond the scope of the statement of task.”** (page 26) (emphasis added)

“Non-IgE-mediated food allergy reactions (e.g., food protein induced enterocolitis) are less common and the mechanisms of the reactions are less well characterized. **Celiac disease is a well-characterized, immune-mediated disease that has food as an exacerbating factor but will not be detailed in this report.**” (page 41) (emphasis added)

**“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) (emphasis added)

“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 [‘For an analysis on Food Allergen Labeling and Consumer Protection Act see Derr (When Food Is Poison), 2006.’], 7 (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) (emphasis added)

“Although no other specific federal or state policies cover higher education in regard to food allergies, some broader policies apply. For example, as noted earlier, food allergy might be considered a disability under the ADA. In fact, in 2009, the U.S. Department of Justice (DOJ) received a complaint about violations of the ADA public accommodations provision at Lesley University in Cambridge, Massachusetts, related to students with celiac disease and/or food allergy. **After concluding that violations had occurred, the DOJ entered into an agreement with the university “to ensure that its students with celiac disease and other food allergies can fully and equally enjoy the university’s meal plan and food services”** (DOJ, 2012). This was a key decision that will guide any future decision regarding implementation and enforcement of the ADA public accommodations provision.” (page 345) (emphasis added)

“BOX C-2 Study Exclusion Criteria - Studies seeking to prevent potential manifestations of food allergy (e.g., atopic eczema/dermatitis or asthma) but not including an explicit diagnosis of sensitization to food or food allergy or **studies investigating celiac disease were excluded**, as well as management guidance documents, narrative reviews, letters to the editor, commentaries, studies that used animal or in vitro models, ecological studies, and studies of transplant patients.” (page 448) (emphasis added)

“Autoimmune outcomes included were type 1 diabetes mellitus (defined serologically

FDA Ref. 2's Committee on Food Allergies: Global Burden, Causes, Treatment, Prevention, and Public Policy was chaired by Dr. Stallings, the Jean A. Cortner Endowed Chair in Gastroenterology, Director of the Nutrition Center at the Children's Hospital of Philadelphia, and professor of pediatrics at the Perelman School of Medicine at the University of Pennsylvania.<sup>226</sup> In total, there were 15 members of the Committee on Food Allergies: Global Burden, Causes, Treatment, Prevention, and Public Policy including Dr. Stallings and Dr. Taylor (who also served on the 2021 FAO/WHO Expert Consultation and Joint FAO/WHO Expert Committee on Food Additives).

FDA Ref. 2 states,

**“This activity [the research and writing of FDA Ref. 2] 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; and nonfederal sponsors: the Asthma and Allergy Foundation of America, the Egg Nutrition Center, Food Allergy Research and Education, the International Life Sciences Institute North America, the International Tree Nut Council Nutrition Research & Education Foundation, the National Dairy Council, the National Peanut Board, and the Seafood Industry Research Fund. Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.”**<sup>227</sup>  
(emphasis added)

Even though the taxpayer supported FDA Ref. 2<sup>228</sup> expressly stated that “Food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated” (page 4),<sup>229</sup> the FDA is defining Food Allergen based on two primary references that expressly excluded Celiac Disease and stated, “do not discuss celiac disease”, as well as Celiac is “not covered in this report because they were beyond the scope of the statement of task.” Additionally, the FDA is relying exclusively on Ref. 1 and Ref. 2 to define “food allergy” in the FDA Draft Guidance (page 7), and that is way too limiting. This is another example of how the Federal government has marginalized the healthcare and consumer protection needs of the Celiac community.

See Section herein entitled, “FDA References in FDAs Draft Guidance.”

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and/or clinically), celiac disease (defined serologically and/or clinically), inflammatory bowel disease, autoimmune thyroid disease, juvenile rheumatoid arthritis, vitiligo, or psoriasis.” (page 508)

<sup>226</sup> <https://www.chop.edu/doctors/stallings-virginia-a> , and

<https://www.med.upenn.edu/apps/faculty/index.php/g275/p7817>

<sup>227</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)

<sup>228</sup> “This activity 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”, page ii,

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

<sup>229</sup> [https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf\\_NBK435943.pdf](https://www.ncbi.nlm.nih.gov/books/NBK435943/pdf/Bookshelf_NBK435943.pdf)



## XI. FALCPA Fell Short in Safeguarding Celiacs

**“Coming from the anaphylactic egg allergy world to celiac land has been crazy.  
I am blown away by the crappy labeling practices for gluten.  
The egg is a scary allergy but SO MUCH EASIER to shop for.”<sup>230</sup>  
--K.S., June 2022**

In order to understand how FALCPA muted the seriousness of Celiac Disease, it is instructive to review the history of FALCPA, as well as the 1999 FAO/WHO Expert Consultation with the 1999 Codex Criteria.

According to the Food and Agriculture Organization of the United Nations,

“The list of 8 major foods and ingredients (**cereals containing gluten**, crustacea, egg, fish, peanut and soybeans, milk, tree nuts) known to cause hypersensitivity [big 8 food allergens] was included into the ‘Codex General Standard for the Labelling of Packaged Foods’ (GSLPF)<sup>231</sup> in 1999.”<sup>232</sup>

On May 9, 2002, Senator Ted Kennedy (D, Massachusetts) addressed the U.S. Senate:

“American families deserve to feel confident about the safety of the food on their tables... The Food Allergen Consumer Production Act will require that food ingredient statements on food packages identify in common language when an ingredient, including a flavoring, coloring, or other additive, is itself, or is derived from, one of the eight main food allergens, or from grains containing Gluten.”<sup>233</sup>

The clear legislative intent of the FALCPA was to protect those consumers with food allergies and Celiac Disease, both of which involve adverse reactions to proteins in food that are immune-mediated to proteins. The requirement that Gluten be labeled on all packaged foods in the U.S. was expressly contemplated in 2002 in the original versions of the FALCPA:

- **S. 2499**<sup>234</sup> – “The Food Allergen Consumer Protection Act of 2002,” as introduced by Senator Kennedy [and Senator Clinton (D, New York)], would require products to list in bold face type the common name any of the eight major food allergens (milk, egg, fish, crustacea, peanuts, tree nuts and soybean), proteins derived from those substances and other ***Glutens such as rye, barley, oats, and triticale***,” according to Inside Health Policy’s FDA Week, August 9, 2002 (page 6). (emphasis added) “For purposes of this Act, the term ‘known food allergen’ means any of the following: A) Milk, Egg, Fish, Crustacea, Tree nuts, **Wheat**,

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<sup>230</sup> As posted on Facebook in a community group with more than 11,000 members where parents and caregivers to children with Celiac and Non-Celiac Gluten Sensitivities share their knowledge and lived experiences with other members who are similarly situated.

<sup>231</sup> [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS\\_001e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/pt/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf)

<sup>232</sup> <https://www.fao.org/food-safety/news/news-details/fr/c/1398460/>

<sup>233</sup> <https://www.govinfo.gov/content/pkg/CREC-2002-05-09/pdf/CREC-2002-05-09-senate.pdf>

<sup>234</sup> <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00>

Peanuts, and Soybeans... C) *Other Grains containing Gluten (Rye, Barley, Oats, and Triticale)*.”<sup>235</sup>

- **H.R. 4704**<sup>236</sup> - The “Food Allergen Consumer Protection Act,” as introduced by Representative Nita Lowey (D, NY-18) in 2002, expressly included “**Grains Containing Gluten**” among the “allergens” within the scope of the legislation’s mandatory labeling scheme. H.R. 4704, 107th Cong. [Section] 3 (2d Sess. 2002). “(3) For purposes of this Act, the term ‘known food allergen’ means any of the following: (A) Milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans” and “Other grains containing gluten (rye, barley, oats, and triticale).”<sup>237</sup>

While the FALCPA was being debated in Congress, the food industry lobbied against the FALCPA in its entirety and insisted that voluntary labeling of food allergens was sufficient. However, the food industry seemingly evolved its position and recognized that there was a convergence of factors, a perfect storm, that finally gave Congress the appetite and resolve to pass the FALCPA. With that recognition, the food industry then demanded certain compromises and concessions.

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] had charged that scientifically, Gluten is an intolerance not an allergen.**”<sup>238</sup>

This was a false premise which was unfortunately not rebutted, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate. The lobbyists seemingly conflated Celiac Disease (a food allergy, auto-immune disease and digestive disease) with Gluten intolerance. As detailed below, information suggests that it was the American Bakers Association and/or American Farm Bureau which argued that scientifically, Gluten is an intolerance, not an allergen. Fast forward to 2022, and the FDA’s Draft Guidance suggests that it still conflates Gluten food allergy with lactose intolerance.<sup>239</sup>

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<sup>235</sup> [https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2\\_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf](https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf)

<sup>236</sup> <https://www.congress.gov/bill/107th-congress/house-bill/4704>

<sup>237</sup> <https://www.congress.gov/bill/107th-congress/house-bill/4704>

<sup>238</sup> [https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2\\_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf](https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_3b58cb1248eb41e8bff67c2c2c3c2f80.pdf)

<sup>239</sup> “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.” Source: <https://www.fda.gov/media/157637/download>

On September 20, 2002, the Center for Science in the Public Interest (CPSI) reported that S.2499 had become “stymied” in the Senate Health, Education, Labor and Pensions (HELP) Committee which was chaired by Senator Kennedy,

“Senate Democrats and Republicans have been working on compromise language to move the legislation out of the Health, Education, Labor, and Pension committee, which Senator Kennedy chairs. Even though Democrats have offered significant concessions, key Republicans on the committee have sided with the food industry, which generally opposes any labeling changes, according to CSPI.”<sup>240</sup>

According to When Food Is Poison,

“Most of the groups involved in advocating for the FALCPA were food allergy groups [such as FAAN, the Food Allergy & Anaphylaxis Network that had been working on food allergy labeling for 20 years]. In contrast, ACTF [American Celiac Task Force, which later became the American Celiac Disease Alliance], which was composed of leaders of national Celiac Disease support groups, medical professionals, research institutions, and representatives of gluten-free food manufacturers, represented individuals with Celiac Disease. ACTF acted as the voice of the celiac community during the push to pass the FALCPA. It was formed in 2003 after the Celiac Disease prevalence study results were released by the University of Maryland Center for Celiac Research. This study ‘opened the doors for people paying much more attention’ to Celiac Disease, according to ACTF Co-chair Andrea Levario... ‘This was a true grassroots effort,’ Levario says. ‘Within the span of 18 months, ACTF was created, it mounted a lobbying effort, and it witnessed the successful passage of the FALCPA. ACTF ‘has no money. This was all done strictly via word of mouth, via the Internet, via e-mail... We were a voice in all this, and it was strictly, totally grassroots, every step of the way, which is pretty phenomenal.’”<sup>241</sup>

“At least one of the three national celiac disease support groups, the Celiac Sprue Association (CSA), supported the FALCPA but advocated for the further labeling of all gluten-containing source ingredients. [CSA is now part of the National Celiac Association.<sup>242</sup>] A provision in a 2002 bill that called for the inclusion of all gluten-containing grains in an allergen labeling scheme was dropped as a part of compromises reached while the bill was in committee.”<sup>243</sup>

Unfortunately, the pleas of the Celiac Sprue Association and others -- that the FALCPA’s original language remain which required that Gluten be labeled -- were ignored. Their thought leadership and efforts at the time could not compete with the well-funded lobbying efforts of the food industry looking for any negotiated concessions (wins) to the FALCPA. In spite of the 1999 Codex Criteria,<sup>244</sup> and in spite of the fact that Gluten disclosures were required on all food labels

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<sup>240</sup> <https://www.cspinet.org/new/200209201.html>

<sup>241</sup> <https://www.jstor.org/stable/26660870> , Page 102, Footnote 217.

<sup>242</sup> <https://nationalceliac.org/>

<sup>243</sup> <https://www.jstor.org/stable/26660870> , Page 142, Footnote 434 and 435.

<sup>244</sup> “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

in the original FALCPA bills and their respective amendments, some critics in the food industry were able to exert their influence on FALCPA's final language as part of a grand bargain. 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.**"<sup>245</sup> (emphasis added)

According to Open Secrets, there were three unique organizations that registered to lobby on S.741: Food Allergen Labeling and Consumer Protection Act of 2004, including: the American Farm Bureau, the Center for Science in the Public Interest and the American Bakers Association (ABA).<sup>246</sup> The ABA touts itself as the "voice of the baking industry since 1897"<sup>247</sup> for its 300+ members,<sup>248</sup> and according to Paul Abenante, ABA President & CEO,

"ABA is a voluntary trade association dedicated to representing the interests of the wholesale baking industry before the United States Congress, federal agencies, state legislatures, and international regulatory authorities. ABA tackles key issues facing the **grain-based foods industry** and initiates key reforms to make positive impacts on the industry. ABA represents approximately 80% of the wholesale bakeries in the U.S. as well as their suppliers...In effect, ABA provides a comprehensive resource to the baking industry that can address most, if not all, sectors of the **grain-based foods industry**, operations and activities."<sup>249</sup> (posted on April 17, 2004) (emphasis added)

According to When Food Is Poison, "Senator Kennedy introduced sister bills to those introduced in the House and helped work out a compromise amendment that was critical to the enactment of the FALCPA."<sup>250</sup> The subsequent compromise bill served as the basis of S. 741, the FALCPA.<sup>251</sup>

It is instructive to review FALCPA's Findings in Section 2, which expressly references Celiac Disease and the "recommended treatment is avoidance of glutens in foods" just like "a food allergic consumer must avoid the food to which the consumer is allergic."

#### **"Section 202. Findings.**

Congress finds that--

(1) it is estimated that—

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containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products."

<sup>245</sup> [https://fd19a27e-adc0-4b2e-a80e-](https://fd19a27e-adc0-4b2e-a80e-88598593a644.usrfiles.com/ugd/fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf)

[88598593a644.usrfiles.com/ugd/fd19a2\\_e352e90b251941a1a5482f10f835f7c8.pdf](https://fd19a2_e352e90b251941a1a5482f10f835f7c8.pdf)

<sup>246</sup> <https://www.opensecrets.org/Lobby/billsum.php?id=s741-108>

<sup>247</sup> <https://vimeo.com/455675294>

<sup>248</sup> <https://americanbakers.org/membership/member-list>

<sup>249</sup>

<https://web.archive.org/web/20040417021001/http://www.americanbakers.org/about/president.htm>

<sup>250</sup> <https://www.jstor.org/stable/26660870> , page 110

<sup>251</sup> <https://www.congress.gov/bill/108th-congress/senate-bill/741/all-info>

- (A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and
  - (B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;
- (2)
- (A) eight major foods or food groups -- milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans -- account for 90 percent of food allergies;
  - (B) at present, there is no cure for food allergies; and
  - (C) a food allergic consumer must avoid the food to which the consumer is allergic;...
- (6)
- (A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;
  - (B) the current recommended treatment is avoidance of glutes in foods that are associated with celiac disease; and
  - (C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population.”<sup>252</sup> (emphasis added)

Unlike the mandatory FALCPA labeling scheme for the Big 8 food allergens in the U.S., Gluten labeling is permissive (voluntary), in the U.S.

In other words, the information strongly suggests that the Celiac community took one for the proverbial team -- the food allergy community -- when the language for the labeling of Gluten was revised from mandatory to voluntary in order to get the FALCPA passed which required labeling of the Big 8 food allergens. This suggests a generosity of spirit by the Celiac community that in addition to the voluntary labeling of Gluten, the Celiac community’s consumer protection needs would be addressed down the road with mandatory labeling of Gluten as a Major Food Allergen. Moreover, there had been a hope that FARE and others would have opened their umbrella wider to embrace Gluten as a food allergen, but to date they have not really done so since their focus appears to have been exclusively on IgE-Mediated food allergies that have the potential to be immediately life-threatening.

In addition to Senator Jeff Sessions (R, Alabama) sponsoring S.741,<sup>253</sup> there was broad bipartisan support for the FALCPA in the Senate with a total of 21 Co-Sponsors (10 Democrats and 11 Republicans) including: Senators Wayne Allard (R, Colorado), Jeff Bingaman (D, New Mexico), Susan Collins (R, Maine), Larry Craig (R, Idaho), Mike Crapo (R, Idaho), John Ensign (R, Nevada), Judd Gregg (R, New Hampshire), Tom Harkin (D, Iowa), Blanche Lincoln (D, Arkansas), Zell Miller (D, Georgia), Richard Shelby (R, Alabama), Pete Domenici (R, New Mexico), Mike Enzi (R, Wyoming), Gordon Smith (R, Oregon), Patty Murray (D, Washington), Orrin Hatch (R, Utah), Mary Landrieu (D, Louisiana), Ron Wyden, D, Oregon), Mark Pryor (D, Arizona), Dick Durbin (D, Illinois), and Maria Cantwell (D, Washington).

Food allergies and Celiac Disease are bipartisan issues since these health issues impact all Americans from every state, from every political party, from every political ideology, etc.

<sup>252</sup> <https://www.fda.gov/media/77570/download>

<sup>253</sup> <https://projects.propublica.org/represent/bills/108/s741>

## **The Watered Down FALCPA and The Resulting Impact on 3 Million Americans with Celiac Disease, Plus Their Parents, Caretakers and Loved Ones**

Since January 1, 2006, FALCPA has *required* that the top 8 Major Food Allergens must be labeled on all food products in the U.S. While there are critics about how FALCPA “fell short of true protection of food allergy sufferers,” this was nonetheless a watershed moment for the IgE-Mediated food allergy community.<sup>254</sup>

However, the Celiac community continued to experience gut-wrenching pain by having to wait a full decade for any type of *voluntary* FALCPA labeling protections to be enacted. It is instructive to understand how FALCPA fell short in so many ways in protecting the Celiac community. According to “When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004”:

“The FALCPA contains a number of provisions designed to address food allergen safety concerns not met by the labeling requirements and to improve scientific, medical, and public knowledge about food allergies. The FALCPA directs that within two years after its enactment, the Secretary [of Health and Human Services] must issue a proposed rule to define and permit voluntary use of the term ‘gluten-free’ on food labels. The FALCPA directs FDA to issue a final rule by August 2008. The House Committee Report (H.R. Rep. No. 108-608<sup>255</sup> at 18) on the FALCPA states that, **‘[g]iven the devastating nature**

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<sup>254</sup> “Despite this important step forward, FALCPA left unregulated the use precautionary statements that warn consumers about the possibility of allergen contamination.<sup>4</sup> This failure has left a back door wide open for makers of foods mark their products with blanket warnings of the potential presence of allergens, regardless of whether they pose an actual risk to consumers. This action may then preclude potential tort liability from consumers who suffer allergic reactions the items, and disables the Food and Drug Administration (FDA) from declaring the products misbranded or adulterated.<sup>5</sup> Food manufacturers thus have a great incentive to use these warnings rather than to monitor products that do not specifically include one of the eight major allergens as an ingredient. Simultaneously, food allergic consumers may waive any right to litigate allergic reactions if they consume foods bearing precautionary warnings. FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants.<sup>6</sup> Restaurants present danger to food allergy sufferers because they lack uniform methods for informing customers of the contents of food and the possibility of allergen contamination. These consumers are instead left to rely on the assurances of wait staff and indirect communication with kitchen workers and chefs.” Source: Roses, Jonathan B. “Food allergen law and the Food Allergen Labeling and Consumer Protection Act of 2004: falling short of true protection for food allergy sufferers.” *Food and drug law journal* vol. 66,2 (2011): 225-42, ii. <https://www.jstor.org/stable/26661195> .

Also see Boyd, Marie C., “Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants.” *Oregon law review* 97 (2018): 109, [https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=2203&context=law\\_facpub](https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=2203&context=law_facpub)

<sup>255</sup> Rep. Barton, Joe. “Minor Use And Minor Species Animal Health Act Of 2004; Food Allergen Labeling And Consumer Protection Act Of 2004.” House of Representatives, 108<sup>th</sup> Congress, 2<sup>nd</sup> Session, Report 108-608, 15 July 2004. chrome-extension://efaidnbmninnibpcapjpcgclclefindmkaj/<https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf> . Accessed 13 May 2022.

**of Celiac Disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.**’ Currently, there is no standard definition of ‘Gluten Free’ in the United States and studies have found that some products proclaiming themselves ‘Gluten Free’ may contain Gluten. The FALCPA calls for the Secretary to consult with experts and stakeholders when drafting the rule.”<sup>256</sup> (emphasis added; page 119)

“While this provision to define ‘Gluten Free’ is a significant step in the right direction, use of this declaration by manufacturers merely is voluntary rather than mandatory. Although people with Celiac Disease will be able to trust ‘Gluten Free’ declarations beginning in 2008 [which did not occur until 2014], **the degree to which safety and convenience will improve for those with Celiac Disease depends on how widespread voluntary usage of the Gluten Free claim becomes. Earlier legislative allergen labeling efforts included provisions requiring the Secretary of HHS to assess, after a ‘Gluten Free’ standard is defined, whether additional labeling of Gluten is necessary on the label.** [‘Bills introduced in the 107<sup>th</sup> Congress, in addition to requiring the promulgation of a standard for ‘gluten-free,’ called for the Secretary of HHS to assess ‘whether additional requirements for the labeling of gluten are warranted and necessary to better inform individuals with celiac disease, and if other labeling is warranted and necessary, identify] the types of such labeling.’ S. 3001<sup>257</sup> and H.R. 5747<sup>258</sup>, 107<sup>th</sup> Cong. Section 6(d) (2d Sess. 2002); see also S. 2499<sup>259</sup>, 107<sup>th</sup> Cong. Section 6(d) (2d Sess. 2002); S. Rep. No. 107-322<sup>260</sup>, at 8 (accompanying S. 2499<sup>261</sup>, as reported in Senate). (‘The committee also expects the Institute of Medicine report to inform a report by the Secretary to Congress on whether additional requirements for the labeling of gluten in food associated with celiac disease are warranted and necessary to better inform individuals with celiac disease. If the Secretary finds that other labeling of gluten in food associated with celiac disease is warranted and necessary, the report is to identify the types of such labeling and should describe why the different types of labeling are

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<sup>256</sup> 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.

<sup>257</sup> Sen. Kennedy, Edward M. [D-MA]. “S.3001 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/3001> . Accessed 13 May 2022.

<sup>258</sup> Rep. Lowey, Nita M. [D-NY-18]. “H.R.5747 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/house-bill/5747?s=1&r=21> . Accessed 13 May 2022.

<sup>259</sup> Sen. Kennedy, Edward M. [D-MA]. “S.2499 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00> . Accessed 13 May 2022.

<sup>260</sup> Sen. Kennedy, Edward M. “Food Allergen Labeling And Consumer Protection Act.” Senate, 107th Congress, 2nd Session, Report 1-7-322, 17 October 2002. <chrome-extension://efaidnbnmnibpcajpcglclefindmkaj/https://www.congress.gov/107/crpt/srpt322/CRP-T-107srpt322.pdf> . Accessed 13 May 2022.

<sup>261</sup> Sen. Kennedy, Edward M. [D-MA]. “S.2499 - Food Allergen Labeling and Consumer Protection Act.” 107th Congress (2001-2002.) <https://www.congress.gov/bill/107th-congress/senate-bill/2499/summary/00> Accessed 13 May 2022.

warranted and necessary.’) **This provision was cut from the FALCPA.**”<sup>262</sup> (page 144) (emphasis added)

**“The clear labeling of wheat under the FALCPA, in fact, may have the perverse effect of harming those who must avoid Gluten. A Gluten Free product always is wheat-free, but the reverse is not true. Children or caregivers of children with Celiac Disease may assume incorrectly that a wheat-free product is Gluten Free if they are not familiar with or do not remember the various terms for gluten-containing ingredients (e.g., rye, barley, and malt) besides wheat... It is clear, however, that including Gluten Containing Grains besides wheat in the FALCPA’s allergen labeling scheme, expressly requiring FDA to consider Celiac Disease in its ingredient exemption decisions and requiring the ‘Gluten Free’ declaration on products without Gluten could have gone significantly further to assist people living with this [Celiac] Disease.”**<sup>263</sup> (pages 143-145) (emphasis added)

It is no wonder that in explaining how Celiac Disease impacts their everyday life, the Celiac Disease Foundation has found that “75% of people find it difficult to explain their dietary needs to others.”<sup>264</sup>

## **XII. The FDA Fell Short for a Decade in Protecting the Celiac Community**

**“What’s past is prologue!”**  
William Shakespeare

In “The Tempest”, Antonio’s words -- “what’s past is prologue” -- have come to convey a double meaning. The optimistic interpretation is that historical actions that have transpired prepare us for opportunities to come. In other words, what’s already happened sets the stage for the really important work that can lead to uplifting empathy, change, happiness and peace. The alternate, more cynical view, would be that what took place in the past inevitably repeats itself because we do not learn from our experiences and mistakes.

As it pertains to the FDA’s Draft Guidance, is the FDA destined to repeat its mistakes of the past or can the past inform the present to take care of underserved communities like the Celiac community with mandatory labeling of Gluten on packaged foods? Unfortunately, the FDA’s Draft Guidance suggests a more cynical view -- a gut-wrenching reminder of how far we have yet to travel as a nation -- that what took place in the past 18 years inevitably repeats itself because the FDA has not learned from its mistakes and shortcomings.

In addition to FALCPA falling short, it is instructive to review how the FDA fell short for a decade in terms of implementing the Congressional mandate of providing consumer protection to

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<sup>262</sup> 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.

<sup>263</sup> 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.

<sup>264</sup> <https://www.facebook.com/photo?fbid=418649703637203&set=a.366572858844888>



the Celiac community. After FALCPA was signed into law by President George W. Bush on August 2, 2004, mandatory labeling of the top 8 Major Food Allergens began on January 1, 2006 (Public Law No: 108-282). However, it took the FDA a decade to implement the voluntary labeling scheme of Gluten Free products on August 5, 2014 (six years past the Congressionally imposed deadline). Congress, consumers and scientists were outraged with the FDA slow-walking this process which lagged behind peer countries to the United States.

Prior to FALCPA, there was a prevailing school of thought with the assumption of risk, “caveat emptor” or let the buyer beware. FALCPA helped to mitigate allergic responses to the top 8 Major Food Allergens, but with respect to the Celiac community and allergic responses to Gluten, the slow walk of the FDA in undertaking the Gluten Free final rule in 2014 suggested an indifference to the saying, let the buyer be ill, and the consumer protection needs of the Celiac community.

According to the FALCPA of 2004,

“Not later than 2 years after the date of enactment of this Act [August 2, 2006], the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term ‘gluten-free’ on the labeling of foods. Not later than 4 years after the date of enactment of this Act [August 2, 2008], the Secretary shall issue a final rule to define, and permit use of, the term ‘gluten-free’ on the labeling of foods.”<sup>265</sup>

On January 23, 2007, the FDA published its proposed rule on the voluntary labeling of Gluten Free products.<sup>266</sup> that for all intents was the final rule ultimately enacted on August 5, 2014. At that point in 2007, the U.S. lagged way behind our peer countries which had all set labeling standards for Gluten Free foods. This unnecessary delay happened notwithstanding the House of Representatives Report on FALCPA stating, “[g]iven the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.”<sup>267</sup> The FDA had acknowledged that FALCPA required the FDA to issue a proposed rule that will define and permit the voluntary use of the term Gluten Free on the labeling of foods by August 2006 and a final rule no later than August 2008.<sup>268</sup>

### **Perfect is the Enemy of Good**

While the consumer protections established by FALCPA and the FDA were far from perfect, the protections were a step in the right direction. That said, in reflecting on the decade long process to implement voluntary Gluten Free labeling, Voltaire’s “perfect is the enemy of good” comes to mind.

On April 28, 2011, The Washington Post reported,

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<sup>265</sup> <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

<sup>266</sup> <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

<sup>267</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

<sup>268</sup> <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#q21>

“For seven years, the Food and Drug Administration has been trying to answer this question: What does it mean to be gluten-free? That is roughly the time it took to build a tunnel beneath the English Channel to connect Britain and France... Three years after the congressional deadline [in 2008 to define a Gluten Free rule as mandated by FALCPA], the FDA is still working on that question, a spokeswoman said. The agency has said the issue is complicated, requiring analyses of various technical issues, including how well manufacturers and regulators can reliably test for the presence of gluten and whether oats are a source of gluten. The agency held a public meeting in 2005, inviting input from millers, foodmakers, medical experts and others, and published a proposed rule in 2007. And then it continued to study the matter. **Meanwhile, Canada, Brazil, Australia and an international body -- the Codex Alimentarius Commission -- have all set labeling standards for gluten-free items. In most cases, that standard is 20 parts per million:** A food can be labeled gluten-free if it contains less than 0.0007 of an ounce of gluten for every 2.2 pounds of food. That level was chosen largely because it’s the minimum amount of gluten that can be reliably detected.”<sup>269</sup>

“Under a 2004 law, Congress gave the FDA until 2008 to establish a uniform definition for companies that want to label their products as gluten-free. But that deadline has come and gone.

‘The FDA has spent years calling upon experts to have open-forum debates, town hall meetings — we’ve been having reiteration and reiteration,’ said Alessio Fasano, medical director of the Center for Celiac Research at the University of Maryland School of Medicine. ‘They’ve been reiterating and listening to Grandma, Grandpa, people on the street corners... I really don’t understand why it’s lingering up in the air when it really should be a no-brainer.’”<sup>270</sup>

“And that [3 years after deadline, FDA still has not defined gluten-free] has caused an explosion in gluten-free foods. The market is projected to reach \$2.6 billion next year, up from \$100 million in 2003. Gluten-free cereal, snacks and other foods carry a premium price, creating an alluring growth market for food companies.”<sup>271</sup>

## Let Them Eat Cake

In May 2011, seven years after FALCPA was signed into law, John Forberger,<sup>272</sup> a triathlete, and Jules Shepard,<sup>273</sup> author of “The First Year: Celiac Disease and Living Gluten-Free,” were frustrated by the lack of progress by the Federal government on the labeling to protect the Celiac community. As part of the Gluten Free Food Labeling Summit, these patient advocates developed a plan to build the world’s tallest Gluten Free cake.<sup>274</sup> Mr. Forberger and Ms. Shepard

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<sup>269</sup> [https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E\\_story.html](https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html)

<sup>270</sup> [https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E\\_story.html](https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html)

<sup>271</sup> [https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E\\_story.html](https://www.washingtonpost.com/politics/3-years-after-deadline-fda-still-hasnt-defined-gluten-free/2011/04/22/AFRq6i8E_story.html)

<sup>272</sup> <https://www.rutgers.edu/news/rutgers-alum-leads-efforts-protect-those-celiac-disease>

<sup>273</sup> <https://gfjules.com/how-we-built-the-world-s-tallest-gluten-free-cake-and-why/>

<sup>274</sup> <https://web.archive.org/web/20110511034354/http://1in133.org/>

rallied leaders throughout the Celiac community including Dr. Fasano, Rep. Lowey and FDA Deputy Commissioner Taylor to join them on May 4, 2011, in Washington, D.C. to kick-off Celiac Awareness Month. Their goal was to refocus attention on the way overdue labeling rules to protect the Celiac community. Their effort, along with the weight of the world's largest gluten-free cake, had an impact that resonated across the country.



World's Largest Gluten Free Cake, Gluten Free Labeling Summit, Embassy Suites D.C., Convention Center, Washington, D.C., May 4, 2011

On August 10, 2011, Mike Taylor, former FDA Deputy Commissioner for Food and Veterinary Medicine, who wrote an article, "Why the Government is Regulating Gluten-Free Foods" in The Atlantic,

"For people with celiac disease, gluten can cause serious health conditions. It's time for them to know their food is safe... **We pledged to move promptly to issue a final rule defining 'gluten free' next year [2012].** This will have a real impact on consumers with celiac disease who now have to navigate the 'gluten free' labels on their grocery store shelves hoping that consuming a particular product won't bring on any of the painful symptoms of their illness, such as abdominal pain or vomiting. Or worse yet lead to chronic serious health effects such as infertility or intestinal cancers, because exposure to gluten over time can rob their bodies of the ability to properly absorb nutrients from foods."<sup>275</sup> (emphasis added)

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<sup>275</sup> <https://www.theatlantic.com/health/archive/2011/08/why-the-government-is-regulating-gluten-free-foods/243415/>

On October 2, 2012, consumer frustration with the FDA missing the 2008 Congressionally imposed deadline to establish a Gluten Free labeling scheme grew. One example manifested itself when a consumer, “J.I.”, posted a petition on the White House Web site for President Barack Obama which stated, “WE THE PEOPLE ASK THE FEDERAL GOVERNMENT TO TAKE OR EXPLAIN A POSITION ON AN ISSUE OR POLICY: Finalize Standards for GLUTEN-FREE Labeling.”

**The October 2, 2012 petition was signed by 40,639 people**, and Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine at the Food and Drug Administration, only responded on or after August 5, 2013 (when the long-delayed proposed Final Rule was issued).<sup>276</sup>

On February 14, 2013, Dr. Whitney Caudill of Manchester College of Pharmacy in Indiana wrote an article, “A response to Verrill et al: Food label usage and reported difficulty with following a gluten-free diet among individuals in the USA with coeliac disease and those with noncoeliac gluten sensitivity”,

“I have coeliac disease (“CD”). CD is a systemic autoimmune disorder caused by exposure to gluten in genetically susceptible people. (Fasano & Catassi, 2012). Gluten is a protein found in wheat, rye, and barley and the derivatives of each. The immune response activated in CD causes the body to attack gluten as if it is an antigen and cause symptoms including chronic diarrhea, weight loss, bloating, and chronic fatigue, among others. (Fasano & Catassi, 2012). Untreated CD can result in osteoporosis, neurologic disorders, and cancer. (Fasano & Catassi, 2012)...

In order for a product to be gluten-free it must be safely free of all gluten: wheat, barley, and rye. Unfortunately, the current law does not meet that standard. The definition of major food allergen includes only wheat. 21 U.S.C. § 321(qq) (2012). It does not include rye and barley, and the derivatives, all of which contain gluten. **The FDA’s definition of major food allergen must include the term ‘gluten’ or the words ‘wheat, barley, and rye’ to safely protect citizens with CD or NCGS.**

Additionally, the FALCP [sic – “FALCPA”] charged the FDA to have final standards for gluten-free labeling in place by 2008, no later than four years after the enactment of FALCP. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. no. 108-282, 118 Stat. 910 (2004). In 2007, following up on the mandate from FALCP, the FDA issued a proposed rule: ‘Food labeling; Gluten-Free Labeling of Foods.’ The proposed rule states that a food is gluten-free if the food does not contain any of the following:

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<sup>276</sup> “The Food Allergen Labeling and Consumer Protection Act required Health and Human Services to set a gluten-free labeling rule by 2008 to aid people with celiac disease, a life-threatening autoimmune condition. The only known treatment is a strict gluten-free diet. An estimated 3 million Americans have celiac and even more may have non-celiac gluten sensitivity. Without adequate labeling, those on a medically prescribed gluten-free diet struggle to make safe food choices and stay well. Children with celiac cannot participate in the National School Lunch Program when food service staff cannot determine if products are gluten-free. Congress did its part by passing the law. It is up to the White House to protect the health of millions of adults and children by finalizing the rule NOW.” Source: <https://petitions.obamawhitehouse.archives.gov/petition/finalize-standards-gluten-free-labeling/>

1. an ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains;
2. an ingredient derived from these grains and that has not been processed to remove gluten;
3. an ingredient derived from these grains and that has been processed to remove gluten, if it results in the food containing 20 or more parts per million (ppm) gluten; or
4. 20 ppm or more gluten.

Food Labeling; Gluten-Free Labeling of Foods, 72 Fed. Reg. 2795 (proposed January 23, 2007) (to be codified at 21 CFR Part 101).<sup>277</sup> These standards are consistent with those adopted in European in 2012. (Verrill, *et al.*, 2013)...

It has been nearly a decade since the FDA was empowered by Congress to establish final rules on gluten-free labeling in the United States. The FDA has taken no final action. The FDA has acknowledged that the lack of standards for gluten-free labeling has created difficulty for patients with CD and NCGS to successfully adhere to the medically required GFD. The FDA has stated that ‘more research is needed in this area.’ (Verrill, *et al.*, 2013). Yet, the FDA has not acted on rules it proposed over five years ago that could assist patients who must adhere to a GFD. It is time for the FDA to take action.”<sup>278</sup>

On July 15, 2013, Rep. Nita Lowey, one of the original sponsors of FALCPA stated,

“I am frustrated that, a decade since the passage of the Food Allergen Labeling and Consumer Protection Act, the FDA has yet to lay out clear standards for the regulation of Gluten Free labeling.”<sup>279</sup>

On August 5, 2013, the FDA proposed a Final Rule, “Food Labeling; Gluten-Free Labeling of Foods” with a compliance date of this final rule set as August 5, 2014.<sup>280</sup> According to Dr. Linda Verrill with the FDA’s Center for Food Safety and Applied Nutrition,

“To comply with a directive in FALCPA, in 2007, the FDA published a proposed rule identifying the criteria the agency proposed to use to define the term GF for voluntary use on the labels of foods under FDA’s regulatory purview (US Food and Drug Administration, 2007). In addition to other possible requirements related to the definition of GF, this rulemaking proposed that a food labelled GF cannot contain 20 or more parts per million (ppm) gluten.”<sup>281</sup>

<sup>277</sup> <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

<sup>278</sup> “In Response: It is Time for Action by the United States Food and Drug Administration on Gluten-Free Labeling Rules”, Whitney Jane A. Caudill, J.D., Associate Dean for Administration & Finance, Associate Professor, Manchester University College of Pharmacy”, February 14, 2013, <https://journalofhumannutritionanddieteticseditor.wordpress.com/2013/02/14/a-response-to-verrill-et-al-food-label-usage-and-reported-difficulty-with-following-a-gluten-free-diet-among-individuals-in-the-usa-with-coeliac-disease-and-those-with-noncoeliac-gluten-sensitivity/>

<sup>279</sup> <https://www.beyondceliac.org/celiac-news/gluten-in-medicine-disclosure-act-an-interview-with-new-york-state-rep-nita-lowey/>

<sup>280</sup> <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>

<sup>281</sup> Verrill, L *et al.* “Food label usage and reported difficulty with following a gluten-free diet among individuals in the USA with coeliac disease and those with noncoeliac gluten

On August 5, 2014, Mr. Taylor also wrote a “New Era of Gluten Free Labeling”, “For most of us, choosing a meal is not a make or break decision. Most people prepare a meal without fearing that it will endanger their health. That’s not the case with people who suffer from celiac disease. I’ve learned first-hand from talking with people with the disease how much it means to them to be able to select gluten-free foods with confidence.”<sup>282</sup>

According to the FDA,<sup>283</sup> “[o]n August 2, 2013, FDA issued a final rule<sup>284</sup> defining ‘Gluten-free’ for food labeling, which is helping consumers, especially those living with celiac disease, be confident that items labeled “gluten-free” meet a defined standard for gluten content. ‘Gluten-free’ is a voluntary claim that can be used by food manufacturers on food labels if they meet all the requirements of the regulations.”

The final rule was implemented as of August 5, 2014 for voluntary labeling of “Gluten Free” claims by manufacturers.

In other words, from August 2, 2004 (when the FALCPA was enacted by President George W. Bush) until August 5, 2014 (when the FDA’s final rule for Gluten Free labeling went into effect), 3,656 days had elapsed! **That was 10 years and 4 days**, but who’s counting? I’ll tell you who has been counting. The Celiac community was counting.

**Figure 7 - Summary of the FDA’s Key Delays for Consumer Protections of the Celiac Community**

From	When	To	When	Total Time Elapsed
August 2, 2004	FALCPA was enacted by President George W. Bush	January 1, 2006	Mandatory labeling of the top 8 Major Food Allergens began	517 days, or 1 year, 4 months, 30 days
August 2, 2004	FALCPA was enacted by President George W. Bush	August 5, 2014	FDA’s final rule for Gluten Free labeling went into effect	3,654 days, or 10 years and 4 days

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sensitivity.” *Journal of human nutrition and dietetics: the official journal of the British Dietetic Association* vol. 26,5 (2013): 479-87. doi:10.1111/jhn.12032, and <https://onlinelibrary.wiley.com/doi/10.1111/jhn.12032>

<sup>282</sup> [https://web.archive.org/web/20150418221744/http://blogs.fda.gov/fdavoices/index.php/2014/08/a-new-era-of-gluten-free-labeling/?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](https://web.archive.org/web/20150418221744/http://blogs.fda.gov/fdavoices/index.php/2014/08/a-new-era-of-gluten-free-labeling/?source=govdelivery&utm_medium=email&utm_source=govdelivery)

<sup>283</sup> “Gluten-Free Labeling of Foods.” U.S. Food & Drug Administration, 7 March 2022. <https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods> . Accessed 13 May 2022.

<sup>284</sup> “Food Labeling; Gluten-Free Labeling of Foods.” Federal Register, 5 August 2013. <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods> . Accessed 13 May 2022.

August 2, 2008	FDA was supposed to implement voluntary Gluten Free labeling	August 5, 2014	FDA's final rule for Gluten Free labeling went into effect	2,195 days, or 6 years and 4 days
January 1, 2006	Mandatory labeling of the top 8 Major Food Allergens began	August 5, 2014	FDA's final rule for Gluten Free labeling went into effect	3,139 days, or 8 years, 7 months and 5 days
January 23, 2007	FDA issued a proposed rule for voluntary Gluten Free labeling <sup>285</sup>	August 5, 2014	FDA's final rule for Gluten Free labeling went into effect	2,752 days, or 7 years, 6 months, and 14 days
August 10, 2011	FDA Deputy Commissioner Taylor pledged in The Atlantic to move promptly to issue a final rule defining 'gluten free' in 2012	August 5, 2013	FDA's final rule for voluntary Gluten Free labeling was proposed	727 days, or 1 year, 11 months, 27 days

### Threshold Levels

It is instructive to note that Congress and the FDA have supported the mandatory labeling of the Major Food Allergens since the passage of FALCPA in 2004, even in the absence of known threshold levels for the Major Food Allergens from 2004 to the present. For example, in a “Conversation with the FDA’s Stefano Luccioli, M.D.”, Dr. Luccioli discussed threshold levels,

“A threshold can mean a lot of things to different people. There can be an individual threshold for food allergens, which is the amount of an allergenic food protein a person has to consume before there is an adverse allergic reaction. Within the allergic population, individual thresholds may vary greatly. For example, some people allergic to peanuts may experience a reaction from a tiny amount, even a few milligrams of peanut, which is equivalent to grains of sand. Others may need to eat a gram or more, equivalent to whole peanuts. **They are all allergic, but their individual thresholds are different.**

There can also be a population threshold. This threshold can be derived from assessing a large number of individual patient thresholds and can be used to predict reaction risks within the food allergic population to certain levels or doses of allergen. Information from population threshold data has been used by some countries to establish reference limits for allergens that may or may not need to bear an allergen advisory statement to protect public health. This is an important area of study and FDA scientists are currently involved in international discussions conducted by the Codex Alimentarius and other authoritative bodies on this topic.

<sup>285</sup> <https://www.govinfo.gov/content/pkg/FR-2007-01-23/pdf/FR-2007-01-23.pdf>

**As of now, the FDA has not established thresholds for any major food allergen.**

However, this does not mean that we do not consider information related to allergen thresholds in our regulatory work. For example, the FDA may consider allergen threshold data in assessing the safety of ingredients exempted from FALCPA allergen labeling requirements. We continue to monitor and evaluate new science that has emerged in the past decade on population threshold dose response to a variety of food allergens.”<sup>286</sup> (emphasis added)

According to the FDA, “There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten. Without a standardized definition of ‘gluten-free,’ these consumers could never really be sure if their body would tolerate a food with that label.”<sup>287</sup>

So why was the FDA seemingly not concerned about thresholds with the Major Food Allergens, even though the FDA endorsed and implemented mandatory labeling schemes of the Major Food Allergens? Compare this with Gluten which was not required to be labeled, but which the FDA delayed even voluntary labeling of for over a decade. It seems that had Gluten just been required to be labeled as a Major Food Allergen, that would have served as the floor of consumer protection upon which years later the Gluten Free Final Rule (i.e., the 20ppm threshold), could have been a complementary consumer protection. This is a just another curious example of the othering of the consumer protection needs of the Celiac community.

**Celiacs Historically Have Received Half a Loaf at Twice the Price**

Based on feedback from various members in the Celiac community and extensive research, we believe that the FDA has had a long-standing implicit bias against the Celiac community with respect to their medically required dietary needs. The analysis suggests that there has been a dietary disconnect to recognizing the public health importance of the consumer protection needs of the Celiac community. See also section herein “The Economics of Celiac Disease The Financial Burden of the Gluten Free Diet” and Figure 9 herein for Market Shopping in the Philadelphia Area as of July 10, 2022.

**Google Trends for Search Requests on Celiac Disease, Gluten & Gluten Free**

It is instructive to review Google Trends<sup>288</sup> with the actual search requests made to Google for: “celiac”, “celiac disease”, “gluten” and “gluten free” from January 2004 to May 2022. While the searches for “celiac” and “celiac disease” appear to have remained relatively flat over the 18 year period, there was a significant upward trend in search requests for “gluten” and “gluten free” that peaked in May 2014 and have continued in a robust manner through to the present.<sup>289</sup>

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<sup>286</sup> <https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape>

<sup>287</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

<sup>288</sup> “Google Trends provides access to a largely unfiltered sample of actual search requests made to Google. It’s anonymized (no one is personally identified), categorized (determining the topic for a search query) and aggregated (grouped together). This allows us to display interest in a particular topic from around the globe or down to city-level geography.”

<https://support.google.com/trends/answer/4365533?hl=en>

<sup>289</sup>

<https://trends.google.com/trends/explore?date=all&geo=US&q=gluten%20free,gluten,celiac,%20Fm%20h1pq>



The spike in searches for “gluten” and “gluten free” from mid-2013 to mid-2014 correlates with the Gluten Free final rule and the Gluten Free fad diet.

On November 21, 2014, Amanda Topper, Director of US Research: Food, Drink, Foodservice, Flavors & Ingredients, at Mintel, stated,

“Non-Celiacs drive Gluten-Free market growth... Many consumers continue to perceive a gluten-free diet as healthier and helpful for weight loss, despite evidence as such. It is these consumers, not those who have to eat a gluten-free diet for medical reasons, who are driving market growth.”<sup>290</sup>

The information suggests that the voluntary labeling scheme of Gluten Free food has been conflated with the voluntary adoption of a GF diet. The information further suggests that a voluntary Gluten Free diet gets conflated with Celiac Disease, a Non-IgE-Mediated food allergy. In turn, since Gluten is not required to be labeled as a Major Food Allergen, that has adversely impacted the Celiac community over time in terms of obfuscating our community’s medical needs and the seriousness with which others perceive the medically required Gluten Free diet.

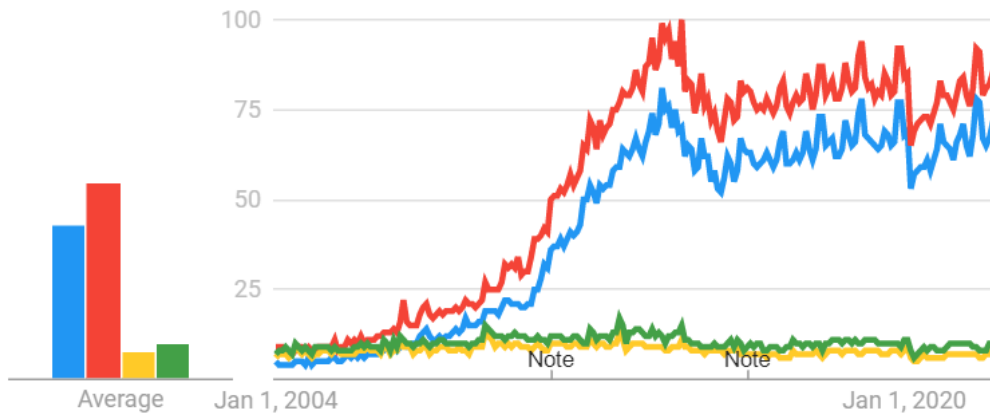
Our research suggests that the medical requirement for a strict Gluten Free diet coupled with the voluntary labeling of Gluten under FALCPA have converged to provide “medical legitimacy” to those who choose to eat Gluten Free. Conversely, to those with Celiac, the voluntary labeling of Gluten and not referring to a Celiac as a food allergy and Gluten as a food allergen, has led to undermining the medical legitimacy of the only treatment available for Celiac – a strict Gluten Free diet. That said, Gluten appears to be uniquely positioned among the potentially life-threatening food allergens, as the only one which has been widely adopted as a lifestyle choice by those who do not medically require avoiding Gluten in their diets.

**Figure 8 - Google Trends – Interest Over Time in Search Requests for Terms: Gluten, Gluten Free, Celiac and Celiac Disease, January 2004 to May 2022**

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<sup>290</sup> <https://www.mintel.com/blog/food-market-news/gluten-free-consumption-trends>

● gluten free ● gluten ● celiac ● Celiac disease



### Dietary Misappropriation of Gluten Free

According to the Cambridge Dictionary, cultural misappropriation is defined as “the act of taking or using things from a culture that is not your own, especially without showing that you understand or respect this culture.”<sup>291</sup>

Along those lines, we suggest that there has been a dietary misappropriation of the medical needs of the Celiac community by a lot of companies (food manufacturers and restaurant operators) which offer expensive Gluten Free foods and/or market “Gluten Free” foods that are not necessarily Gluten Free (often because of the potential for cross contact as in restaurant settings). In other words, one of the many challenges is that the medical requirement of a strict Gluten Free diet is not taken seriously, and it also has been dietarily misappropriated by companies putting their profits ahead of the medical needs of 3 million Americans with Celiac Disease.

### Assuming That The Product Contains Gluten

On January 30, 2022, “The Times and Democrat” newspaper in Orangeburg, South Carolina, added some timely flavor in an article on Gluten labeling and explained some of the challenges with voluntary labeling of Gluten and why we want to have Gluten added to the list of Major Food Allergens and labeled on all packaged foods.

“How do you know whether a food contains gluten? **If a food product is not labeled gluten-free you must assume that the product contains gluten.** Gluten-free labeling is voluntary for all packaged foods that are regulated by the FDA... Labeling is voluntary;

<sup>291</sup> <https://dictionary.cambridge.org/dictionary/english/cultural-appropriation>

therefore, it is the manufacturer's decision whether to label their gluten-free products."<sup>292</sup>  
(emphasis added)

Wheat is required to be labeled, but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. Just because something is Wheat free does not mean its Gluten Free. 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 1/1/23), Gluten Free labeling is permissive, not mandatory 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.

If someone has a nut allergy, that person can rely on a food manufacturer being required to label whether a food product has nuts in it. If someone has Celiac Disease, that person can't rely on food manufacturers labeling Gluten in a food product. Instead, Celiacs must rely on what ingredients are not included in voluntary Gluten Free labeling on food products. That is not very fair and not very safe!

By way of example and not limitation, following are some historical examples of consumer and Celiac advocacy frustration with the FDA:

#### **Example 1 - 1985**

For example, When Food Is Poison memorialized one such situation dating back to 1985,

"For instance, in 1985, FDA required the specific source of 'gluten' be identified on the label when it issued regulations recognizing as generally recognized as safe (GRAS) 'corn gluten' and 'wheat gluten.' 21 C.F.R. 184.1321-. 1322; 50 Fed. Reg. 8997, 8998 (Mar. 6, 1985). FDA stated it believed gluten-sensitive individuals were adequately safeguarded and rejected consumer requests calling for the mandatory identification of products as 'gluten-free.' FDA's stated rationale was that, because the source of gluten (wheat or corn) must be identified by name, 'the labeling already required is adequate to alert the public and protect gluten-sensitive individuals.'" 50 Fed. Reg. 8997, 8997 (Mar. 6, 1985). Although a 'gluten-free' standard was likely scientifically infeasible at the time, FDA's statement nevertheless reflects a failure to appreciate the fact that 'wheat gluten' is but the tip of the iceberg in terms of ingredients that individuals sensitive to gluten must avoid, and that identification of 'wheat gluten' on the label would be only a partial remedy for people with celiac disease in contrast to 'gluten-free' labeling."<sup>293</sup>

#### **Example 2 – September 10, 2008: Citizen Petition to Label Barley and Rye in 2008**

According to the FDA's Draft Guidance,

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<sup>292</sup> [https://thetandd.com/from-attic-to-basement-gluten-labeling/article\\_4ca50969-d47a-5cc5-bde1-77c78896ef61.html](https://thetandd.com/from-attic-to-basement-gluten-labeling/article_4ca50969-d47a-5cc5-bde1-77c78896ef61.html)

<sup>293</sup> 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>, Footnote 196, Page 98. Accessed 16 May 2022.

“In 2008 [September 10], we [FDA] received a citizen petition asking us to [amend] ... FALCPA to include barley and rye in the list of common allergens requiring disclosure on packaging (Ref. 18)... In 2018 [February 6], **“We [FDA] denied the request regarding barley and rye 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).”<sup>294</sup> (emphasis added)

First, it is important to note that there was a 10 year delay from 2008-2018 (encompassing three different Presidential administrations for President George W. Bush, 2001-2009; President Barack Obama, 2009-2017; and President Donald Trump, 2017-2021) for the FDA to summarily deny the petition based on a pretext that the petition did not include adequate information to show that rye and barley are common causes of severe IgE-mediated food allergies

On February 6, 2018 (in response to the citizen petition filed almost a decade earlier on September 10, 2008), Douglas Stearn Deputy Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, wrote,

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

In addition to this response taking 10 years, this response was tone deaf. It also suggests that it was not in compliance with the FDA’s Quality Resource and Development Team which stated,

“In carrying out its public health mission (reference #3) [FDA Mission Statement]<sup>295</sup>, FDA clearly understands that the American public is the primary customer of the agency’s work and the products we regulate.”<sup>296</sup>

In other words, this is no way to treat a customer at all. In the private sector, if that was a customer, they would have likely taken their business elsewhere due to what appears to be non-responsiveness and obfuscation.

### Example 3 – May 2011

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<sup>294</sup> FDA’s 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>

<sup>295</sup> <http://www.fda.gov/opacom/morechoices/mission.htm>

<sup>296</sup> <https://web.archive.org/web/20210309071904/https://www.fda.gov/media/77398/download>

Dr. Diana Gitig opined in Scientific American,

“As of now, FDA labeling laws do not require that the presence of gluten in foods be disclosed. These laws require only that the presence of eight major allergens be declared on food labels. Wheat is one of these allergens, but gluten is not. Manufacturers may label foods as gluten free, but such labeling is voluntary. For the millions of Americans with celiac disease, dermatitis herpetiformis, and gluten intolerance who must ensure that they are not consuming any gluten, this translates to A LOT of time spent reading labels in supermarket aisles.”<sup>297</sup>

#### **Example 4 - 2017**

It is instructive for the FDA to note that in 2017, Fiona Brown started a petition on Change.org entitled “Gluten in the Allergy Disclaimer” which in part stated, “Currently, companies may put gluten in products under different names, making it hard for people with celiac disease or non-celiac gluten sensitivity to know what they can eat. Companies should be required, by law, to state gluten in the allergy disclaimer.”<sup>298</sup>

While the petition is currently closed, there were **a total of 1,048 supporters**.<sup>299</sup> One of the commenters, Matt Maxwell from Peachtree City, Georgia stated,

“I’m signing this because the cigarettes in my pocket have a warning that they cause cancer. Gluten can do the same for us with celiac. We put warnings on every chemical known to man if it can hurt you in some way but not with gluten. Just because it's not an instant reaction like peanuts does to some people the medical issues are there.”<sup>300</sup>

#### **Example 5 – 2020**

In 2020, Galen Rydzik started this petition -- “FDA - Require gluten to be labeled as an allergen!” -- on Change.org and 1,625 people signed the petition,

“Currently, the Food Allergen Labeling and Consumer Protection Act of 2004 requires that all food containing the 8 most common allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) be labeled as having such. **It does not, however, require that gluten be labeled as an allergen. This is extremely problematic because grains such as rye, barley, and triticale do not have to be labeled on food containers.** These grains can be found in ‘ingredients’ that do not specify what they are made of, such as natural flavors, modified food starch, caramel color, and artificial colors. There are many other such ingredients that are more obvious, but this can make it difficult for those who have recently discovered their allergy. Many food manufacturers will use ingredients that are cross-contaminated with barley (such as chocolate), yet they are not required to mention this on their label. In many cases, **it leaves many with Celiac Disease to guess as to whether or not they think there could be any possibility food may be unsafe...** As such, I am asking that the FDA update its guidelines to include gluten on food labels. This would take out the ‘guessing game’ that comes with reading

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<sup>297</sup> <https://blogs.scientificamerican.com/guest-blog/when-and-why-did-everyone-stop-eating-gluten/>

<sup>298</sup> <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer>

<sup>299</sup> <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer>

<sup>300</sup> <https://www.change.org/p/fda-gluten-in-the-allergy-disclaimer/c/701100334>

food labels. This will also help to bring about a greater awareness to the public and the food industry- many with celiac disease find it difficult to dine out when food staff are ignorant of their allergies. Additionally, this lack of labeling may cause serious issues for those with Celiac Disease in the near future; the FDA recently approved substitution of some ingredients in foods that do not include the 8 major allergens due to COVID, but this does not include ingredients that are derived from other gluten containing grains or ingredients that are cross-contaminated with them.”<sup>301</sup>

The Change.org Web site indicates that there was an additional corresponding petition which appears to have been created under the Trump Administration White House, but that is no longer online.<sup>302</sup> As of June 15, 2022, Mr. Rydzik reported that FDA never responded to his petition entitled “FDA - Require gluten to be labeled as an allergen!”<sup>303</sup>

### **Example 6 - 2022**

As recently as February 23, 2022, the National Celiac Association, Beyond Celiac, the Society for the Study of Celiac Disease, the Gluten Intolerance Group, and Celiac Community Foundation of Northern California joined Gluten Free Watchdog in appealing to the FDA about its lack of enforcement action against manufacturers labeling products Gluten Free that list barley malt ingredients,

“We are deeply concerned that the gluten-free labeling rule (21 CFR 101.91) is not being enforced by FDA. Based on a review of FDAs Enforcement Reports page<sup>304</sup> for the period from January 1, 2020 to February 16, 2022, there have been a total of three recalls for products labeled gluten-free containing undeclared barley but these products were recalled for other misbranding problems, specifically undeclared wheat or peanuts. There has not been any public FDA enforcement action for misbranded products labeled gluten-free listing a barley ingredient, namely malt, malt syrup, malt extract, or malt vinegar. This includes at least 14 products reported to FDA by Gluten Free Watchdog during this period.”<sup>305</sup>

### **Example 7 – June 2022**

On June 18, 2022, Britney A. who has a 5 year old child with Celiac, posted the following on Facebook.

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<sup>301</sup> <https://www.change.org/p/food-and-drug-administration-fda-require-gluten-to-be-labeled-as-an-allergen>

<sup>302</sup> This page, “<https://petitions.whitehouse.gov/petition/add-gluten-list-recognized-allergens-food-labels>” just redirects to the Biden-Harris White House Web site. Additionally, this petition does not appear on this Web site, <https://trumpwhitehouse.archives.gov/>

<sup>303</sup> Jon Bari’s email communication with Galen Rydzik, June 15, 2022.

<sup>304</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>

<sup>305</sup> <https://www.glutenfreewatchdog.org/news/lack-of-fda-enforcement-action-against-manufacturers-labeling-products-gluten-free-that-list-barley-malt-ingredients>



“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 celiac disease.  
Accidents.  
Accidental glutening.  
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 glutening like a champ.  
It's a 5 year old who's a super celiac kid.  
Fight on.

Also, 🍷 Vans Waffles for all the boxes looking so similar. Our family who is always so careful made the mistake of grabbing one gf box and one regular box. Half a waffle and hours of pain.”<sup>306</sup>

### **FDA's Decade Long Delay to Voluntarily Label Gluten Free Products Has Become Normalized, Including Serving as a Precedent in the Judicial Branch**

The FDA's 10 year delay in defining the final rule for voluntary Gluten Free labeling<sup>307</sup> has helped normalize and create a domino effect whereby the Federal government has

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<sup>306</sup> <https://www.facebook.com/photo/?fbid=10161476598607289&set=a.10150292089997289> (as publicly posted on Facebook, and as used with written permission by the person who published it, permission on file with author of these Comments).



historically underserved, marginalized, and adversely affected Celiacs with inequality.

The FDA's decade long delay in issuing the final rule for voluntary labeling has even had pernicious ripple effects through other parts of our Federal government, including the judicial system. For example, in a Memorandum and Order from Roslynn Mauskopf, United States District Court Judge for the Eastern District of New York, Judge Mauskopf used the FDA's almost decade long delay to decide matters in a consolidated multi-district litigation involving purported claims that Frito-Lay North America and its parent company, PepsiCo, Inc. deceptively labeled marketed some of its products as "All Natural" when the products contained unnatural, genetically-modified organisms.

**"In an analogous situation, the FDA took nine years to define the requirements a manufacturer must meet before it can label a food gluten-free.** Brady Dennis, 'Nine Years after Congress Request, FDA defines Gluten-free,' Wash. Post, Aug. 2, 2013, available at [https://www.washingtonpost.com/national/health-science/9-years-after-congress-request-fda-defines-gluten-free/2013/08/01/cfeb2c08-faef-11e2-a369-d1954abcb7e3\\_story.html](https://www.washingtonpost.com/national/health-science/9-years-after-congress-request-fda-defines-gluten-free/2013/08/01/cfeb2c08-faef-11e2-a369-d1954abcb7e3_story.html) (last visited Aug. 20, 2013). **This nine-year period was in the face of a mandate from Congress to define the term gluten-free. In the Food Allergen Labeling and Consumer Protection Act, enacted into law on August 2, 2004, Congress directed the FDA to issue a rule to define and permit use of the term gluten-free.** Gluten-Free Labeling of Foods, 78 Fed. Reg. 47,154, 47,156 (Aug. 5, 2013) (to be codified at 21 C.F.R. pt. 101). The agency published the final rule on August 5, 2013 in the Federal Register. Id. A similar deliberative, open, and considered process would likely be undertaken to address labeling of foods containing genetically modified ingredients, and there is no reason to believe that the FDA would abandon its deliberative process in order to respond to the Courts referral through a hurried, ad hoc, and closed manner."<sup>308</sup>

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<sup>307</sup> <https://www.federalregister.gov/documents/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods>

<sup>308</sup> Memorandum & Order, In re Frito-Lay North America, Inc. All Natural Litigation, Case 1:12-cv-04638-RRM-RLM, Document 38, Filed August 29, 2013, Roslynn R. Mauskopf, United States District Court Judge for the Eastern District of New York, [https://www.govinfo.gov/content/pkg/USCOURTS-nyed-1\\_12-cv-04638/pdf/USCOURTS-nyed-1\\_12-cv-04638-1.pdf](https://www.govinfo.gov/content/pkg/USCOURTS-nyed-1_12-cv-04638/pdf/USCOURTS-nyed-1_12-cv-04638-1.pdf)

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

**“Not everything that can be counted counts and  
not everything that counts can be counted!”**

-- Albert Einstein

According to Footnote 6 in the FDA’s Draft Guidance,

“At the time that FALCPA was enacted, these eight foods were believed to account for 90 percent of food allergies and most serious reactions to foods (section 202(2)(A) of FALCPA (21 U.S.C. 343 note); Ref. 6 and Ref. 7). More than 160 foods are known to cause IgE-mediated food allergic reactions of varying severity, many with relatively low prevalence rates, with some as low as single cases (Ref. 7).”<sup>309</sup>

As the FDA evaluates the public health importance of other food allergens other than the Major Food Allergens listed in the FD&C Act, it is instructive to review certain quantitative claims about FALCPA to understand how that can be quite misleading when it comes to those who suffer from Non-IgE-Mediated food allergy adverse reactions to Gluten.

For example, FALCPA expressly cited that “eight major foods or food groups -- milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans -- account for 90 percent of food allergies.”<sup>310</sup> That was an error because it did not quantify the impact of Celiac Disease with Non-IgE-Mediated adverse reactions.

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.’<sup>311</sup> 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-**

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<sup>309</sup> <https://www.fda.gov/media/157637/download>

<sup>310</sup> <https://www.fda.gov/media/77570/download>, Section 202, 2(A)

<sup>311</sup> FALCPA 202(2)(a), 21 U.S.C.A. 343(note).

**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;<sup>312</sup> rather, Big Eight allergens are responsible for about ninety percent of adverse reactions.<sup>313</sup> Although ninety percent of allergic reactions

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<sup>312</sup> “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 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/> “

<sup>313</sup> “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

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.”<sup>314</sup>

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 should start looking in other areas**, but keep the eight so that we can focus there.’<sup>315</sup> **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.’**<sup>316,317</sup>

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.”<sup>318</sup>

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allergen awareness efforts are currently focused on the eight foods that are most frequently implicated in serious allergic responses ...’)” (emphasis added)”

<sup>314</sup> 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.

<sup>315</sup> “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.’”

<sup>316</sup> 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).

<sup>317</sup> 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.

<sup>318</sup> <https://www.fda.gov/food/conversations-experts-food-topics/current-food-allergen-landscape>

To that end, this misperception the 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.

However, it is both instructive and moreover curious to review FDA Ref. 13 which was co-authored by the FDA's Dr. Luccioli to see how "wheat and/or gluten" is/are included as one of the "major food allergens" in this important research:

**"The prevalences of allergy to specific foods within srFA [self-reported food allergy] and ddFA [physician diagnosed food allergy] groups of the most recent 2010 survey are shown in Table 4. Seventy-five percent of adults with srFA and 76% of those with ddFA reported reactions to at least one of the major food allergens (i.e., milk and/or dairy, eggs, fish, shellfish, tree nuts, peanuts, wheat and/or gluten, soy) defined by Food Allergen Labeling and Consumer Protection Act.[23]** In addition, the most frequently implicated foods as causes of allergic reactions within both the srFA and ddFA groups were similar. **Foods associated with the highest prevalence of srFA were** milk and/or dairy (4.1%), shellfish (3.6%), fruits (2.7%), fish (1.7%), and tree nuts and **wheat and/or gluten (1.3% each)**, **whereas foods associated with the highest prevalence of ddFA were** milk and/or dairy (2.0%), shellfish (1.6%), fruits (1.6%), **wheat and/or gluten (0.9%)**, fish (0.8%), tree nuts (0.7%), and peanut (0.6%)."<sup>319</sup>

That said, it is also important to note that I am unaware of any central reporting statistics or database from the FDA, CDC, NIH, DoD or other agency or organization where exposures and adverse reactions to Gluten have been tracked, quantified and/or memorialized. Moreover, since there is no rescue medication available (i.e., antihistamine or adrenaline) for adverse reactions to Gluten exposure for Non-IgE-Mediated Food Allergy with Celiac Disease, the number of emergency department visits for Celiac Disease may likely be limited.

According to the Center for Celiac Disease at the University of Chicago, "If your reaction to [Gluten] exposure is quite violent, such that you're risking dehydration, then a trip to the emergency room is warranted."<sup>320</sup> Even if there are Emergency Room visits to treat quite violent adverse reactions, it is unknown whether these Emergency Room visits are documented and/or quantified in any manner, and may even be coded incompletely for treatment of dehydration or

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<sup>319</sup> According to Table 1 in FDA Ref. 13, "Verbatim FA [food allergy] questions from the 2001, 2006, and 2010 U.S. Food and Drug Administration FSS [U.S. Food and Drug Administration Food Safety Surveys] including the following question in 2010 "Are you allergic to wheat, gluten, corn, or other grains?" were asked (sample size in 2010 was 4,568 adults); Verrill L, Bruns R, Luccioli S. Prevalence of self-reported food allergy in U.S. adults: 2001, 2006, and 2010. Allergy Asthma Proc. 2015 Nov-Dec;36(6):458-67. doi: 10.2500/aap.2015.36.3895. Epub 2015 Oct 8. PMID: 26453524; PMCID: PMC4623408, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4623408/pdf/zsn458.pdf>

<sup>320</sup> <https://www.cureceliacdisease.org/tag/exposure/>

GI upset, for example, without listing the underlying cause of a Non-IgE-Mediated Food Allergy (Celiac Disease) reaction to Gluten exposure.

On May 24, 2022, I received an email from the FDA in response to my inquiry for data on adverse event reports attributed to Gluten,

“Thank you for your inquiry regarding adverse event reports attributed to gluten consumption and mislabeling. FDA’s MedWatch portal offers a database of adverse event reports attributed to products that FDA regulates. It is important to understand that this is a voluntary portal and the information may not be representative of any group of individuals.”<sup>321</sup>

Prior to the publication of the FDA’s Draft Guidance, on March 24, 2022, I received a letter from the FDA in response to my 2022 FOIA request (FOIA Control Number, 2022-2220) for all documents involving: reporting of adverse effects (illness, injury), events and labeling concerns on Gluten including adverse effects of Gluten ingestion (i.e., reports to FDA’s Safety Information and Adverse Event Reporting Program and MedWatch voluntary reports), as detailed here, <https://www.fda.gov/food/nutrition-education-resources-materials/gluten-and-food-labeling> , etc. To date, I have not received any responsive records from my FOIA request.

On June 3, 2022, I visited “MedWatch: The FDA Safety Information and Adverse Event Reporting Program”<sup>322</sup>, and I searched for “gluten”, “non-IgE-mediated”, “celiac”, “gf”, “gluten-free” and “gluten free”. Out of the 692 total entries, there were no matches for any of my search terms detailed above. I also searched for “allergy”, and that only yielded only two results that seemingly had to do with pharmaceuticals. For the record, as a consumer and a caretaker of a child with Celiac, I was unaware of the MedWatch system prior to 2021 when I was doing research on food labeling.

While the FALCPA has arguably made life somewhat easier for those with Celiac Disease since 2014 when the FDA’s final rule for voluntary Gluten labeling was implemented, FALCPA has not made life easy for Celiacs. To the contrary, evidence suggests that the voluntary labeling scheme has marginalized the Celiac community and has perpetuated scientific and societal biases with apathy and complacency including:

- 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.
- With respect to labeling food products in the United States, the voluntary Gluten Free labeling scheme<sup>323</sup> sufficiently protects consumers who are on medically required and very

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<sup>321</sup> Email sent by the FDA to Jon Bari, May 24, 2022, The Food and Drug Administration’s (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 288446.

<sup>322</sup> <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

<sup>323</sup> The FDA’s final rule defining Gluten Free 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

restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.

- 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 health dangers that can arise through Gluten ingestion including by way of example and not limitation: anemia, cancer, failure to thrive, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

Ms. Derr accurately foresaw problems in FALCPA’s legacy in her 2006 article When Food Is Poison when she suggested that there would be issues for marginalized communities with Non-IgE-Mediated food allergies to Gluten - “the meaning and accuracy of this statistic [the Big 8 Major Food Allergens “account for 90 percent of food allergies”] 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.”

To that end, the FDA must exclude the 90% statistic in evaluating the public health importance of Gluten as a food allergen.

#### **XIV. About the Limitations of the Current Voluntary Labeling Scheme of Gluten on Packaged Foods**

**“The heart of the question is whether all Americans are to be afforded equal rights and equal opportunities, whether we are going to treat our fellow Americans as we want to be treated. If an American, because his skin is dark, cannot eat lunch in a restaurant open to the public, if he cannot send his children to the best public school available, if he cannot vote for the public officials who will represent him, if, in short, he cannot enjoy the full and free life which all of us want, then who among us would be content to have the color of his skin changed and stand in his place? Who among us would then be content with the counsels of patience and delay?”**

-- President John F. Kennedy

On August 4, 2022, the Food Labeling Modernization Act of 2021 (“FLMA”: H.R. 4917<sup>324</sup> and S. 2594<sup>325</sup>) was introduced by Senator Richard Blumenthal (D-CT), Senator Sheldon Whitehouse (D-RI), Senator Ed Markey (D-MA), House Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ), and House Appropriations Committee Chairwoman Rosa DeLauro (D-CT). One of the provisions of the FLMA would be to require that Gluten be labeled on all packaged foods.

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<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-gluten-free-labeling-foods#>

<sup>324</sup> <https://www.congress.gov/bill/117th-congress/house-bill/4917>

<sup>325</sup> <https://www.congress.gov/bill/117th-congress/senate-bill/2594/text>

It is instructive to read the comments from Beyond Celiac regarding the introduction of the FLMA including how the voluntary labeling of Gluten scheme is insufficient and how consumer protection could be greatly improved with the requirement that Gluten be labeled on all packaged foods,

“‘Because the gluten-free diet is the only currently available treatment for people with celiac disease, removing barriers to identifying gluten in foods and beverages is an important step to helping them live healthier, less stressful lives,’ said Salvatore Alesci, MD, Beyond Celiac chief scientist and strategy officer. **‘Research has shown that not only is the gluten-free diet difficult to follow due to cross-contact and lack of labeling clarity but that it can have a negative psychological impact on those needing to live gluten-free.’**”

Currently, wheat is the only gluten-containing grain that is required to be disclosed on food and beverage labels. If the legislation passes, barley and rye ingredients would also need to be listed. Because barley and rye ingredients may be included in ingredients such as malt, yeast, and flavorings, but not always, people with celiac disease and other gluten-related disorders may be at a loss to know if they can safely consume that item. This bill would amend the FALCPA (Food Allergen Labeling and Consumer Protection Act) requiring that all gluten-containing grains (including barley and rye) be disclosed on food product packaging. **This would greatly reduce the guesswork currently required for people to safely eat gluten-free.**

For example, currently, a label may state natural smoke flavor in its ingredients. This bill would require that if wheat, barley or rye are used anywhere in that ingredient, they would then need to be called out on the label. Foods labeled gluten-free currently require compliance with a gluten content of less than 20 parts per million. That requirement would not be affected by the passage of the FLMA.

**‘Labeling laws have come a long way since I was first diagnosed with celiac disease, however, we still have a long way to go. The passage of the Food Labeling Modernization Act of 2021 would be a huge step forward in helping those on a gluten-free diet eat safely and without fear.** It gives the gluten-free consumer the power of knowledge. We at Beyond Celiac fully support this bill and are grateful for the work of Congressmen Pallone and Blumenthal, along with the work of my staff and the many celiac disease organization [sic – “organizations”] along with Gluten-Free Watchdog and everyone else who have come together to help get these bills on the floor,’ said Alice Bast, CEO of Beyond Celiac.”<sup>326</sup> (emphasis added)

According to the Celiac Disease Foundation’s comments on the introduction of the FLMA,

“Food labels can play an important role in managing diet-related diseases, yet federal labeling rules have not kept up with the changing marketplace, and current food labels do not provide the simple, straightforward information that celiac patients need to evaluate products and make healthy choices.”<sup>327</sup>

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<sup>326</sup> <https://www.beyondceliac.org/celiac-news/flma-2021/>

<sup>327</sup> <https://celiac.org/flma/>



According to the press release issued announcing the bicameral introduction of the FLMA,

“The FLMA is a game-changer for Americans with celiac disease and other gluten related disorders, said Tricia Thompson of Gluten Free Watchdog. Requiring labels to declare all gluten-containing grains in FDA-regulated foods will give consumers information they need to safely choose products for their medically-prescribed gluten-free diets. Without the FLMA, these consumers remain at risk of unknowingly ingesting foods that are unsafe for them.”<sup>328</sup>

According to Gluten Free Watchdog,

“[t]his Bill [FLMA] amends FALPCA [sic – “FALCPA”]: If an FDA-regulated food product includes a gluten-containing grain, this must be disclosed in the ingredients list or separate Contains statement just like for wheat and the other major allergens. This would be required regardless of whether the food was labeled gluten-free. \*The Bill does not add gluten to the list of major food allergens. It adds gluten to labeling requirements applicable to the major food allergen.”<sup>329</sup>

While we are very appreciative of the spirit of the FLMA with respect to requiring that Gluten be labeled on all packaged foods, we believe that it is a mistake for Gluten not to be added to the list of Major Food Allergens. The unintended consequences of this work-around may have additional real-world implications that undermine consumer protection needs in the U.S. for the Celiac community, just like FALCPA’s voluntary Gluten labeling scheme has had for almost two decades.

It is worth reiterating that the FALCPA does not preclude the FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA’s labeling scheme.<sup>330</sup> 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.”<sup>331</sup> In other words, even though the Food Labeling Modernization Act is still working its way through Congress and may or may not become law at some point, the FDA can still act now in evaluating the public health importance of labeling Gluten and even requiring that Gluten be labeled, absent additional legislation or directive from Congress.

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<sup>328</sup> <https://energycommerce.house.gov/newsroom/press-releases/pallone-delauro-blumenthal-whitehouse-and-markey-introduce-food-labeling>

<sup>329</sup> <https://www.glutenfreewatchdog.org/news/breaking-legislative-news-alert-new-bill-requires-that-products-disclose-gluten-containing-grains-on-labels/>

<sup>330</sup> 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. <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>

<sup>331</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

## **XV. Gluten Got Next – The FDA Should Start with Evaluating the Public Health Importance of Evaluating Gluten as a Food Allergen**

**“We may not be able to get certainty, but we can get probability,  
and half a loaf is better than no bread.”**

-- C. S. Lewis

**“Now faith is the substance of things hoped for, the evidence of things not seen.”**

-- Hebrews 11:1

In principle, we are in alignment with the FDA that it is time for the FDA to evaluate the public health importance of food allergens other than the Major Food Allergens.

In order to go forward, we must look back and see what happened with the legislative history of FALCPA. In the spirit of evidence-based science including general fairness, health equity, President Biden’s Executive Order 13985, the Human Right to Adequate food and U.N. Convention on the Rights of the Child, it is time for the FDA to reckon with the past as it pertains to evaluating and recommending that Gluten be required to be labeled on packaged foods not just internationally, but also domestically (See 2021 FAO/WHO Expert Consultation, which was chaired by the FDA’s Dr. Lauren Jackson).<sup>332</sup>

To reiterate, the FALCPA does not preclude the FDA from expanding via regulation the list of major allergens including Gluten requiring identification under the FALCPA’s labeling scheme.<sup>333</sup> 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.”<sup>334</sup>

Moreover, it is worth reiterating that the 2021 FAO/WHO Expert Consultation, which was chaired by the FDA’s Dr. Lauren Jackson, 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**

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<sup>332</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>333</sup> “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>

<sup>334</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, [sic – “and”] specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”<sup>335</sup> <sup>336</sup> (emphasis added)

FALCPA’s legislative history, the unfinished business of FALCPA and common sense inform us that the FDA should start immediately with evaluating Gluten since the Celiac community really took one for the proverbial team and accepted voluntary Gluten Free labeling in helping to get FALCPA enacted in the first place.

According to When Food Is Poison’s then-contemporaneous accounts of FALCPA’s legislative history:

“Other compromises that the food industry worked with Congress to achieve included:

- **the elimination of requirements regarding gluten identification on food labels**;
- the elimination of the requirement that allergens appear in bold font on the label;
- the elimination of manufacturer recordkeeping and data collection requirements;
- the elimination of fines for manufacturers that fail to adequately label allergens;
- the elimination of the printing of a telephone number on labels;
- the elimination of a provision requiring the use of GMPs [good manufacturing practices] to minimize cross-contamination;
- the elimination of specifications for when advisory labeling may permissibly be employed;
- the elimination of language placing restrictions on advisory labeling; and
- the addition of an exemption from the FALCPA’s labeling scheme where an allergen already is stated in plain English elsewhere in the ingredient list.”<sup>337</sup> (emphasis added)

According to the FDA’s News Release about the FDA’s Draft Guidance,

“Currently, the major food allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans, though more than 160 foods are known to cause food allergic reactions. Sesame becomes the ninth major food allergen, effective Jan. 1, 2023.

‘The nine major food allergens don’t currently represent all foods nationwide that people are allergic to or that cause food hypersensitivities,’ said Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition. ‘This draft guidance is part of the FDA’s efforts to evaluate emerging evidence about other non-listed food allergens that can cause serious reactions in a consistent and transparent manner, which can inform potential future actions to better help protect the health of consumers.’...

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<sup>335</sup> “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.” Source: 2021 FAO/WHO Expert Consultation.

<sup>336</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

<sup>337</sup> 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 16 May 2022.

The draft guidance focuses on immunoglobulin E antibody (IgE)-mediated food allergies, which are capable of triggering anaphylaxis and are considered the most severe and immediately life-threatening food allergies.”<sup>338</sup>

This superset of 160 food allergens was known and discussed at the FDA’s Public Meeting On: The Challenge of Labeling Food Allergens, which was held on August 13, 2001. Ms. Munoz-Furlong from FAAN stated at that meeting,

“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.”<sup>339</sup>

Of the more than 160 foods that are known to cause food allergic reactions, Gluten was the only food allergen that was originally and expressly included in FALCPA along with the Top 8 Major Food Allergens for mandatory disclosure.

Based on an orthodox worldview represented by the American Academy of Allergy, Asthma & Immunology that Dr. Smith memorialized in *Another Person’s Poison*, there was a false pretext that the definition of food allergy must require an IgE-Mediated response.<sup>340</sup> Additionally, based on inaccurate science that some members of the food industry falsely argued (i.e., scientifically, those with Celiac Disease have an intolerance to Gluten as opposed to a food allergy), Gluten unfortunately finished as the “runner up” in FALCPA.

As such, it would seem only prudent and equitable for the FDA to start evaluations with Gluten before starting any evaluations of other food allergens. In reality, the work has already been done by the 2021 FAO/WHO Expert Consultation and the FDA should require that Gluten be labeled on all packaged foods in the U.S.

## **XVI. Sesame Labeling – Voluntary Labeling Disclosure Was Not Enough**

**“Food is national security. Food is economy.  
It is employment, energy, history. Food is everything.”**  
-- Chef José Andrés, founder of World Central Kitchen

According to the FDA’s Draft Guidance,

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<sup>338</sup> FDA News Release, “FDA Takes New Steps Regarding Evaluating Public Health Importance of Additional Food Allergens,” April 18, 2022, <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-regarding-evaluating-public-health-importance-additional-food-allergens> .

<sup>339</sup> FDA, Transcript: Public Meeting On: The Challenge of Labeling Food Allergens 32 (Aug. 13, 2001) (statement of Anne Munoz-Furlong, President and Founder, FAAN).

<sup>340</sup> Smith, Matthew. “Another Person’s Poison: A History of Food Allergy.” New York: Columbia University Press, 2015. pages 153-156, and 184-185.

“In 2014, we received a citizen petition asking us to require that sesame seeds and sesame products be regulated in a manner similar to a major allergen under FALCPA and listed specifically by name (sesame) in ingredient lists of foods, and to add sesame to the list of allergens in a 2005 Compliance Policy Guide Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens (Ref. 19) to address both labeling and cross-contact issues related to sesame in food manufacturing practices (Ref. 20);”<sup>341</sup>

According to the FDA Draft Guidance,

“After considering the data and information submitted to that notice, we announced the availability for public comment of a draft guidance document titled, ‘Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry (Draft Guidance)’ (Ref. 24) (85 FR 71920 (November 12, 2020)). This guidance initiative was intended to provide food manufacturers with FDA’s current views on sesame as an allergen and provide recommendations regarding the voluntary disclosure of sesame in certain circumstances where such disclosure is not currently required, as well as help individuals who are allergic to sesame identify those foods that contain sesame as an ingredient. [Footnote 20] The FASTER Act amended section 201(qq) of the FD&C Act to add sesame to the definition of “major food allergen,” effective January 1, 2023.”<sup>342</sup>

The concept of voluntary labeling of Gluten is just not enough, in a similar way that the voluntary labeling scheme of Sesame has been inadequate.<sup>343</sup>

In spite of the fact that it took the FASTER Act in 2021 to require that Sesame be labeled, the FALCPA did not preclude the FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA’s labeling scheme to include Sesame.<sup>344</sup> Section

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<sup>341</sup> <https://www.fda.gov/media/157637/download>

<sup>342</sup> <https://www.fda.gov/media/157637/download>

<sup>343</sup> Even though no one in our family has a Sesame allergy, my wife and I were honored to participate in the Food Allergy Research & Education’s (FARE’s) Courage at Congress event in March 2021, and I was one of many food allergy allies who had advocated to Congress for Sesame labeling requirements. On April 23, 2021, President Joe Biden signed the Food Allergy Safety, Treatment, Education and Research (FASTER) Act of 2021 (<https://www.congress.gov/117/plaws/publ11/PLAW-117publ11.pdf>) into law, ensuring that Sesame will be labeled on all packaged foods in plain language by January 1, 2023. The FASTER Act will protect about 1.6 million Americans who are allergic to Sesame. This marked the first time since 2004 that a new major food allergen has been added to the top 8 allergens in the U.S. as set forth in the Food Allergen Labeling and Consumer Protection Act (FALCPA). With the FASTER Act, the U.S. joined 46 other countries around the world (<https://farrrp.unl.edu/IRChart>) where Sesame must be labeled on packaged foods including in Canada and across Europe.

<sup>344</sup> “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

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.”<sup>345</sup>

The FDA’s powers are enumerated in Section 203(b) and 403(w). In the spirit of equity, the FDA should change its labeling scheme with FALCPA to require that Gluten be labeled on all packaged foods in the US, in accordance with the findings of the authoritative bodies of the 1999 FAO/WHO Expert Consultation with the 1999 Codex criteria as well as the 2021 FAO/WHO Expert Consultation.

## **XVII. Scientific Factors in the FDA’s Draft Guidance**

**“‘We are moms and busy. We don’t have time to be at the grocery stores, going on Web sites for all the things we need.’**

**--Mother of an allergic child, with income <\$25K”<sup>346</sup>**

The FDA’s Draft Guidance’s “Scientific Factors Relevant to the Public Health Importance of a Non-Listed Food Allergen” in Section IV (“Scientific Factors”) are biased and exclusionary. Therefore, the FDA’s Draft Guidance is inequitable to 3 million Americans with Celiac Disease, their parents and caretakers, and an additional estimated 20+ million others who have Non-Celiac Gluten Sensitivity (“NCGS”)<sup>347</sup>, an IgE-Mediated allergy to Rye, Barley or Oats, or who are following a medically required Gluten Free diet.<sup>348</sup>

Moreover, the Scientific Factors perpetuate flawed scientific, societal and governmental biases: A Gluten Free diet is all that is needed to treat Celiac Disease, as opposed to all that has ever been historically available and with respect to labeling food products in the US, the voluntary Gluten Free labeling scheme is all that is needed when that is all that has ever been available in the US.

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)

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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>

<sup>345</sup> H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

<sup>346</sup> <https://www.foodallergy.org/media/1059/download>

<sup>347</sup> <https://www.verywellhealth.com/how-many-people-have-gluten-sensitivity-562965>

<sup>348</sup> According to the National Celiac Association, there is a demand for Gluten Free food from families with children with an Autism Spectrum Disorder. There are a number of other conditions, particularly gastric and autoimmune conditions, where a Gluten Free diet may diminish symptoms. See <https://nationalceliac.org/wp-content/uploads/2018/04/GF-Food-Assistance-GuideGeneralv3.pdf> , and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7915454/>

typically are not associated with anaphylaxis or other immediately life-threatening conditions.”<sup>349</sup>

By way of example, let’s examine the following from Section IV of the FDA’s Draft Guidance:

“We have identified the following scientific factors that we generally intend to consider when evaluating the public health importance of a food allergen in the United States:

- Factor #1: **evidence of IgE-mediated food allergy**
- Factor #2: **the prevalence of an IgE-mediated food allergy** in the U.S. population
- Factor #3: **the severity of IgE-mediated food allergic reactions**
- Factor #4: **the allergenic potency**

Our scientific factors are consistent with the 1999 Codex criteria (Ref. 25), the revised criteria recommended by the International Life Sciences Institute-Europe (ILSI-EU) (Ref. 26), published frameworks from ILSI-EU and public, private, and academic partners in Europe for the evaluation of public health importance of a food allergen (Ref. 26 and Ref. 27), publications from ILSI-EU and public, private, and academic partners in Europe that evaluate published frameworks (Ref. 28 and Ref. 29), and the National Academy of Sciences, Engineering and Medicine (NASEM) (Ref. 2; the NASEM report). See Appendix A for further discussion of these criteria and frameworks.”<sup>350</sup> (emphasis added)

In truth and in fact, as previously detailed with respect to the 1999 Codex Criteria’s recommendation that the presence of cereals containing Gluten should always be declared on packaged food labels, the FDA’s Scientific Factors are **not consistent** with the 1999 Codex Criteria recommendations as detailed in Ref. 25. Period. Full stop.

According to the 1999 Codex Criteria,

“The revised list of those foods and ingredients known to cause food allergies and intolerance and **whose presence should always be declared** was identified as the following: **cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products**; Crustacea and products of these; Egg and egg products; Fish and fish products; Peanuts, soybeans, and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulfites in concentrations of 10 mg/kg or more.”<sup>351</sup> (emphasis added)

The FDA’s Draft Guidance’s Scientific Factors are also not consistent with the 2021 FAO/WHO Expert Consultation” which should have been expressly referenced in the FDA’s Draft Guidance, Section IV, Scientific Factors (FDA Ref. 45 in FDA’s Draft Guidance) in addition to Ref. 2 and Refs. 25-29.<sup>352</sup>

“In May 2021, FAO [Food and Agriculture Organization of the United Nations]/WHO [World Health Organization] issued a summary report, which, among other things,

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<sup>349</sup> <https://www.fda.gov/media/157637/download>

<sup>350</sup> <https://www.fda.gov/media/157637/download>

<sup>351</sup> [https://apps.who.int/iris/bitstream/handle/10665/42378/WHO\\_TRS\\_896.pdf](https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf)

<sup>352</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>

**identified prevalence** of the immune-mediated hypersensitivity to a specific food, **severity** (i.e., proportion of severe objective reactions to a food/ingredient such as anaphylaxis), and the **potency** of food/ingredient (i.e., the amount of the food/ingredient required to cause objective signs) as the three key criteria that should be used to establish the priority allergen list (Ref. 45).”<sup>353</sup>

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

**“Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”**<sup>354 355</sup>  
(emphasis added)

In order to evaluate the public health importance of food allergens other than the Major Food Allergens, the FDA’s Draft Guidance must include scientific factors using a fair scale and fair metrics. As currently written, the FDA’s Draft Guidance does not do so for Non-IgE-Mediated food allergy mechanisms with Celiac.

#### **Recommended Changes to the Scientific Factors in the FDA’s Draft Guidance**

In Section IV.A., the header of “Evidence of IgE-mediated Food Allergy” should be changed to “Evidence of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.B., the header of “Prevalence of IgE-mediated Food Allergy” should be changed to “Prevalence of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.C., the header of “Severity of IgE-mediated Food Allergy” should be changed to “Severity of IgE-mediated and Non-IgE-mediated Food Allergy”. Additionally, corresponding Non-IgE-mediated food allergy information must be included in that section.

In Section IV.D., the “Allergenic Potency” section should include Non-IgE-mediated food allergy with Celiac Disease.

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<sup>353</sup> <https://www.fao.org/3/cb4653en/cb4653en.pdf> , <https://www.cdc.gov/foodsafety/symptoms.html> , and <https://www.cdc.gov/foodsafety/cdc-and-food-safety.html>

<sup>354</sup> “Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, ... oats, ... should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.”

<sup>355</sup> <http://www.fao.org/3/cb4653en/cb4653en.pdf>



## **FDA's Exclusive Focus On The Most Severe And Immediately Life-Threatening Allergic Reactions, Including Anaphylaxis Works For Evaluating 160 Typical Food Allergens, But Not For Gluten**

The FDA's Draft Guidance's exclusive focus on **"food allergies that are recognized to be the most severe and immediately life-threatening are those that are mediated by immunoglobulin E antibodies (IgE) because IgE-mediated food allergic reactions are capable of triggering anaphylaxis"** is misguided and incongruent with science-based evidence and FDA officials' recommendations in Ref. 45. This focus excludes food allergy with Non-IgE-Mediated mechanism with Celiac Disease (othering Celiac) specifically with respect to the immediacy of a severe allergic reaction.

### **Acuteness - How Quickly Do Food Allergy Symptoms Develop?**

According to the Mayo Clinic, "[IgE-Mediated] Food allergy symptoms usually develop within a few minutes to 2 hours after eating the offending food."<sup>356</sup>

For Non-IgE-Mediated mechanisms with Gluten, research from 2016 has shown that "[m]edian time to symptom onset [following Gluten exposure] was 1 hour (range 10 min to 48 h), and median symptom duration was 24h (range 1 h to 8 days)."<sup>357</sup>

According to research published by Sciences Advances on the acuteness of symptom onset in Non-IgE Cell-Mediated Reactions with Celiac Disease in 2019, "Cytokine release and gastrointestinal symptoms after gluten challenge in celiac disease", if Celiac Disease patients who are following a strict Gluten Free diet "are exposed to gluten-containing food, they typically suffer from gastrointestinal reactions occurring 1 to 2 hours after the gluten exposure."<sup>358</sup>

With respect to challenging this framework -- the most severe and immediately life-threatening allergic reactions, including anaphylaxis -- it is instructive to review a couple of examples of how this framework is not a one size fits all, especially in the context of evaluating the public health importance of Gluten.

### **Example with Foodborne Illness Using "Immediately Life-Threatening" as a Criteria**

Imagine, if in the context of protecting consumers against foodborne illness, the primary focus by the FDA was on the immediacy of a reaction whereby protections against *Staphylococcus aureus* (Staph) were prioritized over *E. coli* (*Escherichia coli*). According to the CDC, *Staphylococcus aureus* (Staph) has symptoms that begin 30 minutes to 8 hours after exposure and include nausea, vomiting, and stomach cramps and diarrhea. With *E. coli* (*Escherichia coli*), symptoms begin 3 to 4 days after exposure and include severe stomach cramps, diarrhea (often bloody), and vomiting. Moreover, around 5-10% of people diagnosed with *E. coli* develop a life-threatening health problem." It is without question that *E. coli* can be very dangerous, even though symptoms begin 3-4 days after exposure.<sup>359</sup> Nonetheless, it does not appear that (just because symptoms of Staph can begin 30 minutes after exposure) consumer protection schemes against preventing *Staphylococcus aureus* are prioritized over preventing *E. coli*.

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<sup>356</sup> <https://www.mayoclinic.org/diseases-conditions/food-allergy/symptoms-causes/syc-20355095>

<sup>357</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5283559/>

<sup>358</sup> Goel et al., Sci. Adv. 2019; 5: eaaw7756 7 August 2019, <https://celiac.org/main/wp-content/uploads/2020/03/NexVax2-Study.pdf>

<sup>359</sup> [www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses](https://www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses)

### **Requiring That Adverse Immunological Reactions Are IgE-Mediated Is A Red Herring, Just Like Saying a Concussion Protocol Should Only Be Undertaken For Head Trauma If A Person Is Knocked Unconscious**

As previously addressed in the legislative history of FALCPA, the well-funded food industry lobbied Congress in 2002-2004 for concessions in FALCPA's mandatory food labeling requirements.

The othering of the consumer protection needs of those with Celiac Disease (a Non-IgE-Mediated adverse reaction, auto-immune disease and digestive disease) was dangerously and scientifically inaccurate. The lobbying disclosures suggest that it was the American Bakers Association and/or the American Farm Bureau which further argued that potentially life-threatening food allergies with Non-IgE-Mediated mechanisms should not be viewed in the same light as those who suffer from potentially life threatening IgE-Mediated food allergies (i.e., peanuts, tree nuts).

The lobbying disclosure statements which appear to have been from the American Bakers Association and/or the American Farm Bureau suggest that these trade organizations lead the charge for the othering of the consumer protection needs of those with Celiac Disease by incorrectly saying that scientifically, Gluten should be viewed as an intolerance and not a food allergy. This was a false premise which was unfortunately not rebutted, or not rebutted well enough, and it ultimately gained strength and support, even though it was dangerously and scientifically inaccurate.

The lobbyists conflated Celiac Disease (a food allergy, auto-immune disease and digestive disease) with Gluten intolerance. Additionally, the information suggests that the food industry othered the public health importance of requiring the labeling 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 health dangers that can arise through Gluten ingestion including by way of example and not limitation: anemia, cancer, failure to thrive, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

The argument from the food industry circa 2002-2004 that Celiacs do not go into anaphylactic shock from Gluten ingestion is a red herring. That is as uninformed as saying that a concussion protocol should not apply to a person who suffers a head injury, but who does not become unconscious.

Today, we treat all head trauma seriously since there can be critical short and long-term consequences from not implementing a concussion protocol, even if the immediate impact of the head trauma is not visible. In other words, after being exposed to Gluten, Celiac patients such as my son can suffer both serious short-term symptoms such as diarrhea and vomiting, and long-term medical complications including liver disease, inflammatory bowel disease, osteoporosis, neurological conditions, immunological scarring and cancer. That is in part why Gluten must be labeled on all packaged foods for those with Celiac Disease, IgE-Mediated Food Allergies to Grains Containing Gluten and Non-Celiac Gluten Sensitivity.

While I appreciate that there are scientific distinctions in the way that the body reacts to an IgE-Mediated Food Allergy (i.e., wheat allergy) vs. a Non-IgE-Mediated Food Allergy (i.e., Celiac),

the bottom line is that what is food for one is poison for another, including for those with Celiac. The FALCPA should have provided equal protection under the law, and it has not for those who live with Celiac, Non-Celiac Gluten Sensitivity and IgE-Mediated food allergies to Grains Containing Gluten.

## **XVIII. Suggested Definitions to Be Revised or Added in the FDA's Draft Guidance**

**“If we cannot now end our differences,  
at least we can help make the world safe for diversity.”**

-- President John F. Kennedy

In revising the FDA's Draft Guidance (Section II.A - Definitions of Terms Used in This Guidance, Table 1), it is my suggestion that these existing terms as detailed be revised to be more inclusive of those with a Non-IgE-Mediated food allergy in order to provide a clearer, more inclusive and comprehensive understanding of Celiac Disease in the context of evaluating the public health importance of Gluten in addition to the Major Food Allergens. The suggested revisions are just that, suggestions, and could be further revised, but the spirit is to make these terms more inclusive.

The definition of “Allergenic potency” should be changed from:

“The amount of food allergenic protein required to elicit an IgE-mediated food allergic reaction in an already sensitized individual”

to

“The amount of food allergenic protein required to elicit an IgE-mediated or Non-IgE-mediated food allergic reaction in an already sensitized individual”

The definition of “Clinically cross-reactive food allergy” should be changed from:

“Cross-reactivity in which the Immunoglobulin E antibody (IgE) directed to one food binds to another food and causes IgE-mediated responses (including clinical symptoms) to that other food. (See also the definition of cross-reactivity.)”

to

“Cross-reactivity in which the Immunoglobulin E antibody (IgE) and/or Non-IgE-Mediated adverse reaction directed to one food binds to another food and causes IgE-mediated or Non-IgE-Mediated responses (including clinical symptoms) to that other food. (See also the definition of cross-reactivity.)”

Notes: While I am not a scientist, and as such, this revised definition may need further refinement, the idea here is to not exclude Non-IgE-Mediated reaction since someone may have a Gluten allergy and an IgE-Mediated allergy to another food.

FDA Ref. 11 stated that “Cereal grains (eg, wheat, rye, barley and oat) share homologous proteins with grass pollens and each other.” Additionally, the clinical implications of

cross-reactivity between Wheat and other Gluten Containing Grains (Barley, Rye, Oats) is 20%.<sup>360</sup> In other words, among those with an IgE-Mediated mechanism Wheat allergy, 20% of patients will have an IgE-Mediated allergic reaction to Barley, Rye or Oats. In addition to protecting the Celiac community, there are other consumers who need protection from Gluten and that is another reason why Gluten should be named a Major Food Allergen and have Gluten required to be labeled on packaged foods in the U.S.

Also see section herein entitled “IgE-Mediated Food Allergies to Gluten with Rye and Barley.”

The definition of “Documented sensitized individual” should be changed from:

“An individual with documented evidence of IgE sensitization to relevant food or component(s) of food (e.g., confirmed by positive skin percutaneous test (SPT) or in vitro allergen specific IgE test)”

to

“An individual with documented evidence of IgE or Non-IgE sensitization to relevant food or component(s) of food (e.g., confirmed by positive skin percutaneous test (SPT), in vitro allergen specific IgE test, serology, endoscopy)”

The definition of “Food allergen” should be changed from:

“The food or component(s) of a food (often a protein) that elicits specific, IgE-mediated immunologic reactions (Ref. 1 and Ref. 2)”

to

“The food or component(s) of a food (often a protein) that elicits specific, IgE-mediated or Non-IgE-Mediated immunologic reactions (Ref. 1, Ref. 2, Ref. 25, Ref. 45)”

Note that this “Food allergen” definition should comport with Section III. Background in the FDA’s Draft Guidance.

The definition of “Food allergy” should be changed from:

“An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food (Ref. 1 and Ref. 2)”

to

“An adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food (Ref. 1, Ref. 2, Ref. 25, Ref. 45, When Food Is Poison)”

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<sup>360</sup> Sicherer S.H., Clinical implications of cross-reactive food allergens. J Allergy Clin Immunol. 2001; 108: 881-890. <https://www.jacionline.org/action/showPdf?pii=S0091-6749%2801%2963295-0>

Note that this “Food allergy” definition should comport with Section III. Background in the FDA’s Draft Guidance.

The definition of “Objective signs of food allergy” should be changed from:

“Symptoms that are elicited by food challenge and visible or ascertainable to an observer (e.g., hives, swelling, wheezing)”

to

“Symptoms that are elicited by food challenge and visible or ascertainable to an observer (e.g., hives, swelling, wheezing, vomiting, diarrhea, intestinal damage)”

Note that the FDA should be aware that Celiac Disease is often referred to as an invisible illness. According to Beyond Celiac, “this serious genetic autoimmune disease has a major impact on people’s health – even if you can’t see it.”<sup>361</sup> Whereas someone with hives, swelling or wheezing may be observable in public, for example, vomiting and diarrhea (two classic symptoms of adverse reactions to Gluten) may occur in private in a bathroom. The intestinal damage is an objective sign, but only ascertainable through an endoscopy.

The definition of “Subjective symptoms of food allergy” should be changed from:

“Symptoms that are elicited by food challenge but not visible or ascertainable to an observer (e.g., tingling, chest tightness, nausea)”

to

“Symptoms that are elicited by food challenge but not visible or ascertainable to an observer (e.g., brain fog, tingling, chest tightness, nausea, migraines)”

The definition of “Well-characterized allergic individual” should be changed from:

“An individual with documented history of IgE-mediated food allergic reactions [i.e., typical and reproducible clinical allergic signs or symptoms in close temporal association (e.g., within a few hours) of food consumption or positive food challenge] and documented evidence of IgE sensitization to relevant food or component(s) of food (e.g., positive reaction in SPT or in vitro allergen specific IgE test)”

to

“An individual with documented history of IgE-mediated and/or Non-IgE-Mediated food allergic reactions [i.e., typical and reproducible clinical allergic signs or symptoms in close temporal association (e.g., within a few hours) of food consumption or positive food challenge] and documented evidence of IgE or Non-IgE sensitization to relevant food or component(s) of food (e.g., positive reaction in SPT or in vitro allergen specific

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<sup>361</sup> <https://www.beyondceliac.org/invisible-illness-infographic/>

IgE test, serology, endoscopy)

Any Definition in Section II.A of the FDA’s Draft Guidance that expressly mentions IgE-Mediated as a limiting factor should be evaluated, including, for example, “Self-reported reactive individual”, “Self-reported sensitized individual”, “Sensitization”, and “Severity dose-response.”

In addition, it is my suggestion that these new terms as detailed below should be added to the FDA’s Draft Guidance (Section II.A - Definitions of Terms Used in This Guidance, Table 1) in order to provide a clearer, more inclusive and comprehensive understanding of Celiac Disease in the context of evaluating the public health importance of Gluten in addition to the Major Food Allergens.

- “Iron deficiency Anemia” – “Anemia, also referred to iron deficiency anemia, is a decrease of red blood cells due to a lack of iron.”<sup>362</sup> Iron is an important micronutrient that may be depleted in Celiac Disease. Iron deficiency and anemia may complicate well-established celiac disease, but may also be the presenting clinical feature in the absence of diarrhea or weight loss.<sup>363</sup>
- “Inflammation” – “When people with celiac disease eat foods that contain gluten, their immune systems attack the lining of the intestine. This causes inflammation (swelling) in the intestines and damages the villi, the hair-like structures on the lining of the small intestine. Nutrients from food are absorbed by the villi. If the villi are damaged, the person cannot absorb nutrients and ends up malnourished, no matter how much he or she eats.”<sup>364</sup>
- “Intestinal damage” – “If you have celiac disease, eating gluten triggers an immune response in your small intestine. Over time, this reaction damages your small intestine’s lining and prevents it from absorbing some nutrients (malabsorption). The intestinal damage often causes diarrhea, fatigue, weight loss, bloating and anemia, and can lead to serious complications.”<sup>365</sup>
- “Immunological scarring” – with respect to the term “immunological scarring”, please see: “Celiac disease permanently reshapes immune cells in the intestine”<sup>366</sup> and “Chronic Inflammation Permanently Reshapes Tissue-Resident Immunity in Celiac Disease”<sup>367</sup>
- Malnutrition – Malnutrition occurs if someone’s small intestine cannot absorb enough nutrients. Malnutrition can lead to iron deficiency anemia and weight loss. In children, malnutrition can cause slow growth and short stature.<sup>368</sup>

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<sup>362</sup> <https://www.beyondceliac.org/celiac-disease/related-conditions/anemia/#>

<sup>363</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4541375/>

<sup>364</sup> <https://my.clevelandclinic.org/health/diseases/14240-celiac-disease#>

<sup>365</sup> <https://www.mayoclinic.org/diseases-conditions/celiac-disease/symptoms-causes/syc-20352220>

<sup>366</sup> <https://www.uchicagomedicine.org/forefront/gastrointestinal-articles/celiac-disease-permanently-shapes-immune-cells-in-the-intestine>

<sup>367</sup> Mayassi et al., 2019, Cell 176, 967981 February 21, 2019, <https://www.cell.com/action/showPdf?pii=S0092-8674%2818%2931653-2>

- Non-IgE-Mediated allergic reaction (including clinical symptoms and well-characterized Non-IgE-Mediated allergic (Celiac) individual
- Glutening, Glutened - when someone with a IgE-Mediated or Non-IgE-Mediated food allergy (i.e., Celiac) has adverse reactions after consuming gluten.
- Failure to thrive – “Failure to thrive is defined as decelerated or arrested physical growth (height and weight measurements fall below the third or fifth percentile, or a downward change in growth across two major growth percentiles) and is associated with abnormal growth and development. The reason for failure to thrive is inadequate nutrition.”<sup>369</sup>

## **XIX. Suggested Edits to Table 2, Abbreviations Used in FDA’s Draft Guidance**

**“Good food is the foundation of genuine happiness.”**

--Auguste Escoffier

It is my suggestion that these Abbreviations (Section II.B - Definitions of Terms Used in This Guidance, Table 2) in order to provide a clearer, more inclusive and comprehensive understanding of Celiac Disease in the context of evaluating the public health importance of Gluten in addition to the Major Food Allergens.

The definition of “**1999 Codex Criteria**” should be changed from:

“Criteria, recommended to Codex by the Food Allergens Labelling Panel, for determining whether there are foods, in addition to the list of foods adopted by Codex in 1999, whose presence should always be declared in the list of ingredients on a food label because of their allergenic properties”

to

“In June 1999, Codex adopted a list of those foods or food products whose presence should always be declared in the list of ingredients on a food label, because of their allergenic properties (Ref. 25). This list included: 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.”

It is important to memorialize the specifics of the 1999 Code Criteria.

In addition, Non-IgE-Mediated food allergy should be added to the list of abbreviations in “Table 2. Abbreviations use in this guidance.”

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<sup>368</sup> <https://www.mayoclinic.org/diseases-conditions/celiac-disease/symptoms-causes/syc-20352220#:~:text=Untreated%2C%20celiac%20disease%20can%20cause,slow%20growth%20and%20short%20stature.>

<sup>369</sup> <https://www.chop.edu/conditions-diseases/failure-thrive#>

## **XX. “Contact with Manufacturer” & “Ask Questions About Ingredients and Preparation When Eating at Restaurants” - Real World Examples**

“We are moms and busy. We don’t have time to be at the grocery stores, going on Web sites for all the things we need.”  
– Mother of an allergic child, with income <\$25K”<sup>370</sup>

According to the FDA, “If you have any doubts about a product’s ingredients and whether or not the product is gluten-free, the FDA recommends that you should contact the manufacturer or check its website for more information.”<sup>371</sup> The FDA also advises that “consumers who are allergic to particular foods to ask questions about ingredients and preparation when eating at restaurants or any place outside the consumers home.”<sup>372</sup>

It is instructive to view research published in the Academy of Management, “The Effects of Mandatory and Voluntary Regulatory Pressures on Firms Environmental Strategies: A Review and Recommendations for Future Research.”

“This article presents an in-depth review of scholarship on how mandatory and voluntary regulatory pressures on firms affect their environmental strategies and performance. Although mandatory regulation typically has a strong and positive influence on firms’ environmental performance, studies of the effects of voluntary pressures demonstrate that by themselves they are unlikely to bring about significant improvement in environmental outcomes.”<sup>373</sup>

From this analogy, one can glean how these same findings arguably apply with respect to mandatory vs. voluntary labeling of potentially life-threatening food allergens by the food industry.

“Nearly all the literature works we have reviewed confirm that the mandatory powers of government are the most effective lever that society has to alter firm environmental strategies and performance. However, potential negative implications on competitiveness have generated a mixed and relevant debate. In this review, we have shown that voluntary programs have arisen to supplement mandatory regulation; however, research has found that often the results of these programs are disappointing.”<sup>374</sup>

Here are just a few illustrative, but not exhaustive, examples of how contacting the manufacturer or checking the Web site for more information can lead a consumer in circles and not provide any clarifying details. We can attest to the time consuming nature and frustration associated with

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<sup>370</sup> <https://www.foodallergy.org/media/1059/download>

<sup>371</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

<sup>372</sup> <https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers#>

<sup>373</sup> <https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/2020-01/annals.2018.0014.pdf>

<sup>374</sup> Academy of Management Annals 2020, Vol. 14, No. 1, 339365.  
<https://doi.org/10.5465/annals.2018.0014>



reaching out to food manufacturers. Moreover, these examples below illustrate that in the absence of mandatory labeling schemes, many companies revert to doing the minimum. In other words, they revert to doing only what is legally required and that leaves consumers vulnerable to dangerous ingestion of potentially life-threatening food allergens, in this case Gluten.

### Example A - Wells Manufacturing

Following is an email exchange between Leslie Bari and Halo Top Consumer Response on May 2, 2022:

From: Halo Top Consumer Response <ConsumerResponse@halotopcreamery.com>

Date: Mon, May 2, 2022 at 2:31 PM

Subject: Halo Top Consumer Response Ticket #865550

To: <leslie@theconstitutional.com>

“Thank you for contacting Halo Top Consumer Response. We appreciate hearing from our valued consumers. Wells Enterprises, Inc. (“Wells”), manufacturer of ice cream and frozen novelty products, **follows all federal laws and regulations** and is committed to supplying the highest quality and safest ice cream and frozen novelty products to its consumers. **While many of our branded ice creams and frozen novelty products are free of gluten, Wells does not presently validate or certify that our products are “gluten-free” and, consequently, we do not label our (Wells) branded products as such. We provide all required nutritional information on the nutrition facts panel and ingredient label on each package to assist consumers in purchasing products that meet their dietary and lifestyle needs.** Or you may call us at 1-800-331-0830 and ask about your favorite flavors. If I can be of additional assistance, feel free to contact me.

-- Julie, Consumer Response Representative”<sup>375</sup> (emphasis added)

### Example B - Dreyer’s Ice Cream

Following is an FAQ on Dreyer’s Grand Ice Cream as visited on May 2, 2022:

**“Is Dreyer’s Ice Cream Gluten Free?**

**As a general rule, the gluten in Dreyer’s frozen dessert products is present only in the added bakery products, such as cookies, cake or brownies. We always label the eight major food allergens on our package by their common name.** We recommend to always check the label for the most current information before purchasing and/or consuming a product. The exception to this rule is our Slow Churned French Silk ice cream, which contains gluten in the natural flavors.”<sup>376</sup> (emphasis added)

### Example C – Gatorade

PepsiCo<sup>377</sup> presents a tale of different food allergens: the Top 8 Major Food Allergens vs. Gluten.

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<sup>375</sup> Email from Halo Top Consumer Response to Leslie Bari, May 2, 2002.

<sup>376</sup> <https://www.icecream.com/us/en/brands/dreyers/faq#:~:text=Is%20Dreyer's%20Ice%20Cream%20Gluten,package%20by%20their%20common%20name.>

<sup>377</sup> “PepsiCo products are enjoyed by consumers more than one billion times a day in more than 200 countries and territories around the world. PepsiCo generated \$79 billion in net revenue in 2021, driven by a complementary beverage and convenient foods portfolio that includes Lay's, Doritos, Cheetos, Gatorade, Pepsi-Cola, Mountain Dew, Quaker, and SodaStream. PepsiCo's

## The Top 8:

**“Question:** If I have food allergies, how will I know which of your beverages I can safely drink?

**Answer:** If one of our products contains milk, eggs, peanuts, tree nuts, fish, crustacean shellfish, wheat or soy, it is identified on the product’s label. You can also check for these eight common allergens in the Allergen Lookup chart below.”<sup>378</sup>

**“Question:** What is special about the eight categories of allergens you list on your products?

**Answer:** The U.S. Food & Drug Administration identifies these eight categories of allergens - milk, eggs, peanuts, tree nuts, fish, crustacean shellfish, wheat and soy in its Food Allergen Labeling and Consumer Protection Act. The eight categories of allergens 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.”<sup>379</sup>

## Gluten:

**“Question:** Does Gatorade contain gluten?

**Answer:** Gluten is typically found in certain grains such as wheat, barley and rye. None of the ingredients in Gatorade ready-to-drink, Gatorade mix (bulk and sticks), G2 products, Recover Protein Shakes, Recover Protein Powders, Prime Energy Chews, and Gatorade Endurance products are derived from grains or flours that have been linked to gluten sensitivity. While these products are not formulated using gluten-containing ingredients, they have NOT been tested to be gluten-free. There is a possibility the ingredients were exposed to/stored next to gluten-containing foods during processing.”<sup>380</sup>

This doubletalk from PepsiCo is nonsense. However, this is an anecdotal example of living with Celiac in terms of trying to determine whether food products have Gluten in them because of FALCPA’s voluntary labeling scheme.

We as a community have the right to know whether food products like Gatorade have Gluten in them, just like the top 9 Major Food Allergens (Sesame as of January 1, 2023). If Gluten was required to be labeled, the response would have been, “If one of our products contains Gluten, it is identified on the product’s label.”

Anecdotally, I have heard many soccer sideline discussions and participated in numerous online discussions among parents and caretakers of kids with Celiac about Gatorade when we try to

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product portfolio includes a wide range of enjoyable foods and beverages, including many iconic brands that generate more than \$1 billion each in estimated annual retail sales.” Source:

<https://www.pepsico.com/who-we-are/about-pepsico>

<sup>378</sup> <https://www.pepsicobeveragefacts.com/home/allergens>

<sup>379</sup> <https://www.pepsicobeveragefacts.com/home/allergens>

<sup>380</sup> <https://contact.pepsico.com/gatorade/article/does-gatorade-contain-gluten?>

understand whether Gatorade is safe to consume. Curiously, as per our personal experience in Italy in August 2022, Gatorade in Italy is clearly marked “SENZA GLUTINE” (Gluten Free).<sup>381</sup>

#### **Example D – Frozen Peas: Are These Celiac Safe?**

On January 22, 2022, a member of a Celiac Facebook group posted the following question, “Hi! Does anyone know if Aldi’s Simply Nature brand frozen peas<sup>382</sup> (or generally frozen fruits and veggies) are celiac safe?”<sup>383</sup> The 16 comments from the support group offered various opinions about the safety of this product given the absence of labeling information about Gluten.

According to the Celiac Disease Foundation,

“Fresh and frozen fruits and vegetables are naturally gluten-free. **However, it is important to read labels on any processed fruits and veggies,** as well as dried fruit and pre-prepared smoothies. Additionally, packaged frozen potatoes are not always gluten-free, and labels should be read carefully when considering these products.”<sup>384</sup>

This is an anecdotal example of how conditioned consumers are to be on alert and need to buy premium priced foods since there are so many unknown Gluten containing ingredients potentially lurking in the voluntary labeling scheme.

#### **Example E – M&Ms Milk Chocolate**

The Gluten guessing game goes on every day in the absence of mandatory labeling of Gluten as a Major Food Allergen. The efforts made and anxiety endured by parents and caretakers is palpable. Social media groups are replete with the Celiac community trying to decipher lots of confusing consumer information, and it is not just limited to Halloween or other candy-oriented holidays. One Celiac mom posted about M&Ms, “I do not understand how so much conflicting information is out there. Every time I reach out to Mars, call or email, this is the inconsistent information I get.” Hm&m. Here are some examples:

##### **January 4, 2021**

“Thank you for contacting Mars Wrigley. We appreciate your interest in M&M’S® Milk Chocolate. **Although our M&M’S® Milk Chocolate do not contain gluten,** we do not have a gluten free statement on our packaging because this product is made in a facility where other products that do contain gluten are manufactured. We understand that people with food allergies have to be careful with the food they eat. Moving forward please feel free to check the back of the package for allergen information.”<sup>385</sup> (emphasis added)

##### **March 16, 2022**

“Hello Kelly... **Any ingredient which contains gluten, such as wheat, barley, rye, and oats, is listed on the ingredients list on the pack.**

In areas where gluten may be present, we always provide a statement (i.e. May contain wheat, etc.). There are really strict controls in our factories surrounding gluten and other

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<sup>381</sup> Author’s personal shopping experience in Rome, Italy, August 2022.

<sup>382</sup> <https://www.aldi.us/en/products/frozen-foods/frozen-fruit-vegetables/detail/ps/p/simply-nature-organic-peas-or-corn/>

<sup>383</sup> <https://www.facebook.com/photo/?fbid=10227561920775964&set=gm.10158038672492245>

<sup>384</sup> <https://celiac.org/gluten-free-living/gluten-free-foods/>

<sup>385</sup> Response to Michele H. from Mars Wrigley, 1/4/21 (on file with author)

allergens. We make sure that sufficient cleaning structures are in place to avoid any cross-contamination.

**Although the product does not contain gluten**, we do not have a gluten-free statement on our packaging because this product is made in a facility where other products that do contain gluten are also manufactured.

**At this time, we do not have a list of gluten free products for chocolate. All our chocolate products either have gluten or could be made on machinery that does.** We hope that this information has been helpful.”<sup>386</sup> (emphasis added)

**October 28, 2022**

“Thank you for contacting us about M&M’S. **We do not label our Chocolate products as gluten-free.** This is because all our Chocolate products either have gluten, are made on machinery that also makes products containing gluten, or is made in a facility that uses gluten in other products. **Whether or not the product includes a ‘may contain’ statement, it is never labeled as gluten-free because we cannot guarantee that it is gluten-free despite the cleaning and other protocols that we use at our sites.** We hope this information has been helpful. If you have further questions or concerns, please don’t hesitate to reach out to us.”<sup>387</sup> (emphasis added)

#### **Example F - Children’s Hospital of Philadelphia’s (CHOP) Food Court**

As discussed, our son Jax has been treated for Celiac Disease at Children’s Hospital of Philadelphia (“CHOP”). When I viewed the online menu filtering at CHOP’s Food Court (see screen shots below), it revealed a blind spot to serving Celiac safe Gluten Free food to meet the medical needs CHOP’s patients, staff and visitors who cannot eat Gluten. For example, I was shocked when I saw that Gluten was not even listed as an Allergen or Intolerance.

Instead “Made without Gluten” was listed as a “Food Preference” along with Vegan and Vegetarian options.<sup>388</sup> How could one of the world’s leading pediatric treatment and research hospitals allow this? How could Aramark, one of the world’s leading managed outsourced food services companies<sup>389</sup> which CHOP contracts with to operate the CHOP Food Court, allow this?

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<sup>386</sup> Mars Wrigley North America Email to Kelly P. From Chris, Mars Customer Care, 3/16/22, ref:00D0Y34dhp.\_5008d480m3:ref (on file with author)

<sup>387</sup> Email to Jon Bari from Jaja, Mars Customer Care, Case ID: 03036440,10/28/22 (on file with author)

<sup>388</sup> <https://chop.healthcaredish.com/LocationsAndMenus/MainCampus/FoodCourt>

<sup>389</sup> “Aramark (NYSE: ARMK) proudly serves the world’s leading educational institutions, Fortune 500 companies, world champion sports teams, prominent healthcare providers, iconic destinations and cultural attractions, and numerous municipalities in 19 countries around the world with food, facilities, and uniform services. Because our culture is rooted in service, our employees strive to do great things for each other, our partners, our communities, and our planet. Aramark ranked No. 1 In the Diversified Outsourcing Services Category on FORTUNE’s 2022 List of Worlds Most Admired Companies and has been named to DiversityInc’s Top 50 Companies for Diversity list, the Forbes list of Americas Best Employers for Diversity, the HRC’s Best Places to Work for LGBTQ Equality and scored 100% on the Disability Equality Index.” And

<https://www.aramark.com/content/dam/aramark/en/about/newsroom/Aramark%20Capabilities%20-%20Apr%202022.pdf>

My child's medically required need for Gluten Free food is not a food preference in any way! However, that is one example of society's bias with viewing the medically required Gluten Free needs of the Celiac community as less serious than the medical needs of the typical IgE-Mediated food allergy.

When one does filter out for both Wheat as an allergy and intolerance, and Gluten Free as a "food preference," one sees that there are no real choices left on the menu for those who medically require a strict Gluten Free diet.

## CHOP Food Court, Main Hospital, Web Site, Landing Page

The screenshot shows the landing page of the CHOP Food Court website. The URL is chop.healthcareshop.com/LocationsAndMenus/MainCampus/FoodCourt. The page features a large image of a salad and a sidebar with a table of standard hours. The hours are listed for Breakfast, Morning Grab & go, Lunch, Afternoon Grab & go, Dinner, and Overnight, all from Monday to Sunday. The main content area describes the location and offers various food options, including grill specials, brick oven pizza, and gluten-free selections. There are links for 'Mai Nutritional Information', 'Taco & Burrito Menu', and 'Fooda Menu'. At the bottom, there are buttons for 'Today Lunch', 'Change', 'Allergens & Intolerances', and 'Food Preferences'.

Standard Hours	
<b>Breakfast</b>	
Mon - Sun	6:30AM - 10:30AM
<b>Morning Grab &amp; go</b>	
Mon - Sun	10:30AM - 11:00AM
<b>Lunch</b>	
Mon - Sun	11:00AM - 3:30PM
<b>Afternoon Grab &amp; go</b>	
Mon - Sun	3:30PM - 4:00PM
<b>Dinner</b>	
Mon - Sun	4:00PM - 7:30PM
<b>Overnight</b>	
Mon - Sun	1:00AM - 4:00AM

The Food Court is located in the Main Hospital at CHOP on the 1st floor. We offer various options throughout the Food Court, including: grill specials, brick oven pizza, made-to-order breakfast sandwiches and omelets, a create-your-own salad bar, gluten free selections, made-to-order deli sandwiches, rotating daily soup selections, Fooda pop-up restaurants, two restaurant partners, and more!

- [Mai Nutritional Information](#)
- [Taco & Burrito Menu](#)
- [Fooda Menu](#)

Today Lunch [Change](#) [Allergens & Intolerances](#) [Food Preferences](#)

## CHOP Food Court, Main Hospital, Web Site, "Allergens & Intolerances" Selected

The screenshot shows the CHOP Food Court website with the 'Allergens & Intolerances' modal open. The modal allows users to select items to exclude from their meal. The selected items are Eggs, Fish, Milk, Peanuts, Shellfish, Soy, Tree Nuts, and Wheat. The modal also includes a disclaimer about COVID-19 and supply chain disruptions, stating that the website may not be current and that ARAMARK cannot guarantee that any food item will be completely free of allergens. The modal has a 'Save' button at the bottom right.

**Allergens & Intolerances**

Select Items to Exclude and press Save

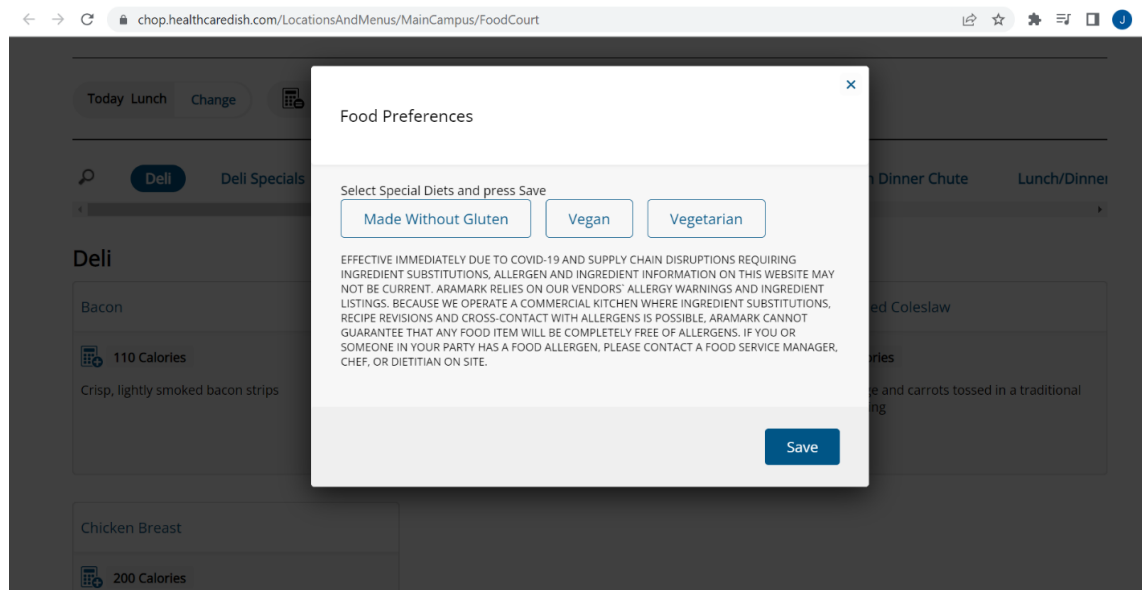
Eggs Fish Milk Peanuts Shellfish

Soy Tree Nuts Wheat

EFFECTIVE IMMEDIATELY DUE TO COVID-19 AND SUPPLY CHAIN DISRUPTIONS REQUIRING INGREDIENT SUBSTITUTIONS, ALLERGEN AND INGREDIENT INFORMATION ON THIS WEBSITE MAY NOT BE CURRENT. ARAMARK RELIES ON OUR VENDORS' ALLERGY WARNINGS AND INGREDIENT LISTINGS. BECAUSE WE OPERATE A COMMERCIAL KITCHEN WHERE INGREDIENT SUBSTITUTIONS, RECIPE REVISIONS AND CROSS-CONTACT WITH ALLERGENS IS POSSIBLE, ARAMARK CANNOT GUARANTEE THAT ANY FOOD ITEM WILL BE COMPLETELY FREE OF ALLERGENS. IF YOU OR SOMEONE IN YOUR PARTY HAS A FOOD ALLERGEN, PLEASE CONTACT A FOOD SERVICE MANAGER, CHEF, OR DIETITIAN ON SITE.

[Save](#)

## CHOP Food Court, Main Hospital, Web Site, "Food Preferences" Selected



The bottom line is that in the absence of mandatory labeling schemes, Aramark and CHOP revert to doing the minimum. In other words, they revert to doing only what is legally required and that leaves consumers vulnerable to dangerous ingestion of potentially life-threatening food allergens, in this case Gluten.

## **XXI. The Only Available Treatment for Celiac – Gluten Free Food – Must Be Viewed as a Human Right**

**“Make a career of humanity. Commit yourself to the noble struggle for equal rights.  
You will make a better person of yourself, a greater nation of your country,  
and a finer world to live in.”**

-- Dr. Martin Luther King

In the seminal work by Juliana Nadal at the Department of Nutrition, Food Quality and Nutrition at the Federal University of Parana in Brazil, “The principle of human right to adequate food and Celiac Disease,” Nadal linked the Human Right to Adequate Food with Celiac Disease,

“By understanding food as a basic human right, it is less complex to understand the fact that the absence of foods that address this particular need, such as that of Celiac individuals, represents a concrete case that this group of people are having, constantly, their rights – to adequate nutrition – violated and, in turn, they are in a state of food and nutrition insecurity.”<sup>390</sup>

<sup>390</sup> Nadal, J., Ferreria, S.M., et al. “The principle of human right to adequate food and celiac disease: advancements and challenges.” 2013, <https://www.e-publicacoes.uerj.br/index.php/demetra/article/download/5991/7652> , Demetra; 2013; 8(3); 411-423

Yvonne Vissing Ph.D. and Christopher Moore-Vissing advanced Nadal's discussion and provided thought leadership in their article, "Going Gluten Free as a Human Rights Issue",

"Because Celiac Disease can be considered the most common food intolerance in the world, it is one that both individuals and social structures need to address as a mainstream issue. **From how laws and consumer protections are designed at the macro level, to how food is made available and prepared at the micro level, rights of people with Celiac Disease hang in limbo.** Some places and people are very attentive to their rights protections while others are not. Nadal contextualizes food and nutrition insecurity that afflicts individuals with Celiac Disease with specific regard to the principle of the Human Right to Adequate Food (HRAF)." (emphasis added)

"When you've got Celiac Disease and people aren't attentive to making sure you can eat gluten-free foods that are safely prepared and not contaminated, you can end up very sick in the short-run. The short-term effects may include symptoms such as gastrointestinal upset, migraines, fuzzy brain, sweats, and general malaise. As a fundamental right, what one eats should ensure people's access to a healthy, dignified and full life. People who have been "glutened" do not feel dignified as they writhe in pain, wrestle with fears of embarrassment, or modify their lifestyle and social schedules to accommodate the illness. In the long-run, if someone is continually exposed to gluten in foods, a variety of serious preventable health conditions may result. Unlike a peanut allergy that can directly kill you, exposure to gluten may result in morbidity and early mortality for people in an indirect fashion. Adhering to a gluten-free diet is of paramount importance to avoid health problems such as compromising one's weight and pubertal development, fertility, bone mineral density, and deficiencies of micro and macronutrients, not to mention the increased risk of developing malignancies, especially in the gastrointestinal system. Because the health effects of ingesting gluten for someone with Celiac Disease are less visible to those who don't experience them, they [Celiac patients] have been easier to ignore. Thanks to vocal advocates who now know that going gluten-free can save their lives, it is obvious that the lack of attention to making sure people can eat safely is a violation of their rights."<sup>391</sup>

### **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 of all members of the human family".<sup>392</sup> To those ends, the intent of the United Nations Charter is to "promote social progress and better standards of life..." As a preface, for Celiac Disease patients and their caretakers, the "right to feed oneself in dignity" underpins the human right to adequate (safe) food, and these rights can be greatly impacted by perpetual circumstances including:

- 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,

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<sup>391</sup> Vissing, Yvonne; Moore-Vissing, Christopher, "Going Gluten Free as a Human Rights Issue." Journal of Gluten Sensitivity, Summer 2016 Issue, 11 July, 2016.

<https://www.celiac.com/articles.html/going-gluten-free-as-a-human-rights-issue-r3798/>

<sup>392</sup> "Universal Declaration of Human Rights," United Nations. 10 December 1948.

[https://www.ohchr.org/EN/UDHR/Documents/UDHR\\_Translations/eng.pdf](https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf)

etc. (and not having any medicine that can treat the auto-immune cascade response triggered from the ingestion of Gluten),

- Worrying about cross contact with every meal and snack with short term sickness and long-term damage to one's small intestine,
- Scrutinizing voluntary Gluten Free labeling and other food labels for accurate and comprehensive ingredient lists,
- 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),
- Being hungry and not being able to find safe Gluten Free food options (i.e., eating out away from home including at school and while travelling),
- 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 health complications, and
- Having the medical requirements of a strict Gluten Free diet not be taken as seriously as the Major Food Allergens by government and society

### **Universal Declaration of Human Rights (UDHR)**

For the estimated 75 million people worldwide with Celiac Disease, the Universal Declaration of Human Rights expressly and directly links “health and well-being” with adequate food.

In 1948, the United Nations Universal Declaration of Human Rights (UDHR)<sup>393</sup> was established as a foundational document in the history of human rights. “Drafted by representatives with different legal and cultural backgrounds from all regions of the world, the Declaration was proclaimed by the United Nations General Assembly in Paris on 10 December 1948 by General Assembly resolution 217 A (III) as a common standard of achievements for all peoples and all nations. It sets out, for the first time, fundamental human rights to be universally protected.” Article 25 of the Universal Declaration of Human Rights states,

“1. Everyone has the right to a standard of living adequate for the **health and well-being** of himself and of his family, **including food**, clothing, housing and medical care and necessary social services, and **the right to security in the event of** unemployment, **sickness, disability**, widowhood, old age or other lack of livelihood in circumstances beyond his control.

2. Motherhood and **childhood are entitled to special care and assistance**...”<sup>394</sup>  
(emphasis added)

According to the UN's “Plain Language Version” of the UDHR, Article 25.1 means,

“You have the right to have whatever you need so that you and your family: **do not fall ill; do not go hungry**...”<sup>395</sup> (emphasis added)

Even though the Universal Declaration of Human Rights holds the Guinness World Record as the most translated document in the world (into more than 500 languages as of 2019<sup>396</sup>), there are

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<sup>393</sup> <https://www.un.org/en/conferences/human-rights>

<sup>394</sup> <https://www.un.org/en/about-us/universal-declaration-of-human-rights>

<sup>395</sup> <https://www.ohchr.org/sites/default/files/Documents/Publications/ABCannexesen.pdf>



many people who are still unaware of their basic rights as human beings, including public servants in the United States government and even those in the Celiac community with the Right to Adequate Food.

### **The United Nations Convention on the Rights of the Child**

The United Nations Convention on the Rights of the Child expressly and directly links the importance of “combating (pediatric) disease and malnutrition, including within the framework of primary health care... through the provision of adequate nutritious foods”. Additionally, the Convention on the Rights of the Child addresses “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.”<sup>397</sup> Additionally, the concept that “childhood is entitled to special care and assistance” as enshrined in the United Nations Universal Declaration of Human Rights is expressly included in the Preamble to the “Convention on the Rights of the Child” that went into effect on September 2, 1990.

According to Article 3.1.,

“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.**”<sup>398</sup> (emphasis added)

According to Article 24.1,

“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.”<sup>399</sup>

According to Article 24.2,

“(b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;

(c) **To combat disease and malnutrition**, including within the framework of primary health care, through, inter alia, the application of readily available technology **and through the provision of adequate nutritious foods** and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;...

(e) To ensure that all segments of society, in particular parents and children, **are informed, have access to education and are supported in the use of basic knowledge**

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<sup>396</sup> “Most Translated Document,” Guinness World Records. 2009.

<https://www.guinnessworldrecords.com/world-records/most-translated-document>

<sup>397</sup> “Convention on the Rights of the Child.” United Nations. 20 November 1989.

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

<sup>398</sup> <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

<sup>399</sup> <https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

**of child health and nutrition**, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;” (emphasis added)<sup>400</sup>

The bottom line is that to address how the Celiac community has been historically underserved by the Federal government, including but not limited to the underfunding of Celiac Disease research, the voluntary labeling of Gluten and the disqualification from service in the military, the “legislative bodies” such as the U.S. Congress and the “administrative authorities” such as FDA, NIH, CDC, and DoD should use the Convention on the Rights of the Child as a guiding principle in the allocation of resources for the protection of consumers (labeling of Gluten) and funding of research: “the best interests of the child shall be a primary consideration.”

To those ends, the legislative and administrative bodies should “recognize the right of the child to the enjoyment of the highest attainable standard of health” whereby “[t]o combat disease and malnutrition, including within the framework of primary health care,... through the provision of adequate nutritious foods” is foundational. In addition to research for a treatment and a cure, appropriations from the USDA and DoE should be allocated “[t]o ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition” with respect to Celiac Disease.

**The Right to Adequate Food, United Nations Office of the Commissioner for Human Rights**  
According to the United Nations Office of the Commissioner for Human Rights “The Right to Adequate Food, Fact Sheet No. 34,”

**“Combating hunger and malnutrition is more than a moral duty or a policy choice; in many countries, it is a legally binding human rights obligation.** The right to food is recognized in the 1948 Universal Declaration of Human Rights as part of the right to an adequate standard of living, and is enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights.”<sup>401</sup> (emphasis added)

As a preliminary matter, it is important to note that one of the common misconceptions about the Right to Food. According to the United Nations,

**“The right to food is NOT the same as a right to be fed.** Many assume that the right to food means that Governments have to hand out free food to anyone who needs it. They conclude that this would not be feasible or might cause dependency. This is a misunderstanding. **The right to food is not a right to be fed, but primarily the right to feed oneself in dignity. Individuals are expected to meet their own needs, through their own efforts and using their own resources.**”<sup>402</sup> (emphasis added)

### **What is the Right to Food?**

According to the United Nations, food must be available, accessible and adequate:

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<sup>400</sup> “Convention on the Rights of the Child.” United Nations. 20 November 1989.  
<https://www.ohchr.org/sites/default/files/Documents/ProfessionalInterest/crc.pdf>

<sup>401</sup> “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.  
<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

<sup>402</sup> “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.  
<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

- “Availability requires on the one hand that food should be available from natural resources either through the production of food, by cultivating land or animal husbandry, or through other ways of obtaining food, such as fishing, hunting or gathering. On the other hand, it means that food should be available for sale in markets and shops.”
- **“Accessibility requires economic and physical access to food to be guaranteed.** Economic accessibility means that food must be affordable. Individuals should be able to afford food for an adequate diet without compromising on any other basic needs, such as school fees, medicines or rent.”
- **“Adequacy means that the food must satisfy dietary needs,** taking into account the individual’s age, living conditions, **health**, occupation, sex, etc. For example, if children’s food does not contain the nutrients necessary for their physical and mental development, it is not adequate. Food that is energy-dense and low-nutrient, which can contribute to obesity and other illnesses, could be another example of inadequate food. **Food should be safe for human consumption and free from adverse substances, such as contaminants** from industrial or agricultural processes, including residues from pesticides, hormones or veterinary drugs. Adequate food should also be culturally acceptable. For example, aid containing food that is religious or cultural taboo for the recipients **or inconsistent with their eating habits** would not be culturally acceptable.”<sup>403</sup> (emphasis added)

According to Vissing and Moore-Vissing in their article entitled, “Going Gluten Free as a Human Rights Issue,”

**“The issue of gluten contamination contributes to a constant situation of food and nutritional insecurity to holders of this special dietary need.** The celiac diet must be completely gluten-free, which allows people to have a life relatively free of major pathological complications. Maintaining a totally gluten-free diet is not an easy task because the violation of the diet may occur voluntarily or involuntarily, and **range from incorrect information on food labels to the gluten** contamination of processed products. Difficulties in the availability and access to food without gluten violates the principle of the [United Nations] human right to adequate food. **The condition of being a Celiac individual exposes one to permanent food and nutrition insecurity, which could cause loss of quality of life, socialization, and health of the individual, both in the short and long term.**”<sup>404</sup> (emphasis added)

### **The Link Between the Right to Adequate Food and Other Human Rights**

According to the United Nations Office of the Commissioner for Human Rights “The Right to Adequate Food, Fact Sheet No. 34,”

“Human rights are interdependent, indivisible and interrelated. This means that violating the right to [adequate] food may impair the enjoyment of other human rights, such as the right to health, education or life, and vice versa.”<sup>405</sup>

<sup>403</sup> “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/Documents/Publications/FactSheet34en.pdf>

<sup>404</sup> Vissing, Yvonne; Moore-Vissing, Christopher, “Going Gluten Free as a Human Rights Issue.” Journal of Gluten Sensitivity, Summer 2016 Issue, 11 July, 2016.

<https://www.celiac.com/articles.html/going-gluten-free-as-a-human-rights-issue-r3798/>

<sup>405</sup> “The Right to Adequate Food, Fact Sheet No. 34.” United Nations.

<https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

For example, according to the United Nations, the Right to Adequate Food is interdependent and interrelated with these rights:

- **“The right to health. Nutrition is a component of both the right to health and the right to food... When a child is suffering from diarrheal disease but denied access to medical treatment, it cannot enjoy an adequate nutritional status even if he or she has access to food.”**
- **“The right to life.** When people are not able to feed themselves and face the risk of death by starvation, **malnutrition or resulting illnesses, their right to life would also be at stake.”**
- **“The right to information.** Information is crucial for the right to food. It enables individuals to know about food and nutrition, markets and the allocation of resources. It strengthens people’s participation and free consumer choice. **Protecting and promoting the right to seek, receive and impart information thus facilitates the enjoyment of the right to food.”**<sup>406</sup> (emphasis added)

## **XXII. The Economics of Celiac Disease – The Financial Burden of the Gluten Free Diet**

**“Strict adherence to a gluten-free diet is the *only* available treatment. But, as our celiac disease researchers agree, ‘There is no such thing as a truly gluten-FREE diet’ because of the constant risk of cross-contact with gluten, and gluten is in 80% of our foodstuffs.”**<sup>407</sup>

-- Dr. Stefano Guandalini and Dr. Bana Jabri of the  
University of Chicago Celiac Disease Center

**“Oh, beautiful for spacious skies,  
For amber waves of grain,  
For purple mountain majesties  
Above the fruited plain!  
America! America!  
God shed his grace on thee,  
And crown thy good with brotherhood  
From sea to shining sea.”**  
-- Katharine Lee Bates

The food insecurity and treatment burden for Celiac Disease (i.e., constant threat of cross contact, Gluten is in 80% of all foodstuffs, and Gluten is not required to be labeled on all packaged foods in the US) is compounded by the increased cost of a “market basket” of Gluten Free products against a comparable market basket of Gluten containing products whereby research from Columbia University indicated that Gluten Free products were 183% more

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<sup>406</sup> <https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet34en.pdf>

<sup>407</sup> <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. Dig Dis Sci 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>

expensive nationwide.<sup>408</sup> For the average American family with Celiac Disease, NCGS or with any other medical needs that require a Gluten Free diet, that additional cost may represent an incredible expense, and one that can contribute to poor adherence to maintaining a strict Gluten Free diet, which in turn can cause more serious health issues. Families with low incomes, who have at least one member with Celiac Disease or NCGS, are disproportionately impacted to an even greater extent in terms of food insecurity. According to the 2019 Columbia University study, “The study market basket was based on the food and beverage portion of the USDA market basket which includes breakfast cereal, bread, milk, coffee, wine, chicken, service meals, and snacks based on national consumption data from the United States Department of Labor statistics.”<sup>409</sup>

On July 26, 2022, the Washington Post reported, “Over the past 18 months, Americans have faced ongoing waves of steep price hikes as inflation hit 40-year highs.”<sup>410</sup> We can personally attest to how inflation has impacted us, including with regard to the ever-increasing prices of Gluten Free foods (which already had premium prices pre-pandemic). To that end, we recently conducted our own market basket research in Philadelphia, and the Gluten Free product prices were much higher when compared to their Gluten containing products.

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<sup>408</sup> <https://www.celiacjourney.com/post/food-insecurity-in-the-context-of-celiac-disease>

<sup>409</sup> <https://celiacdiseasecenter.columbia.edu/wp-content/uploads/2019/07/2019-Persistent-Economic-Burden-of-the-Gluten-Free-Diet.pdf>

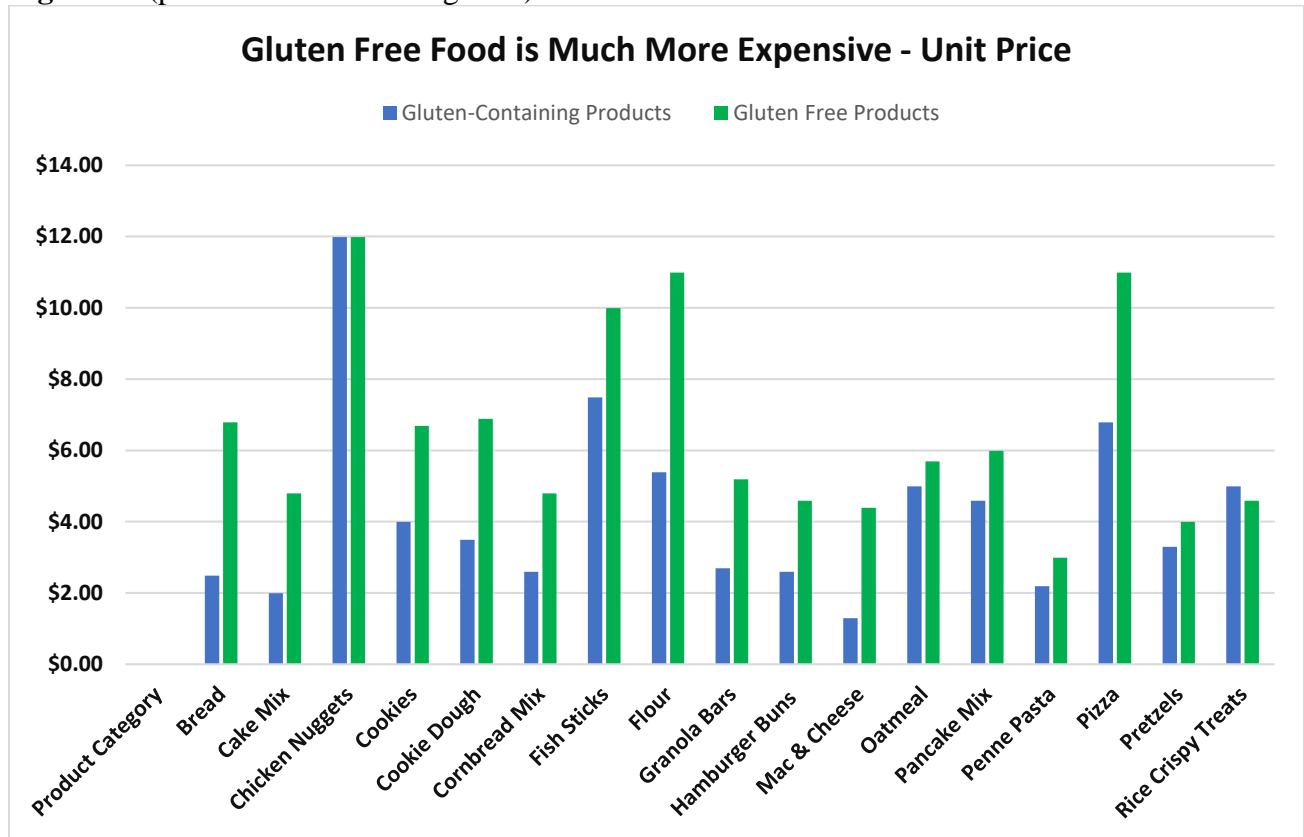
<sup>410</sup> <https://www.washingtonpost.com/business/2022/07/26/inflation-causes/>

**Figure 9 - Market Shopping in the Philadelphia Area as of July 10, 2022** (See Sources in Exhibit A herein)<sup>411</sup>

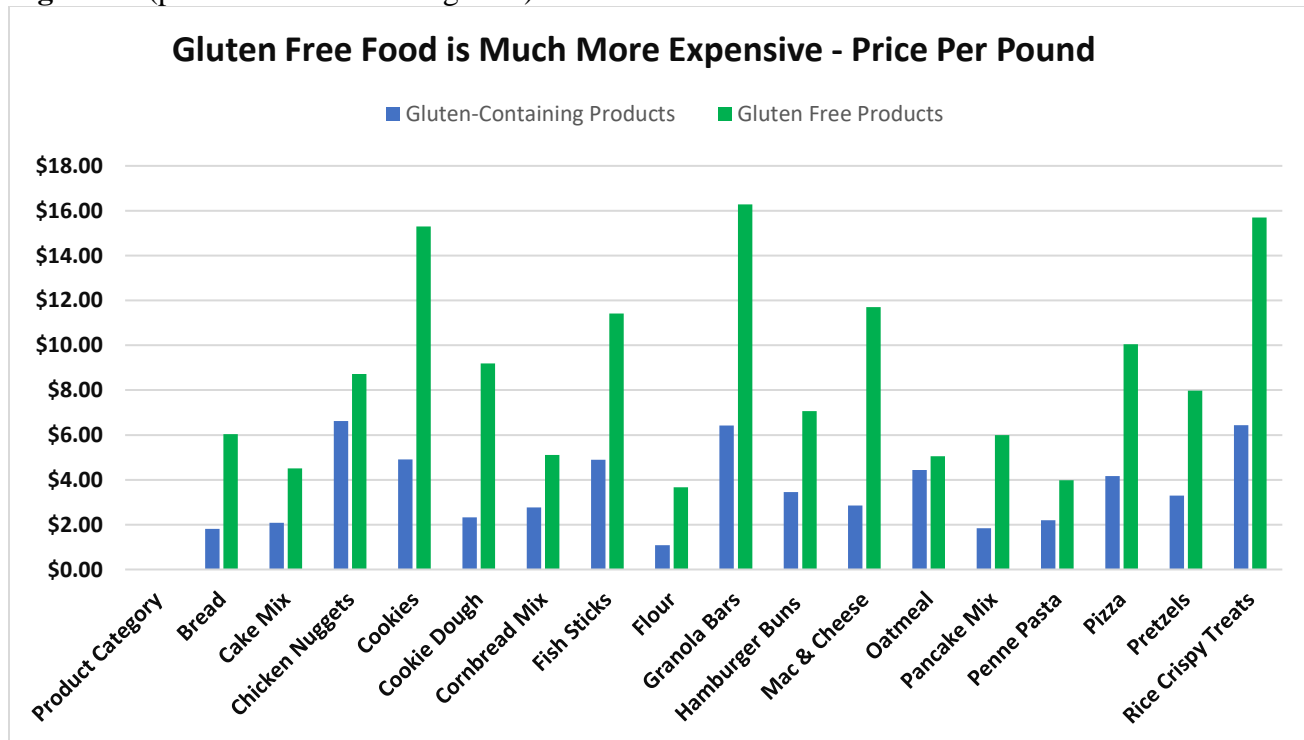
Product Category	Gluten-Containing Products			Gluten Free Products		
	Standard Packaged Food	Price	Price Per Ounce	Gluten Free Packaged Food	Price	Price Per Ounce
<b>Bread</b>	Stroehmann King White Sandwich Bread - 22oz, 26 slices [1]	\$2.49	\$0.11	Canyon Bakehouse Gluten Free Mountain White Bread - 18oz, 15 slices [2]	\$6.79	\$0.38
<b>Cake Mix</b>	Pillsbury Funfetti Cake mix, 15.25 oz [3]	\$1.99	\$0.13	Pillsbury Gluten Free Funfetti Cake Mix, 17 oz [4]	\$4.79	\$0.28
<b>Chicken Nuggets</b>	Perdue Simply Smart chicken Nuggets, 29 oz [5]	\$11.99	\$0.41	Perdue Simply Smart Gluten Free Chicken Nuggets, 22 oz [6]	\$11.99	\$0.55
<b>Cookies</b>	Chips Ahoy original 13 oz [7]	\$3.99	\$0.31	Tate's Gluten Free Chocolate Chip Cookies, 7 oz [8]	\$6.69	\$0.96
<b>Cookie Dough</b>	Pillsbury Chocolate Chip Cookie Dough - 16oz/24ct [33]	\$3.49	\$0.15	Sweet Loren's Gluten Free Vegan Chocolate Chunk Cookie Dough - 12oz, 12ct [34]	\$6.89	\$0.57
<b>Cornbread Mix</b>	Krusteaz Cornbread Mix, 15 oz. [9]	\$2.59	\$0.17	Krusteaz Cornbread Mix Gluten Free, 15 oz. [10]	\$4.79	\$0.32
<b>Fish Sticks</b>	Gorton's Fish Sticks, 24.5 oz. [11]	\$7.49	\$0.31	Ian's Gluten Free Fish Sticks, 14 oz. [12]	\$9.99	\$0.71
<b>Flour</b>	King Arthur All Purpose Flour, 5 lbs [13]	\$5.39	\$0.07	King Arthur Measure for Measure Flour, 48 oz [14]	\$10.99	\$0.23
<b>Granola Bars</b>	Quaker Chewy chocolate chip granola bars, 6.7 oz, 8 count [15]	\$2.69	\$0.40	Made Good Granola Bars, chocolate chip, 5.1 oz. 6 count [16]	\$5.19	\$1.02
<b>Hamburger Buns</b>	Wonder White Hamburger Buns, 12oz, 8 buns [17]	\$2.59	\$0.22	Udi's Gluten Free Hamburger Buns, 10.4 oz, 4 buns [18]	\$4.59	\$0.44
<b>Mac &amp; Cheese</b>	Kraft Macaroni & Cheese Dinner Original & Cheese Dinner, 7.25oz [19]	\$1.29	\$0.18	Kraft Gluten Free Macaroni & Cheese Original Flavor, 6.0oz [20]	\$4.39	\$0.73
<b>Oatmeal</b>	Quaker Oats 100% Whole Grain Old Fashioned - 18 Oz [21]	\$4.99	\$0.28	Quaker Select Starts Gluten Free Oats Quick 1-Minute - 18 Oz [22]	\$5.69	\$0.32
<b>Pancake Mix</b>	Bisquick original pancake mix, 40 oz. [23]	\$4.59	\$0.11	Bisquick Gluten Free Pancake Mix, 16 oz [24]	\$5.99	\$0.37
<b>Penne Pasta</b>	Barilla Penne Pasta, 16 oz. [25]	\$2.19	\$0.14	Barilla Penne Pasta Gluten Free, 12 oz. [26]	\$2.99	\$0.25
<b>Pizza</b>	Freschetta Pizza, 26.11 oz [27]	\$6.79	\$0.26	Freschetta Gluten Free pizza, 17.5 oz [28]	\$10.99	\$0.63
<b>Pretzels</b>	Snyders of Hanover Pretzels dipping sticks, 12 oz [29]	\$3.29	\$0.21	Snyders of Hanover, Gluten Free Pretzel Sticks, 8 oz [1]30	\$3.99	\$0.50
<b>Rice Crispy Treats</b>	Rice Krispie Treats, 12.4 oz, 16 count [31]	\$4.99	\$0.40	Made Good Vanilla Crispy Squares, 4.68 oz, 6 count [32]	\$4.59	\$0.98

<sup>411</sup> Stores shopped: Target (4000 Monument Road, Philadelphia, PA 19131) and Acme (Philadelphia/Bala Cynwyd, 121 E. City Avenue, Bala Cynwyd, PA 19004); stores are located within 1 mile of each other. Note that the citations for the products and prices can be found in Exhibit A at the end of the Comments.

**Figure 10** (prices derived from Figure 9)



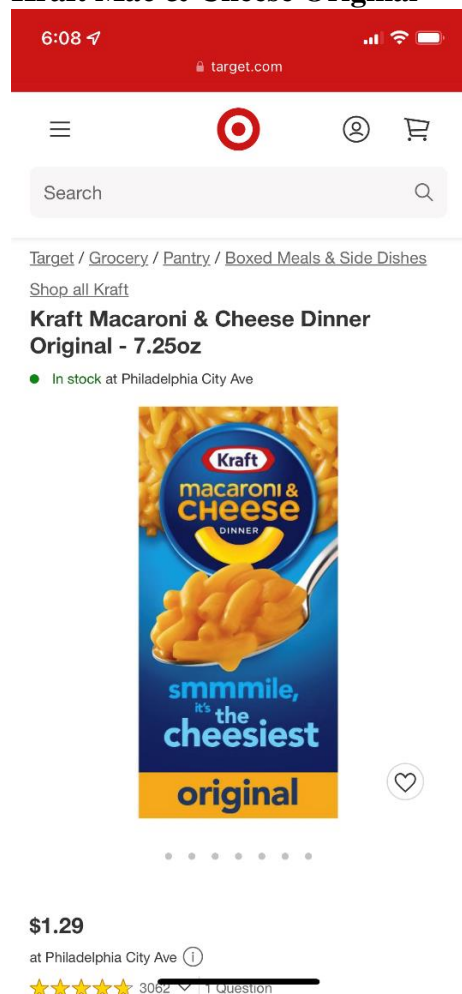
**Figure 11** (prices derived from Figure 9)



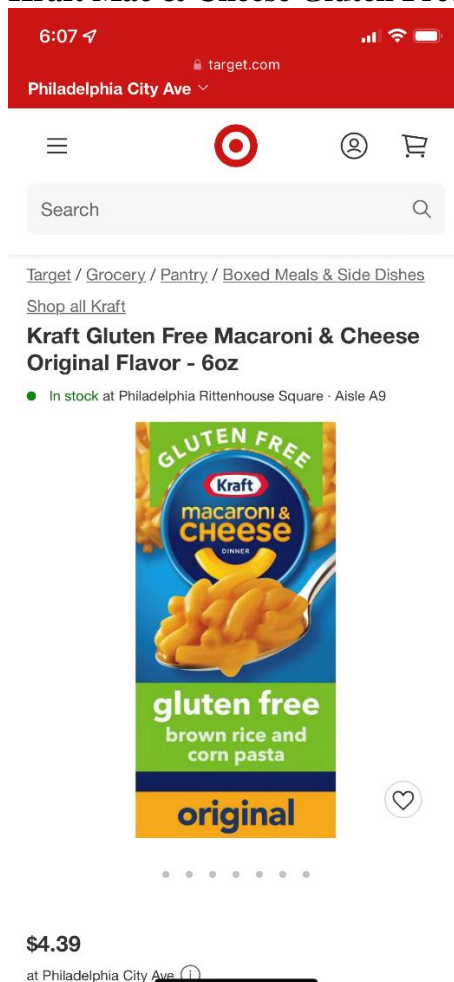
## A Tale of Two Kraft Mac & Cheese Dinners

Kraft considers its Mac & Cheese as “comfort food.”<sup>412</sup> While we are appreciative that Kraft offers a Gluten Free version of this comfort food, we take no comfort in the fact that Kraft Macaroni & Cheese Dinner Original, 7.25oz sells for \$1.29<sup>413</sup> (\$0.18 per ounce), whereas Kraft Gluten Free Macaroni & Cheese Original Flavor, 6.0oz sells for \$4.39<sup>414</sup> (\$0.73 per ounce).

### Kraft Mac & Cheese Original



### Kraft Mac & Cheese Gluten Free



Some would suggest that the price disparity is because there are more ingredients used in the Gluten Free versions of food. However, in terms of ingredients in this example, the Kraft Mac & Cheese Dinner Original contains more ingredients than the Gluten Free counterpart. The Original contains “Enriched Macaroni (Wheat Flour, Durum Flour, Niacin, Ferrous Sulfate [Iron], Thiamin Mononitrate [Vitamin B1], Riboflavin [Vitamin B2], Folic Acid)”, but is replaced in the Gluten Free version with “Gluten Free Pasta (Corn Flour, Brown Rice Flour).”<sup>415 416</sup>

<sup>412</sup> <https://www.cnn.com/2022/06/22/business-food/kraft-mac-and-cheese-name/index.html>

<sup>413</sup> <https://www.target.com/p/kraft-macaroni-38-cheese-dinner-original-7-25oz/-/A-12954218>

<sup>414</sup> <https://www.target.com/p/kraft-gluten-free-macaroni-38-cheese-original-flavor-6oz/-/A-79684594>

<sup>415</sup> <https://www.target.com/p/kraft-macaroni-38-cheese-dinner-original-7-25oz/-/A-12954218>



According to The New York Times, in a 2014 article entitled, “A Big Bet on Gluten-Free,”

“Rebecca Thompson, a marketing manager at General Mills, said relying on the data on levels of celiac and gluten sensitivity in the population to predict the staying power of consumer demand underestimated how many people were eating gluten-free products.

‘When you think about the dynamics in a household, where there are likely to be three other people eating at the same time as one person with celiac or gluten sensitivity, it’s much easier to prepare one meal for everyone.’”<sup>417</sup>

While it may be healthy for General Mills’ bottom line to benefit from a family of four maintaining a Gluten Free household when just one member of the family requires a Gluten Free diet, it can be quite expensive for the average American who requires a Gluten Free diet for one, let alone someone who may want to prepare one meal for everyone in the household that they can all eat together. This speaks to how costs can be multiplied throughout a household, especially for premium products such as Gluten Free foods, and moreover how for families with low incomes, they are disproportionately impacted to an even greater extent in terms of inequity and food insecurity.

According to Grocery Dive’s 2017 article, “Is gluten-free still worth the investment for retailers?”,

“Retailers have enjoyed the higher margins and intense customer loyalty that come with gluten-free. And many remain fully invested in the trend. But others see warning signs that a much-anticipated downturn could still lie ahead. At the very least, capitalizing on gluten-free demand presents a complex proposition for supermarkets one that requires both smart merchandising and consumer outreach, which seeks to meet diverging needs for the same products.”<sup>418</sup>

In 2009, General Mills attributed growth in multiple categories including cereals and baking products to the introduction of gluten-free products.<sup>419</sup> In 2011, even when other categories were performing poorly, Gluten Free products broke the trend and still produced as General Mill noted that Gluten Free products that were introduced had good initial sales results.<sup>420</sup>

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<sup>416</sup> <https://www.target.com/p/kraft-gluten-free-macaroni-38-cheese-original-flavor-6oz/-/A-79684594>

<sup>417</sup> Strom, Stephanie. “A Big Bet on Gluten-free.” The New York Times, 17 February 2014. <https://www.nytimes.com/2014/02/18/business/food-industry-wagers-big-on-gluten-free.html> . Accessed 26 June 2022.

<sup>418</sup> <https://www.grocerydive.com/news/grocery---gluten-free-grocery-investment/535453/>

<sup>419</sup> “General Mills Reports Strong Results for Fiscal 2010 First Quarter.” SEC, 23 September 2009. <https://www.sec.gov/Archives/edgar/data/0000040704/000095012309045055/c53735exv99w1.htm>.

<sup>420</sup> “General Mills Reports Fiscal 2011 First-Quarter Results.” SEC, 22 September 2022. <https://www.sec.gov/Archives/edgar/data/0000040704/000095012310087965/c60382exv99w1.htm>.

In their 2015 Annual Report, General Mills described their Gluten Free product offerings as an attempt to meet consumer demand: “For example, nearly 30 percent of U.S. consumers have purchased gluten-free products as recently as our fourth fiscal quarter, so we’ve increased our gluten-free cereal offerings to include varieties of granola and hot oatmeal. And starting this summer, five varieties of Cheerios will be gluten free.”<sup>421</sup> In 2022, General Mills’ status as the third largest producer of gluten-free food in the U.S. is considered a fiscal highlight for the company.<sup>422</sup>

According to Grand View Research, some of the prominent manufacturers in the Gluten Free products are: “Conagra Brands, Inc.; The Hain Celestial Group Inc.; General Mills Inc.; Kellogg Co.; The Kraft Heinz Company; Hero AG; Barilla G. e R. Fratelli S.p.A; Seitz glutenfrei; Freedom Foods Group Limited; Ecotone.”<sup>423</sup>

The bottom line is that Gluten Free food market today is big business. According to a report by Global Market Insights Inc., the Gluten Free Food market was “estimated at USD 8.90 billion in 2020 and is projected to be valued at more than USD 17.05 billion by 2027, registering with a CAGR of 9.5% from 2021 to 2027.”<sup>424</sup>

### **The Premium & Lucrative Market Developed for Gluten Free Food**

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) found,

#### **“Premium buyers / They spend more**

Food Allergy Consumers are premium buyers, spending five percent more on average for groceries per month than the average surveyed consumer, with 32 percent indicating they are willing to spend more on the highest quality ingredients.”<sup>425</sup>

As have seen herein, there is a significant premium cost associated with maintaining a Gluten Free diet.

If the labeling of Gluten was mandatory on all products, it is our belief that the number of Gluten Free food products available to those who have Celiac Disease or NCGS would greatly expand

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<sup>421</sup> “General Mills – 2015 Annual Report.”

[https://s22.q4cdn.com/584207745/files/doc\\_financials/2015/annual/Gen-Mills-AR-2015a-FINAL.pdf](https://s22.q4cdn.com/584207745/files/doc_financials/2015/annual/Gen-Mills-AR-2015a-FINAL.pdf).

<sup>422</sup> “General Mills Highlights Progress in 2022 Global Responsibility Report.” General Mills Press Releases, 19 April 2022. <https://investors.generalmills.com/press-releases/press-release-details/2022/General-Mills-Highlights-Progress-in-2022-Global-Responsibility-Report/default.aspx>.

<sup>423</sup> “Gluten-Free Products Market Size, Share & Trends Analysis Report By Product (Bakery Products, Dairy/Dairy Alternatives), By Distribution Channel (Supermarkets & Hypermarkets, Convenience Stores), By Region, And Segment Forecasts, 2022 – 2030.” Grand View Research. <https://www.grandviewresearch.com/industry-analysis/gluten-free-products-market>.

<sup>424</sup> <https://www.globenewswire.com/news-release/2022/03/01/2393849/0/en/The-Gluten-Free-Food-Market-to-exceed-USD-17-05-billion-by-2027-says-Global-Market-Insights-Inc.html>

<sup>425</sup> <https://www.foodallergy.org/media/1059/download>

just by virtue of food products that do not contain Gluten being labeled as such. Additional research would be worthwhile to analyze this in more detail.

In the absence of required labeling, coupled with a voluntary consumer diet fad for Gluten Free foods, we believe that this has caused Gluten Free food, in part, to be much more expensive than regular food items by creating a premium or gourmet-like high-priced market segment. While allergen free foods are more expensive than their allergen containing counterparts, anecdotal evidence suggests that allergen free foods do not appear to be marked up nearly as much as Gluten Free products are compared with their Gluten containing counterparts, albeit further research is needed on these economic issues.

### **Offsetting the Cost of Gluten Free Food**

While the following is likely out of the direct purview of the FDA, it is nonetheless instructive for the FDA to understand these financial implications of the Gluten Free diet.

Given the high price of Gluten Free food, there should be some financial offset to compensate individuals, families and caretakers who purchase Gluten Free food for someone who medically requires being on a Gluten Free diet. While in theory there are some tax deductions available for medical expenses associated with Gluten Free food, not many people are able to take advantage of these deductions based on the complex and cumbersome IRS filing requirements.<sup>426</sup> In addition to potentially changing the tax code to allow for all Celiac patients and their families the right to deduct the incremental cost for Gluten Free food, another potential idea for example to accommodate the high cost of Gluten Free food would be for all of the associated expenses therefore to qualify as medical expenses towards meeting certain health insurance plan deductibles.

### **The Merchandising of Gluten Free Food**

According to the FDA, “‘Gluten-Free’ Means What It Says -- Not long ago, gluten-free foods on the grocery shelves could be hard to find. Not so much, now.”<sup>427</sup>

While it may be easier to find Gluten Free food since the voluntary Gluten Free labeling final rule went into effect in August 2014, it is certainly not easy! Period. Full stop. That is a meaningful distinction with a difference. The FDA’s “not so much, now” statement suggests another example of food privilege that does not acknowledge the perpetual state of food insecurity that many Celiacs like my son can face every day with every bite in the absence of mandatory labeling.

While I understand that the FDA is not directly involved in food merchandising, it is though instructive for the FDA to consider the downstream merchandising implications and consumer behavior that flow from voluntary Gluten Free labeling and how that can contribute to consumer confusion and undermine consumer protection during the shopping experience for Gluten Free food.

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<sup>426</sup> “Tax deductions for gluten-free food.” National Celiac Association.  
<https://nationalceliac.org/resources/tax-deductions-gluten-free-food/>

<sup>427</sup> <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

In a video from Children's National Hospital in Washington, D.C. "What does 20ppm gluten really look like?", there is a discussion on the voluntary labeling scheme for Gluten Free products which illustrates how consumer confusion can easily arise.

"Voluntary labeling. Now it's important to remember that there are thousands of products in a grocery store that are naturally gluten free or are manufactured using gluten-free ingredients that will not have a gluten-free label. **You mean that there are things that are Gluten Free that don't say it on the package? Yes [on screen: 'It might be a law, but labeling it is not.'], the FDA law is a voluntary rule which means that a company doesn't have to label their product as Gluten Free unless they want to and have tested it to make sure it complies with the 20 ppm standard.** The bottom line is that you always need to check food labels. If there are any questions, contact the manufacturer directly to find out how the product is made."<sup>428</sup> (emphasis added)

According to Gluten-Free Living in June 2015,

"Many shoppers are seeking out stores with stand-alone gluten-free sections, and food retailers of all sizes are filling the need. At Sprouts, every location has a dedicated area that contains only certified-gluten-free products. 'This is an important differentiator for people with celiac disease because it allows them to have a simpler shopping experience by focusing on this one aisle rather than having to search throughout the store for various gluten-free products,' explains Little [Director of Nutrition, Sprouts Farmers Market]."<sup>429</sup>

The Food Network published "The Beginners Guide to Gluten-Free Grocery Shopping, Your primer to navigating the grocery store in search of gluten-free products", and it speaks to some of the many challenges in food shopping depending on how merchandising of Gluten Free food is done, which can vary greatly from chain to chain and even from one store in a chain to another store within the same chain. There are also geographic variability with the availability of Gluten Free food items whereby some areas appear to have stores which stock more Gluten Free food products more than other areas.

"Ask customer service where to find gluten-free products. Sure, you could just walk up and down every aisle the best way to really get to know a supermarket, and worth the time if you regularly shop at the same store. You can also ask if there's a natural foods section, which usually has shelves stocked with gluten-free goods. Otherwise, some stores have dedicated gluten-free aisles for fast shopping, while others blend in gluten-free products with their gluten-full counterparts."<sup>430</sup>

In other words, there is no consistent merchandising scheme for Gluten Free foods at various retailers. For example, some retailers have a dedicated Gluten Free aisle(s) for consumer packaged foods, including for refrigerated and/or frozen items. However, in the case when there is not a dedicated Gluten Free aisle(s), coupled with the voluntary labeling scheme for Gluten, then consumers are left to go on a search through the store and read many labels, which can result in a very time consuming and costly trip to the market. According to "The Food Allergy

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<sup>428</sup> [https://youtu.be/aaQhIJ\\_06Vw?t=190](https://youtu.be/aaQhIJ_06Vw?t=190)

<sup>429</sup> <https://www.glutenfreeliving.com/gluten-free-foods/shopping-gluten-free/supermarkets/>

<sup>430</sup> <https://www.foodnetwork.com/healthyeats/2016/05/the-beginners-guide-to-gluten-free-grocery-shopping>

Consumer Journey, Defining Challenges, Overcoming Obstacles, Creating a Blueprint for Food Allergen Labeling Success” conducted by McKinsey & Company, Northwestern University and Global Strategy Group, 71% of consumers “check food labels every time they shop – some for 3-5 minutes per product.”<sup>431</sup> In that particular scenario where there is not a dedicated Gluten Free aisle(s), it is even more important to have Gluten labeled on all food products which will reduce time spent deciphering labels and mitigate adverse health effects from accidental Gluten ingestion.

According to Gluten-Free Living,

**“The level of competition** among bread manufacturers - large and small - **for shelf space is fierce**, according to Scott Owen, the grocery merchandiser at Seattle-based PCC Natural Markets. He says that ultimately it’s not the brand name that dictates whether a product stays or goes -- **sales numbers dictate the fate of all products**. Sprouts assesses the sales data of gluten-free products more frequently than other store categories because of continued improvements, product selection and consumer demand, says Little.”<sup>432</sup> (emphasis added)

The Gluten Free Living article speaks to the financial pressures that retailers are under to maximize sales in terms of shelf space (real estate) in markets. Manufacturers are also under intense financial pressures to increase sales volume and product margins, and the Gluten Free marketplace helps them achieve these business goals. In other words, stores will regularly reallocate shelf space and pull products when certain products and segments are not performing as well as they would like.

### **Our Lived Experience with Gluten Free Food Shopping**

From our personal lived experience, some of our neighborhood supermarkets previously had dedicated aisles to Gluten Free food, including for refrigerated and frozen foods. Then some of the neighborhood markets eliminated the dedicated aisles and/or refrigerator/freezer cases, reduced the amount of Gluten Free foods that they carried and interspersed the more limited array of Gluten Free products throughout the rest of the market. From personal experience, Wegman’s sets the gold standard for the variety of Gluten Free foods and the manner in which these Gluten Free food products are curated and merchandised in dedicated aisles and refrigerator/freezers. However, the closest Wegman’s to our home is about 14 miles (about a 26 minute ride by car), which is not very convenient.

Shortly after Jax first began his Celiac journey at age 5 in 2018, I realized that Celiac had been an abstract disease to us, and I was struggling with ways of sharing with friends and family how dangerous and challenging this life changing disease was. Then came the pandemic, and COVID provided experiences for all that emulated some of our lived experiences with Celiac. For example, the abstract concepts of isolation, social distancing, fear, uncertainty, scarcity, and inflation with Celiac were now being experienced by many within the context of COVID.

Let me explain. When I first studied marketing at the Wharton School as an undergraduate student at the University of Pennsylvania, I studied how consumer packaged goods companies

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<sup>431</sup> <https://www.foodallergy.org/fare-consumer-journey-infographic> ; and <https://www.foodallergy.org/food-allergy-consumer-journey>

<sup>432</sup> <https://www.glutenfreeliving.com/gluten-free-foods/shopping-gluten-free/supermarkets/>

market their products to children and display them at their eye level in the supermarket (cereals, snacks, candy, drinks, etc.). Since Jax's 2018 Celiac diagnosis, I have often wandered through supermarkets with my wife, Leslie, and son trying to identify safe Gluten Free products and realizing how hard this "eye candy" must be to Jax when so many of the food products that catch his eye and make him salivate are now items that he simply could not eat without getting very sick. It was then, and it is still now, heartbreaking to think how limited Jax and the 3 million other Celiacs are in the vastly limited subset of foods that they can safely eat!

I wondered how I could visually and verbally communicate this to others -- this level of food insecurity with the limited availability of safe food. When the pandemic and supply chain issues caused store shelves to be bare, I thought that this was a powerful analogy. When pandemic prices for almost all groceries soared including for cereal and baked goods; dairy; meat, poultry and eggs; as well as fruits and vegetables, I thought that the analogy became even more compelling.<sup>433</sup> The empty shelves with a very limited supply of certain food items, coupled with soaring prices, symbolized to me a Celiac's everyday reality with the limited amount of available, affordable and safe food in any given market.

### **The Voluntary Gluten Free Diet Fad May Fade**

I have also worried that as with all fad diets, the voluntary Gluten Free diet preference will fade over time, the number of voluntarily labeled Gluten Free products will contract, and the amount of shelf space allocated at retailers for voluntarily labeled Gluten Free products will contract. As discussed, we have already seen dedicated Gluten Free shelves, sections and aisles disappear in chain retailers like Acme and Giant in the Philadelphia area. The negative feedback cycle could also likely also cause less voluntarily labeled Gluten Free products to be introduced into market and ultimately, there will be fewer products voluntarily labeled Gluten Free.

According to "Against the Grain" as published by the New Yorker,

"Fad dieting is nothing new in America; it's what we do instead of eating balanced, nutritiously wholesome meals. Scarsdale, Atkins, South Beach, Zone, flexitarian, pescatarian, and paleo have all been awarded their fifteen minutes of fame and then shoved aside for the next great diet. They are rarely effective for long. **Some nutrition specialists say that the current preoccupation with gluten-free products reminds them of the national obsession with removing fats from foods in the late nineteen-eighties.** 'Low-fat' foods are often packed with sugar and calories to make up for the lack of fat. The same is true of many products that are advertised as 'gluten-free'."<sup>434</sup>  
(emphasis added)

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<sup>433</sup> According to the Washington Post on August 10, 2022, "Food costs have climbed every month this year. Groceries are 12.2 percent higher now than they were last summer the biggest year-over-year spike in 43 years, federal data shows. Fruits and vegetables cost 8 percent more, staples such as bread and cereal have jumped 14 percent, and butter and margarine are up a whopping 26 percent." See <https://www.washingtonpost.com/business/2022/08/10/food-prices-rising/> and "Increased food prices led by rise in cost of grains and dairy, Percent change in consumer price index since July 2021, seasonally adjusted", <https://www.washingtonpost.com/business/2022/inflation-charts/>

<sup>434</sup> <http://www.newyorker.com/magazine/2014/11/03/grain>

While many market analysts continue to predict a growing Gluten Free market, some believe that the Gluten Free market could collapse based on the enormous disconnect in numbers between those who need a Gluten Free diet due to medical reasons and those who are choosing to pursue a Gluten Free diet without any medical need simply because Gluten Free may be perceived as healthier.

However, some studies also show that although the Gluten Free market has continued to expand, more and more people are growing skeptical that eating Gluten Free has health benefits for those who are not allergic or intolerant to Gluten. According to Grocery Dive's 2017 article, "Is gluten-free still worth the investment for retailers?",

"Considering that gluten-free products are typically pricier than their conventional counterparts, why are they purchased by people who don't need them? Gluten-free skepticism is trickling down to the consumer level. A 2015 Mintel study found that 47% of consumers think gluten-free is a fad, up from 31% who said the same two years earlier."<sup>435</sup>

According to economist Dr. Vikram Mansharamani<sup>436</sup> in an article published in Fortune entitled "We're in a gluten-free bubble that is about to burst,"

"Gluten-free. It's among the hottest trends in food today. It competes with non-GMO, local and organic for mindshare among today's health-conscious, price-insensitive, and trend-following foodies, yuppies, and self-anointed amateur nutritionists... Like financial bubbles, the herd behavior identified by such popular attention is never sustainable. Here's the big disconnect that captures the essence of the problem: less than 1 percent of the population has celiac disease, approximately 6 percent are gluten intolerant, and ... drum roll please ... almost 30 percent of American adults are trying to avoid gluten. One of the main reasons consumers avoid gluten is they feel it's healthier. It's generally not."<sup>437</sup>

"The blunt reality is that many gluten-free foods are not healthier for the 93 percent of the population that doesn't have celiac disease or gluten sensitivity. Consider that a Glutino Original New York Style Bagel has 26 percent more calories, 250 percent more fat, 43

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<sup>435</sup> Wells, Jeff. "Is Gluten-Free Still Worth the Investment for Retailers?" Grocery Dive, 15 February 2017. <https://www.grocerydive.com/news/grocery---gluten-free-grocery-investment/535453/>. Accessed 26 June 2022.

<sup>436</sup> "Dr. Vikram Mansharamani is a global trend-watcher who shows people how to anticipate the future, manage risk, and spot opportunities. He is the author of the recently-released *THINK FOR YOURSELF: Restoring Common Sense in an Age of Experts and Artificial Intelligence* and *BOOMBUSTOLOGY: Spotting Financial Bubbles Before They Burst*. He has been a frequent commentator on issues driving disruption in the global business environment. Vikram's ideas and writings have also appeared in *Bloomberg*, *Fortune*, *Forbes*, *The New York Times* and a long list of other publications. LinkedIn twice listed him as their #1 Top Voice for Money, Finance and Global Economics and *Worth* has profiled him as one of the 100 most powerful people in global finance. Millions of readers have enjoyed his unique multi-lens approach to connecting seemingly irrelevant dots." Source: <http://www.mansharamani.com/>

<sup>437</sup> Mansharamani, Vikram. "We're in a gluten-free bubble that is about to burst." *Fortune*, 5 May 2015. <https://fortune.com/2015/05/05/gluten-free-foods/>

percent more sodium, 50 percent less fiber and double the sugar of a Thomas Plain Bagel. Further, because many gluten-free products utilize rice flour, they are also at risk of containing higher levels of arsenic than desirable or healthy.<sup>438</sup>

And then there's the cost. The Glutino bagel I just described costs 74 percent more than the Thomas bagel. Nabisco's Gluten-Free Rice Thins cost 84 percent more per cracker than Nabisco's Multigrain Wheat Thins. And when it gets to baking products, the costs are even higher. Betty Crocker's gluten-free brownie mix is more than 3 times the cost per serving of Duncan Hines regular mix.

While economic logic might lead you to conclude that higher prices would lead to lower demand, you'd be wrong. In a classic indicator of bubble dynamics, higher prices have been met with higher demand."<sup>439</sup>

On July 12, 2015, the BBC published an article entitled "The great gluten-free diet fad" which stated: "A report on the US gluten-free market by Mintel values it at almost \$9bn, because 'the health halo surrounding the gluten-free category continues to drive general consumer interest'. The singer Miley Cyrus encapsulated the mood in a tweet: 'Gluten is crappppp anyway!'<sup>440,441</sup>

According to Glutagen, an Australian biopharmaceutical company focused on providing clinically-relevant and scientific evidence-based complementary medicines to support the health and wellbeing of individuals with gluten-related issues,

"Disappointingly, the researchers [on the cost of a Gluten Free diet] found an ongoing increase in overall GF product prices and an ongoing drop in GF product availability. They noted that other studies had found similar patterns in several countries, including the UK, Austria and Chile."<sup>442</sup>

### **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**

Prior to the pandemic, when I shared with others my concern that the demand for Gluten Free foods may contract one day because a new fad diet will replace the voluntary elected Gluten Free diet, which could then in turn cause the amount of Gluten Free products available to contract, which could then result cause prices to spike even higher, I felt that my concerns were dismissed as if I was an alarmist. Then the pandemic hit, and unimaginable realities set in on a multitude of fronts. This became even more focused during the baby formula shortage of 2022.

According to the Washington Post,

"The nationwide formula shortage has focused on the plight of infants. But some older children and adults depend on specially formulated powders, much of it made by Abbott, to compensate for a variety of ailments, from malformed bowels and allergies to

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<sup>438</sup> <https://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm>

<sup>439</sup> Mansharamani, Vikram. "We're in a gluten-free bubble that is about to burst." Fortune, 5 May 2015. <https://fortune.com/2015/05/05/gluten-free-foods/>

<sup>440</sup> <https://twitter.com/MileyCyrus/status/189209905415192578>

<sup>441</sup> <https://www.bbc.com/news/magazine-33486177>

<sup>442</sup> <https://glutagen.com/the-cost-of-a-gluten-free-diet/#:~>



problems processing nutrients like protein. While most healthy babies can switch easily from brand to brand, for these people, a poorly chosen substitute can either taste intolerable or prompt dehydration, seizures and even death.”<sup>443</sup>

In Congressional testimony on May 25, 2022 from Dr. Robert Califf, FDA Commissioner, Frank Yiannas, MPH, Deputy Commissioner, Food Policy and Response, and Dr. Susan Mayne, Director, Center for Food Safety and Applied Nutrition on Formula Safety And Supply: Protecting The Health Of America’s Babies,

“Chair DeGette, Ranking Member Griffith, and members of the Subcommittee, thank you for inviting us here today to testify before you on supply disruptions in infant formula. We have all seen the images of empty store shelves and heard the stories of parents of kids unable to find the food their children need to survive. This situation is unacceptable. The staff at the U.S. Food and Drug Administration (FDA or the Agency) feel this not just as public servants whose job it is to ensure that these critical products are safe and nutritious, but also as parents and grandparents. Our top priority now is addressing the dire need for infant formula in the U.S. market, and our teams are working night and day to help make that happen.”<sup>444</sup>

In that same vein as it pertains to the only available treatment for Celiac Disease -- a strict Gluten Free diet for life -- we are appealing to the FDA, as public servants, parents and grandparents, for help! We rely on you, the FDA, to ensure critical food products are safe and nutritious, but also readily available. For Celiacs, in addition to products being on store shelves, products must not contain Gluten. There are many products that are free from Gluten but just not labeled since there is no mandatory labeling scheme.

It is illustrative to let the baby formula fiasco be a wake-up call so we do not repeat this again, including with the market for specialized foods 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”) can be disrupted by macro-economic, micro-economic, supply chain, operational shocks, etc.

Before the baby formula recall, “Abbott controlled 40% of the infant formula market, including Similac, but the market share of other companies such as Reckitt Benckiser Group PLC (RKT.L)

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<sup>443</sup> <https://www.washingtonpost.com/health/2022/06/03/baby-formula-shortage-metabolic-disorder/>

<sup>444</sup> TESTIMONY OF ROBERT M. CALIFF, M.D. COMMISSIONER OF FOOD AND DRUGS FRANK YIANNAS, M.P.H. DEPUTY COMMISSIONER, FOOD POLICY AND RESPONSE SUSAN T. MAYNE, PH.D. DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS COMMITTEE ON ENERGY AND COMMERCE U.S. HOUSE OF REPRESENTATIVES Formula Safety And Supply: Protecting The Health Of Americas Babies, May 25, 2022, <https://www.fda.gov/media/158739/download>

has grown since then.”<sup>445</sup> While there may not be one company that controls 40% of the Gluten Free market today, there are some large multinational food companies (as previously discussed herein) involved in producing Gluten Free food.

In the event that tastes change and the market for Gluten Free food declines among those consumers who voluntarily elect to pay these premiums (i.e., the “Gluten Free tax”) and 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.

### **XXIII. FDA’s Name and Corresponding Organizational Structure Are Incongruent In Adequately Protecting American Consumers**

**“Let food be thy medicine and medicine be thy food.”**

-- Hippocrates

**“All disease begins in the gut.”**

-- Hippocrates

**“Although many patients are convinced of the importance of food in both causing and relieving their problems, many doctors’ knowledge of nutrition is rudimentary. Most feel much more comfortable with drugs than foods, and the ‘food as medicine’ philosophy of Hippocrates has been largely neglected.”<sup>446</sup>**

-- Richard Smith, Editor, BMJ

On June 7, 2022, Robert Califf, M.D., Commissioner of the FDA, stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session on June 7, 2022 that the first letter in FDA is “F for food.”<sup>447</sup>

However, it is instructive to look at the information that has surfaced regarding the 2022 baby formula crisis and understand how that information suggests that the FDA’s organizational and operational structures have also hampered the FDA’s consumer protection of food. On May 25, 2022, The Washington Post reported that the whistleblower report filed in October 2021 “alleging a host of unsanitary conditions at an Abbott infant formula factory” did not reach the FDA’s top official for food safety, Frank Yiannas, Deputy Commissioner for Food Policy and Response, until four months after it was filed.

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<sup>445</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/abbott-raises-2022-profit-forecast-2022-07-20/#:~>

<sup>446</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC318470/>

<sup>447</sup> Robert Califf, M.D., Commissioner of the FDA stated in opening plenary remarks at the White House Conference on Hunger, Nutrition, and Health Regional Listening Session, June 7, 2022.

**“The national fallout over the Abbott case has exposed a fractured structure at an agency that has long prioritized drugs and medicine over food safety,** experts say — a problem exemplified by its handling of the whistleblower complaint and other warning signs of problems at the plant.”<sup>448</sup>

“The essential thing is that you’ve got three major operating components that are reporting only to the [FDA] commissioner, who, by tradition and current reality is a physician who is focused on medical products and doesn’t have the bandwidth or the inclination to spend time providing the leadership that’s needed for the food program to be successful, said Michael R. Taylor, who was deputy commissioner for foods and veterinary medicine during the Obama administration.”<sup>449</sup> (emphasis added)

For the record, our Comments on the FDA’s Draft Guidance are also being sent directly to Frank Yiannas, Deputy Commissioner for Food Policy and Response.

#### **XXIV. Disparities Among Gastrointestinal Disorders in Research Funding From the NIH**

**“Why should there be hunger and deprivation in any land, in any city, at any table, when man has the resources and the scientific know-how to provide all mankind with the basic necessities of life? There is no deficit in human resources. The deficit is in human will.”**

--Dr. Martin Luther King Jr.

To understand the historically inadequate NIH funding of Celiac Disease, it is instructive to read the peer reviewed academic analysis published in 2017 by the American Gastroenterological Association entitled, “Disparities Among Gastrointestinal Disorders in Research Funding From the National Institutes of Health.” This analysis was written by some of the world’s leading GI researchers, which found that, 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. “Barrett’s esophagus, with a prevalence of approximately 1%, received \$64.1 million over the 5-year period. Celiac disease, with prevalence very similar to that of Barrett’s Esophagus at approximately 1%, received significantly less funding over the 5-year period at \$15.4 million -- the lowest amount of all the diseases studied.”
- D. “Although there is no global metric for disease importance, it is difficult to justify on medical and scientific bases a reason for such large and persistent funding differences. Although Crohn’s disease has many available and emerging treatment options, celiac disease, for example, is more prevalent and has no current treatment available to patients beyond the burdensome gluten-free diet; however, celiac disease received only a small fraction of the funding that Crohn’s disease received from the NIH over the 5-year period.”
- E. “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,

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<sup>448</sup> <https://www.washingtonpost.com/politics/2022/05/25/whistleblower-fda-yiannas-report-abbott-baby-formula/>

<sup>449</sup> <https://www.washingtonpost.com/politics/2022/05/25/whistleblower-fda-yiannas-report-abbott-baby-formula/>

and available treatment options are considered. Plausible reasons for this disparity include varying numbers of established research programs to recruit young investigators, fewer grants submitted because of a lack of investigators in the field owing to poor funding, and narrow expertise of peer reviewers on NIH review committees. In contrast with disorders with low funding levels, ample public and private funding of Crohn's disease allows for excellent research, which in turn, favors more awards of research funding. This may seem circuitous; however, funding of Crohn's disease research provides an example of the way in which success breeds success."<sup>450</sup>

Over the past decade, only about \$3 million has been annually appropriated by Congress and spent by the NIH on Celiac research – that's only about \$1 per American, per year, with Celiac and that is not nearly enough!

**Alex Azar, Former Secretary of Health and Human Services, Stated Celiac is “Incurable”**  
It was heartening to see the FDA finalize the rule related to Gluten Free labeling for foods containing fermented hydrolyzed ingredients on August 12, 2020. It was also heartening that Alex Azar, Former Secretary of Health and Human Services, shared his personal diagnosis with Celiac. However, there were numerous members of the Celiac community who were very disappointed to read Secretary Azar's statement which referred to Celiac Disease as “*incurable*” and a condition that millions of Americans including you and my 9 year old son Jax simply “*live with*.”

“These new compliance requirements for labeling a product gluten-free will protect individuals with celiac disease, an incurable, hereditary disorder that millions of Americans, including myself, live with, said HHS Secretary Alex Azar. The FDA's final rule helps to ensure common products labeled gluten-free really are gluten-free, equipping consumers to make the best choices for their health and their families.”<sup>451</sup>  
(emphasis added)

This was a once in a generation opportunity when Secretary Azar served as the nation's top health official to move the ball down the field for greater consumer protection of Celiacs, including for labeling Gluten on all packaged foods as well as researching treatments other than a strict Gluten Free diet for life and a cure. Instead, this represented another example of how underserved the Celiac community has been by the Federal government.<sup>452</sup>

Research in Celiac Disease has lagged behind in the biomedical imagination of other more well NIH funded research diseases including digestive diseases, autoimmune disorders, food allergies and foodborne illnesses. This has been a vicious cycle adversely impacting the Celiac Disease research ecosystem whereby there have been fewer grant submissions, more limited interest among young researchers as well as very limited funding available from the private and

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<sup>450</sup> “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](https://www.gastrojournal.org/article/S0016-5085(17)36084-5/pdf)

<sup>451</sup> <https://www.fda.gov/news-events/press-announcements/fda-finalizes-rule-related-gluten-free-labeling-foods-containing-fermented-hydrolyzed-ingredients>

<sup>452</sup> [www.celiacjourney.com/azar](http://www.celiacjourney.com/azar)

philanthropic sectors. Public funding is perceived as validation of the seriousness of a disease and its research needs. Absent public funding validation, a vacuum is created, which causes private funding to be scarce. In contrast, the NIH funded Crohn's disease research model is an example of "success breeds success" that has created a positive feedback loop (network effects) with ongoing and meaningful government validation, more established research programs recruiting more young investigators, increased grant submissions, increased private sector funding, and increased philanthropic funding.

## **XXV. IgE-Mediated Food Allergies to Gluten from Rye and Barley**

**"Back at the beginning, I sold a lot of my belongings along with receiving food stamps and WIC just to afford food, as you can't use food banks when you have allergies.**

**They think it's a luxury. For us, it's life."**

--Mother of child with food allergy and annual income <\$50K<sup>453</sup>

### **Cautionary Tale on the Dangers of Grains Containing Gluten - Anaphylactic Shock**

In December 2020, Hillary Carter, food allergy mom and advocate (FARE Board of Governors), bravely shared her family's harrowing ordeal. "When 'Safe' Food Isn't... Our Applegate Anaphylaxis Story" is about her son Grayson who ate chicken nuggets that were labeled Gluten Free and casein-free, in addition to free of the Top 8 allergens per the manufacturer's Web site. However, after eating the nuggets, Grayson went into anaphylactic shock because the product somehow contained traces of Gluten.<sup>454</sup>

Thankfully, after receiving four doses of Epi and enduring an overnight hospital stay, Grayson recovered. However, one cannot help but think that this happened to a young boy from eating a product that was labeled Gluten Free that somehow got cross contaminated with Gluten. While this is a cautionary tale over the real risks of cross contamination, it is also an important cautionary tale of why mandatory labeling of Gluten must now be enacted because of all of the places where Gluten can hide in plain sight and be dangerous to those who consume even trace amounts of Gluten, regardless of what biologically happens in the body (i.e., IgE-Mediated and Non-IgE-Mediated food allergies).

According to General Mills, "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 [foreign grains, including wheat, barley, rye and triticale] is inevitable."<sup>455</sup>

While 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, there are those like Grayson who are allergic to Grains Containing Gluten and can suffer a severe IgE-Mediated allergic reaction from even a trace ingestion of Gluten, including from Rye, Barley and Oats.

### **Rye Allergy – IgE Mediated**

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<sup>453</sup> <https://www.foodallergy.org/fare-consumer-journey-infographic>

<sup>454</sup> <https://www.hillarytollecarter.com/post/when-safe-food-isn-t-our-applegate-anaphylaxis-story>

<sup>455</sup> <https://patents.google.com/patent/US9968937B2/en>

The Web site of the Institute of Agriculture and Natural Resources, Food Allergy Research and Resource Program (“FARRP”) at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Barley and Rye.<sup>456</sup>

According to the University of Manchester:

“Rye is specifically used in rye bread and crisp breads. Rye can substitute for wheat in many foods.”

“Individuals with wheat allergy often react to closely related cereals like barley and rye, less frequently to the more distant relative, oats.”<sup>457</sup>

According to ThermoFisher’s Allergen Encyclopedia that was reviewed by Dr. Fabio Lachetti, Senior Medical Manager at ThermoFisher Scientific,<sup>458</sup>

“Allergens from rye show profound cross-reactivity with other cereal grains like wheat, barley, and limited cross-reactivity with oat and even potato extracts... Sensitized individuals are advised to avoid rye flour in diet and strict labeling laws to label gluten-containing cereals have been established in various countries.”<sup>459</sup>

“Ingestion of rye can trigger food allergy symptoms in the gut and skin and may cause anaphylaxis (5).<sup>460</sup> Anaphylaxis following the ingestion of rye has been documented. A case of a 61-year old woman without any history of drug allergy, suffering from rye-dependent exercise-induced anaphylaxis upon ingestion of toasted rye bread, has been reported. The woman developed generalized erythema, dizziness, hypotension, and facial angioedema after a 30-minute walk, one-hour post-ingestion of rye (24).<sup>461</sup> A 32-year old Japanese baker with a history of ARC presented with anaphylactic symptoms including urticaria in the upper body, facial swelling, dyspnea, and angioedema on eyelids after consumption of bread containing 50% rye flour (23). Similarly, another study demonstrated a case of a 38-year old male baker with a history of urticaria on arms after exposure to rye flour (21).<sup>462,463</sup>

“Baur et al. (1998) studied the frequency of work-related asthma in 89 bakers from the Bochum area (Group A). They summarized the data from a previous study involving 104

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<sup>456</sup> <https://farrp.unl.edu/informallcerealsgrains>

<sup>457</sup> <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=48>

<sup>458</sup> <https://www.linkedin.com/in/iachetti/>

<sup>459</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f5#>

<sup>460</sup> Rizzello C.G. DAM, Coda R. et al. Use of selected sourdough lactic acid bacteria to hydrolyze wheat and rye proteins responsible for cereal allergy. *Eur Food Res Technol.* 2006;223:40511.

<sup>461</sup> Garcia-Menaya JM CG, Cordobes-Duan, Mahecha AC, Bobadilla-Gonzalez P. Rye-dependent exercise-induced anaphylaxis. *Ann Allergy Asthma Immunol* 2016;117(5):566-8.

<sup>462</sup> Ehrlich R. PR. Bakers asthma with a predominant clinical response to rye flour. *American Journal of Industrial Medicine* 2005;48:153-5.

<sup>463</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

bakers (Group B) filing compensation claims for the baker's asthma. The study involved a control group with 43 healthy people of the same area who did not work in the bakeries. They found that 34% of the subjects from Group A, 50% from Group B, and only 10% of the Control group were positive for rye flour in IgE determination tests (11).<sup>464</sup> A study on 24 Spanish employees (92% males) from the baking industry with a history of baker's asthma showed that 71% of the workers were positive for rye flour in skin prick tests (SPTs), and 67% showed positive IgE to rye flour (12).<sup>465,466</sup>

“A cross-sectional study was performed across 31 bakeries involving 517 workers across supermarket stores in South Africa to study the asthma phenotypes in these workers exposed to flour dust in the bakery. It was found that about 33% of workers documented work-related asthma due to rye flour specifically. However, these workers handled only a small proportion of products made up of rye flour (13).<sup>467</sup> A study from a Korean allergy clinical center involving 5340 patients with different allergic diseases demonstrated the IgE sensitization rate and cross-reactivity to different home-made agricultural products and observed that rye grain sensitization rate was 9.5% (14).<sup>468</sup> Allergy to rye has also been reported in Japan and other western countries (15).<sup>469,470</sup>

### **Barley Allergy – IgE Mediated**

The FARRP Web site at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Barley.<sup>471</sup> According to the University of Manchester:

“Barley is used to make beer. It is also found in bread, soups, stews and museli [alternatively spelled Muesli in the U.S.].”<sup>472</sup>

“Individuals with wheat allergy often react to closely related cereals like barley and rye, less frequently to the more distant relative, oats.”<sup>473</sup>

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<sup>464</sup> Baur X DP, Sander - Bakers asthma: Still among the most frequent occupational respiratory disorders. *J Allergy Clin Immunol.* 1998;102:984-97.

<sup>465</sup> Quirce S. F-NM, Escudero C., Cuesta J., de Las Heras M., Sastre J. . Bronchial responsiveness to bakery-derived allergens is strongly dependent on specific skin sensitivity. *Allergy* 2006;61(10):1202-8.

<sup>466</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

<sup>467</sup> Baatjies R LA, Sander I et al. Determinants of asthma phenotypes in supermarket bakery workers. *Eur Respir J.* 2009;34:825-33.

<sup>468</sup> Yoon S.H. KYM, Kim S.H., Suh C.H., Nahm D.H., Park H.S. The sensitization rate and cross-reactivity to homemade agricultural products in adult allergy patients. *Korean J Asthma Allergy Clin Immunol.* 2005;25(4):269-75.

<sup>469</sup> Gangal S.V. MBK. Food allergy-how much of a problem really is this in India? *Journal of Scientific and Industrial Research* 2003;62:755-65.

<sup>470</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?>

<sup>471</sup> <https://farrp.unl.edu/informallcerealsgrains>

<sup>472</sup> <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=63>

<sup>473</sup> <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=48>

According to ThermoFisher's Allergen Encyclopedia that was reviewed by Dr. Fabio Lachetti, Senior Medical Manager at ThermoFisher Scientific,<sup>474</sup>

"The majority of case reports about barley allergy have focused on adult patients with respiratory allergy known as baker's asthma induced by barley flour, or with allergy from beer containing barley. Two cases of barley allergy have been reported in children who displayed severe anaphylactic reactions. However, few studies have evaluated barley allergy in relation to the level of barley-specific IgE and, to date, the prevalence of barley allergy has not been evaluated in a population-based study (3).<sup>475,476</sup>

"Barley cross-reactivity has been demonstrated to wheat, rye, oats and Job's tears (also known as adlay) (3<sup>477</sup>, 16<sup>478</sup>). A case report from a patient with clinically defined beer and Rosaceae allergy had serum which cross-reacted with a 10 kDa protein from apple and peach (likely LTPs, but unknown at the time) and LTP from peach peel, carrot and broccoli (Asero et al, 2001). The barley 10 kDa was likely to be the classic LTP, also known as Hor v 14 (11)<sup>479,480</sup>.

"One large-scale, multi-center case study in Korean children and adolescents showed that barley was the cause of 0.2% of immediate-type food allergy. A study including 42 Korean children (20 with clinically defined barley allergy and 22 atopic controls) demonstrated that levels of barley IgE were significantly higher in the allergic group vs the control group. After ingestion of barley in the allergic group, symptoms were mostly cutaneous (90.0%) or respiratory (40.0%), with anaphylaxis being observed in 35.0% (3).<sup>481,482</sup>

## Oats Allergy – IgE-Mediated

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<sup>474</sup> <https://www.linkedin.com/in/iachetti/>

<sup>475</sup> Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. *J Korean Med Sci.* 2020;35(3):e23.

<sup>476</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>

<sup>477</sup> Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. *J Korean Med Sci.* 2020;35(3):e23.

<sup>478</sup> Srisuwatchari W, Piboonpocanun S, Wangthan U, Jirapongsananuruk O, Visitsunthorn N, Pacharn P. Clinical and in vitro cross-reactivity of cereal grains in children with IgE-mediated wheat allergy. *Allergol Immunopathol (Madr).* 2020;48(6):589-96.

<sup>479</sup> Navarro L, Lazo L, Pineda P, Labrador-Horrillo M, Roger A, Basaga. Anaphylaxis Induced by Beer. *J Investig Allergol Clin Immunol.* 2021;31(4):334-6.

<sup>480</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>

<sup>481</sup> Lee E, Jeong K, Lee J, Jeon SA, Park B, Lee H, et al. Clinical and Laboratory Findings of Barley Allergy in Korean Children: a Single Hospital Based Retrospective Study. *J Korean Med Sci.* 2020;35(3):e23.

<sup>482</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f6>



The FARRP Web site at the University of Nebraska-Lincoln links to the University of Manchester for additional information on cereals and grains including Oats.<sup>483</sup> Oats are used to make porridge and a wide variety of cakes and biscuits. According to the University of Manchester: “Oats are also found in muesli or granola. Beer can be made from oats.”<sup>484</sup>

According to ThermoFisher’s Allergen Encyclopedia that was reviewed by Dr. Magnus Borres, Professor of Pediatrics, Uppsala University & Medical Director ThermoFisher Scientific,<sup>485</sup>

“Oats are small cereal grains rich in fiber and antioxidants and possess various health benefits. It belongs to the genus *Avena*. Oats are used as cereal, fodder, hay, straw beds, grains, etc. They are more popularly consumed in Europe and are a source of food allergy. Ingestion of oat cereal or inhalation of oat flour has been reported to cause allergic reactions in sensitive individuals.

Clinically, oat allergies are reported to cause Oral Allergy Syndrome (OAS), anaphylaxis, gastro-intestinal symptoms, skin reactions, and respiratory symptoms such as rhinitis, rhino-conjunctivitis, and asthma in sensitized individuals. Children with atopic dermatitis constitute a risk group of developing epicutaneous sensitization to oats and subsequently acute allergies on using oat-containing cosmetics.

Allergens in oats haven’t yet been characterized but various studies have shown different IgE-binding proteins from oats. Cross-reactivity between gliadins from wheat and hordeins in barley, avenins from oats, coixins in Jobs tears, and secalins from rye has been observed. Additionally, cross-reactivity has been demonstrated between rice, millets, oats, and grass pollen.

Avoidance of oats is suggested as a preventative strategy against the allergic reaction caused by oat.”<sup>486</sup>

In terms of the Epidemiology and worldwide distribution, ThermoFisher stated:

“A cross-sectional study with 365 allergic Honduran children (age ranging from 1 to 18 years) showed positive skin prick test (SPT) for oats in 3% (11 out of 365) participants.”<sup>487</sup>

Worm et al. (2006) extracted a random sample of 13,300 Germans out of which 408 self-reported the prevalence of atopic dermatitis (AD). AD was confirmed in 146 individuals out of which 111 were clinically examined and 28 were diagnosed with active eczema lesions. Among them, 14.8% had a positive skin prick test (SPT) to oatmeal and barley

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<sup>483</sup> <https://farrp.unl.edu/informallcerealsgrains>

<sup>484</sup> <http://research.bmh.manchester.ac.uk/informall/allergenic-food/?FoodId=35>

<sup>485</sup> [https://scholar.google.co.uk/citations?user=\\_ZOrQwQAAAAJ&hl=en](https://scholar.google.co.uk/citations?user=_ZOrQwQAAAAJ&hl=en)

<sup>486</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

<sup>487</sup> Gonzales-Gonzalez VA, Diaz AM, Fernandez K, Rivera MF. Prevalence of food allergens sensitization and food allergies in a group of allergic Honduran children. *Allergy Asthma Clin Immunol.* 2018;14:23.

flour.<sup>488</sup>

Boussault et al. (2007) conducted an extensive study on oat sensitization in children with AD in France. The study showed that out of 302 children, 98 (32.5%) were sensitized to oat and among them, 19.2% (58/302) were positive to oat in SPT and 14.6% (44/302) in Atopy patch test (APT).<sup>489</sup>

A study evaluated the prevalence of oat allergy in children diagnosed to have wheat allergy in Maryland, USA. Out of 185 wheat allergic patients, 10% reacted to oat extracts.<sup>490,491</sup>

“Oats have been found to be linked with the cases of oral allergy symptoms.<sup>492</sup> Oat-related food allergies may be induced through the gastrointestinal (GI) tract and skin.<sup>493</sup> Contact allergy to oat protein present in moisturizers has also been reported.<sup>494</sup> Anaphylaxis associated with oat allergy has also been reported in a few studies<sup>495 496 497,498</sup>

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<sup>488</sup> Worm M, Forschner K, Lee HH, Roehr CC, Edenharter G, Niggemann B, et al. Frequency of atopic dermatitis and relevance of food allergy in adults in Germany. *Acta Derm Venereol.* 2006;86(2):119-22.

<sup>489</sup> Boussault P, Leaute-Labreze C, Saubusse E, Maurice-Tison S, Perromat M, Roul S, et al. Oat sensitization in children with atopic dermatitis: prevalence, risks and associated factors. *Allergy.* 2007;62(11):1251-6.

<sup>490</sup> Keet C, Matsui E, Dhillon G, Lenehan P, Wood R. Barley and oat allergy in children with wheat allergy. *Journal of Allergy and Clinical Immunology.* 2009;123(2):S110.

<sup>491</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

<sup>492</sup> Skypala IJ. Food-Induced Anaphylaxis: Role of Hidden Allergens and Cofactors. *Front Immunol.* 2019;10:673.

<sup>493</sup> Ototake Y, Inomata N, Sano S, Takahashi S, Aihara M. A case of an anaphylactic reaction due to oats in granola. *Allergol Int.* 2015;64(4):386-7.

<sup>494</sup> Boussault P, Leaute-Labreze C, Saubusse E, Maurice-Tison S, Perromat M, Roul S, et al. Oat sensitization in children with atopic dermatitis: prevalence, risks and associated factors. *Allergy.* 2007;62(11):1251-6.

<sup>495</sup> Ototake Y, Inomata N, Sano S, Takahashi S, Aihara M. A case of an anaphylactic reaction due to oats in granola. *Allergol Int.* 2015;64(4):386-7.

<sup>496</sup> Tomas-Perez M, Iglesias-Souto FJ, Bartolome B. Oat Allergy: Report on 2 Cases. *J Investig Allergol Clin Immunol.* 2020;30(3):199-201.

<sup>497</sup> Prados-Casta, Pi-Saavedra M, Leguisamo-Milla S, Pastor C, Cuesta P, Bartolom. Anaphylaxis Due to Oat Ingestion. *Journal of investigational allergology & clinical immunology.* 2016;26(1):68.

<sup>498</sup> <https://www.thermofisher.com/diagnostic-education/hcp/us/en/resource-center/allergen-encyclopedia/whole-allergens.html?key=f7>

## XXVI. FDA References in FDA's Draft Guidance

**“Injustice anywhere is a threat to justice everywhere. We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly, affects all indirectly.”**

-- Dr. Martin Luther King, Jr.

The FDA's Draft Guidance's sources/citations are detailed in Section “VIII. References” which while part of the FDA's Draft Guidance was published by the FDA as a stand-alone document.<sup>499</sup> While the nature of having a stand-alone document is challenging enough with respect to cross referencing and accessing the underlying research (as opposed to just using footnotes or endnotes in the primary document (FDA's Draft Guidance), many of the FDA's reference documents cannot be accessed without an academic license, paid subscription, paid license or purchase, or visiting the FDA in person in Rockville, Maryland, etc.

Section VIII. References of the FDA's Draft Guidance states,

“The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff [Office]. FDA has verified the website addresses, as of the date the notice of availability for this document.”<sup>500</sup>

For example, I had trouble accessing:

- Ref. 26 B. Björkstén, Crevel R, Hischenhuber C, et al. Criteria for identifying allergenic foods of public health importance. *Regulatory Toxicology and Pharmacology* 2008;51:42-52.<sup>501</sup>
- Ref. 28 - van Bilsen JHM, Ronsmans S, Crevel RWR, et al. Evaluation of scientific criteria for identifying allergenic foods of public health importance. *Regulatory Toxicology and Pharmacology* 2011;60(3):281-289.<sup>502</sup>
- Ref. 29 - Chung YJ, Ronsmans S, Crevel RWR, et al. Application of scientific criteria to food allergens of public health importance. *Regulatory Toxicology and Pharmacology* 2012;64(2):315-23.<sup>503</sup>

In order to promote equity of access to information while honoring copyright restrictions, it would seem that the FDA could secure some type of large volume license to be able to provide digital copies of the research on demand as requested by interested parties like the Bari family who do not have access to the underlying research without paying to acquire a license. Having

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<sup>499</sup> <https://www.regulations.gov/document/FDA-2021-N-0553-0007>

<sup>500</sup> <https://www.regulations.gov/document/FDA-2021-N-0553-0007>

<sup>501</sup> <https://www.sciencedirect.com/science/article/abs/pii/S027323000800007X>

<sup>502</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0273230010001510?>

<sup>503</sup> <https://www.sciencedirect.com/science/article/abs/pii/S027323001200147X?>

the ability to travel to Rockville, Maryland during business hours to review documents in person is impracticable for the majority of Americans.

## **Exhibit A – Sources of Prices for Figure 9, Market Shopping in the Philadelphia Area as of July 10, 2022**

- [1] <https://www.target.com/p/stroehmann-king-white-sandwich-bread-22oz/-/A-47092531#>
- [2] <https://www.target.com/p/canyon-bakehouse-gluten-free-mountain-white-bread-18oz/-/A-15386018#>
- [3] <https://www.target.com/p/pillsbury-funfetti-premium-cake-38-cupcake-mix-15-25oz/-/A-13187216#>
- [4] <https://www.target.com/p/pillsbury-gluten-free-funfetti-cake-17oz/-/A-17079672#>
- [5] <https://www.acmemarkets.com/shop/product-details.960266697.html>
- [6] <https://www.acmemarkets.com/shop/product-details.960312114.html>
- [7] <https://www.target.com/p/chips-ahoy-original-chocolate-chip-cookies-13oz/-/A-12959729>
- [8] <https://www.target.com/s?searchTerm=gluten+free+chocolate+chip+cookies>
- [9] <https://www.target.com/p/king-arthur-flour-unbleached-all-purpose-flour-5lbs/-/A-14777928#>
- [10] <https://www.target.com/p/krusteaz-gluten-free-honey-cornbread-38-muffin-mix-15oz/-/A-48329859#>
- [11] <https://www.target.com/p/gorton-39-s-frozen-breaded-minced-fish-sticks-24-5oz-44ct/-/A-13436113#>
- [12] <https://www.target.com/p/ian-39-s-gluten-free-frozen-fish-sticks-family-pack-14oz/-/A-14760805#>
- [13] <https://www.target.com/p/krusteaz-honey-cornbread-38-muffin-mix-15oz/-/A-12927489#>
- [14] <https://www.target.com/p/king-arthur-gluten-free-measure-for-measure-flour-48oz/-/A-51341846#>
- [15] <https://www.target.com/p/quaker-chewy-chocolate-chip-granola-bars-8ct/-/A-13315265#>
- [16] <https://www.target.com/p/madegood-cookies-38-creme-granola-bar-5-1oz-6ct/-/A-79223072#>
- [17] <https://www.target.com/p/wonder-white-hamburger-buns-12oz-8ct/-/A-47778448#>
- [18] <https://www.target.com/p/udi-s-gluten-free-frozen-hamburger-buns-10-4oz/-/A-16856731#>
- [19] <https://www.target.com/p/kraft-macaroni-38-cheese-dinner-original-7-25oz/-/A-12954218>
- [20] <https://www.target.com/p/kraft-gluten-free-macaroni-38-cheese-original-flavor-6oz/-/A-79684594>
- [21] <https://www.acmemarkets.com/shop/product-details.111050087.html>
- [22] <https://www.acmemarkets.com/shop/product-details.960153874.html>
- [23] <https://www.target.com/p/bisquick-original-pancake-and-baking-mix-40oz/-/A-13066864#>
- [24] <https://www.target.com/p/bisquick-gluten-free-pancake-baking-mix-16oz/-/A-14879881#>
- [25] <https://www.target.com/p/barilla-penne-16oz/-/A-13156215#>
- [26] <https://www.target.com/p/barilla-gluten-free-penne-12oz/-/A-14922284#>
- [27] <https://www.target.com/p/freschetta-natural-rising-four-cheese-medley-frozen-pizza-26-11oz/-/A-13376392#>
- [28] <https://www.target.com/p/freschetta-gluten-free-four-cheese-frozen-pizza-17-5oz/-/A-16222856#>
- [29] <https://www.target.com/p/snyder-39-s-of-hanover-pretzel-old-fashioned-dipping-sticks-12oz/-/A-14491453#>
- [30] <https://www.target.com/p/snyder-39-s-of-hanover-gluten-free-plain-pretzel-sticks-8oz/-/A-15847567#>
- [31] <https://www.target.com/p/rice-krispies-treats-original-bars-16ct-kellogg-s/-/A-12992349#>
- [32] <https://www.target.com/p/madegood-vanilla-crispy-squares-6pk/-/A-82079644#>
- [33] <https://www.target.com/p/pillsbury-chocolate-chip-cookie-dough-16oz-24ct/-/A-13016503#>
- [34] <https://www.target.com/p/sweet-loren-39-s-gluten-free-vegan-chocolate-chunk-cookie-dough-12oz/-/A-53054658#>