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3 days ago

13 min read

White House Conference on Hunger, Nutrition & Health: Reduce Diet-Related Disease By Labeling Gluten



The Bari Family at President Joe Biden's Soul of the Nation Speech at Independence Hall in Philadelphia, 9/1/22.

In advance of the White House Conference on Hunger, Nutrition, and Health on September 28, 2022 ("White House Conference"), Bari Consulting Group, Celiac Journey and Gluten Free Finds released a [comprehensive report](#) which includes their top policy objective that has the potential to dramatically improve nutrition, reduce food insecurity and reduce diet-related disease in the near-term for 3.3 million Americans with Celiac Disease ("Bari Report").

Informing the National Strategy of the White House Conference: Reduce Diet-Related Disease by Labeling Gluten as a Major Food Allergen

The intention of the Bari Report is to inform the National Strategy that will be announced at the White House Conference with the recommendation of naming of Gluten as the 10th Major Food Allergen and requiring that Gluten be labeled on all packaged foods. This recommendation comports with the “White House 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.”

Labeling Gluten will better protect an estimated 3.3 million Americans with Celiac Disease, a severe food allergy and auto-immune disease, from getting sick when they consume even a trace amount of Gluten.

Labeling Gluten on all packaged foods in the US is in alignment with the previous 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 (“FAO”)/World Health Organization (“WHO”) 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”).
- **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”).

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).” (emphasis added)

The Bari Report and policy objective for the White House Conference was also informed by many of the 1,576 public comments submitted to the FDA during Summer 2022 on evaluating the public health importance of protecting Celiac consumers with labeling Gluten as a Major Food Allergen.

Labeling Gluten will also protect an estimated 20+ million other Americans who have Non-Celiac Gluten Sensitivity (i.e., Gluten intolerance), a food allergy to Rye, Oats or Barley, or who are following a medically required Gluten Free

diet for other health issues.

Comments from Dr. Virginia Stallings to the FDA on Labeling Gluten as a Food Allergen

It is instructive to read Dr. Virginia Stallings' comments to the FDA dated August 4, 2022. [Dr. Stallings](#) is board-certified nutrition pediatrician, Professor of Pediatrics and Director of the Nutrition Center at the Children's Hospital of Philadelphia. In addition, Dr. Stallings served as the Editor and Chair of the National Academies of Sciences, Engineering, and Medicine, Committee on Food Allergies: "Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management and Public Policy." In the [FDA's Draft Guidance](#) ("Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders - Draft Guidance, April 19, 2022"), the FDA appears to have relied on Finding a Path to Safety in Food Allergy to exclude the evaluation of the public health importance of labeling Gluten as a food allergen.

Dr. Stallings' August 4, 2022 comments highlight that the FDA's Draft Guidance is inconsistent with the findings and recommendations of the 1999 FAO/WHO Expert Consultation and 2021 FAO/WHO Expert Consultation. In addition, it is instructive to read Dr. Stallings' comments which rebut what appear to be the FDA's objections to labeling Gluten, including that Celiac is not a food allergy, that Gluten is not a food allergen and that Celiac is not potentially life-threatening. As detailed by Dr. Stallings, the 1999 FAO/WHO Expert Consultation and 2021 FAO/WHO Expert Consultation, Celiac is a food allergy (and auto-immune disease), Gluten is a food allergen and Celiac is potentially life-threatening.

According to [Dr. Stallings' comments](#) to the FDA,

"Our Food Allergy Committee's work for the National Academy found that 'food allergy has two key classifications: immunoglobulin E (IgE)-mediated or non-IgE-mediated' (page 4) such as Celiac Disease...

While a Non-IgE-Mediated food allergy does not trigger anaphylaxis and is not immediately life-threatening, people with Celiac Disease face potentially life-threatening and severe adverse health effects that can arise through gluten ingestion including by way of example and not limited to: anemia, cancer, heart disease, immunological scarring, intestinal damage and malnutrition...

A gluten free diet is not all that is needed to treat Celiac Disease; rather a gluten free diet is all that has ever been historically available to treat Celiac Disease. Additionally, with respect to labeling food products in the United States, the voluntary gluten free labeling scheme does not sufficiently protect consumers who are on medically required and very restrictive gluten free diets. My strong recommendation is that gluten be labeled on all packaged foods in the United States, in accordance with the 2021 FAO/WHO Expert Consultation, just like it is in more than 85 countries around the world. I respectfully request that the FDA draft guidance be revised to include evaluating gluten as a food allergen and changing the voluntary labeling rule to a mandatory labeling rule to keep the 3 million Americans with Celiac Disease safe."

"Given that this is largest whole-of-government initiative to improve the national food system in more than 50 years, I believe that the White House Conference is a once in a generational opportunity to catalyze the public and private sectors around a coordinated strategy to accelerate progress and drive transformative change in the U.S. to help eliminate hunger, improve nutrition and reduce diet-related disease. To that end, I am hoping that the White House's National Strategy includes addressing the historically underserved and unmet needs of 3.3 million Americans with Celiac Disease with the naming of Gluten as a Major Food Allergen and the labeling of Gluten on all packaged foods." --Jon Bari, President of Bari Consulting Group

Requesting a Patient Advocacy Seat at the Table at the White House Conference

Jon and Leslie Bari provided their lived experience and research input to the White House Conference including:

- Participated in and provided spoken comments in the Breakout Room for Pillar 2 in the Listening Session, June 7, 2022;
- Met with Dr. Sandi Ford, Special Assistant to the President for Health and Science, to inform the White House about the unmet needs of the Celiac community, especially the pediatric community, including with labeling Gluten and funding Celiac research, May 6, 2022;
- Submitted written comments via email to the White House Conference, July 15, 2022;
- Worked with various organizations, doctors, scientists as well as individuals with Celiac, their parents, caretakers and loved ones, to help generate 1,576 public comments submitted to the FDA on the labeling of Gluten, which represented 82.6% of the 1,907 total comments that the FDA received on Docket number: FDA-2021-N-0553; and
- Submitted Bari Comments to the FDA's Draft Guidance, "Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders, Draft Guidance," April 19, 2022, Docket Number: FDA-2021-N-0553, August 16, 2022.

Plenary Remarks by FDA Commissioner Dr. Robert Califf at the White House Conference Listening Session

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

"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." (emphasis added)

With the mitigation of the burden of chronic disease in mind, it is instructive to understand the following current perplexing paradigm. Unlike the Food Allergen Labeling and Consumer Protection Act ("FALCPA") labeling scheme for the top 9 Major Food Allergens in the U.S. (Sesame as of January 1, 2023), Gluten Free labeling is permissive (not mandatory) in the U.S. 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 Americans 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.

"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." (emphasis added)

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 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." (emphasis added)

President Biden's Executive Order 13985

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. Using that lens and framework, the FDA's Draft Guidance released on April 19, 2022 suggests systemic food privilege that contributes to food insecurity, and the White House Conference and FDA can work to redress historical inequities in various agencies' policies and processes, including in the White House Conference's National Strategy and the FDA's Draft Guidance.

Section 2(a) of Executive Order 13985 provides that,

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

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability under the ADA [1] and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences 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 and learning are major life activities that can be impacted on a daily basis, and there are various bodily systems which can be impacted, including the digestive system, nervous system and integumentary system.

It is also 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." For those with food allergies such as Celiac Disease, we further define food insecurity as the limited or uncertain availability of food that is adequate, nutritious, safe and affordable, regardless of socioeconomic status, and limited or uncertain ability to acquire acceptable foods in socially acceptable ways.

The inequities in FALCPA and the FDA's Draft Guidance 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.

Celiacs Have Been Historically Underserved by the Federal Government

The Celiac Disease community has been historically underserved and marginalized by our Federal government (i.e., funding medical research for Celiac Disease, labeling Gluten only with a voluntary scheme, disqualifying Celiacs from service in the military,[2] excluding Celiac Disease from the CDC's Index of Diseases & Conditions, 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[3] sufficiently protects consumers who are on medically required and very restrictive Gluten Free diets, as opposed to all that has ever been historically utilized labeling-wise.
3. Othering the consumer protection needs for Celiacs in the United States with not evaluating the public health importance of Gluten as a food allergen because this Non-IgE-Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening, while seemingly ignoring that Celiacs face potentially life-threatening and severe adverse health effects that can arise through Gluten ingestion, including by way of example and not limitation: anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

Praise from President Biden

On August 17, 2021, President Biden recognized Jax Bari's advocacy efforts to help millions of Americans with Celiac Disease. If an 8 year old boy can help millions of Americans with Celiac, imagine what the President of the United States can do.

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

To that end, we hope that the Bari Report will now further inform the White House Conference with actionable and reasonable steps to better protect Celiacs!

FDA Has Legal Authority to Label Gluten Under Existing Law Codified With FALCPA

FALCPA does not preclude the FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme.[4] 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."[5] (emphasis added)

The Bottom Line

The research is done, the world is watching, and moreover our kids are watching. Yes, our kids are our future, but they are also our present. The United States is not in a leadership position when it comes to consumer protection for the Celiac community. Instead, the U.S. 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 Federal government 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, and we are respectfully requesting that it is included in National Strategy at the White House Conference.

The White House Conference can be the time when the movement and moment connect on the labeling of Gluten and mitigating the impact of diet-related disease for 3.3 million American Celiacs, including my 9 year old son Jax.

Notes

[1] 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

[2] 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/>

[3] 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#>

[4] “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.”

[5] H.R. Rep. No. 108-608, at 18. (2004).