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Alex M. Azar II  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Via Email: alex.azar@hhs.gov, brian.harrison@hhs.gov,  
secretary@hhs.gov

Dear Secretary Azar:



My 7 year old son (Jax) has **Celiac Disease**. He has been inspired by your public service and that of his uncle, former VA Secretary David Shulkin. Before school on November 16, Jax excitedly watched you on Good Morning America celebrating the two new COVID vaccines. It was a great day for public health and hope! In addition to your COVID work, Jax has felt a Celiac connection with you.

With you serving as the sitting Secretary of HHS, I am hoping that you can help us capitalize on this once in a generation opportunity to meaningfully move the ball down the field with Celiac Disease research. I appreciate you considering our feedback and timely suggestions.

### **FDA Final Rule on Gluten Free Labeling - Celiac Disease is Not 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 you shared your personal diagnosis with Celiac. That said, we were very disappointed to read your statement which referred to Celiac Disease as “*incurable*” and a condition that millions of Americans including you and Jax “*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>1</sup>  
(emphasis added)

Yes, we “live with” Celiac Disease today. But it is not incurable. Jax has wondered when you were diagnosed with Celiac because Jax was diagnosed right before he started Kindergarten in August 2018, and it has not been an easy journey on our family in many respects. As a father, I do not want Jax to have to just live with Celiac Disease for the rest of his life, or worry that one day my 15 year old daughter (Lexi) or any of my future grandchildren develop Celiac.

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<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/fda-finalizes-rule-related-gluten-free-labeling-foods-containing-fermented-hydrolyzed-ingredients>

## **The Gluten Free Diet Is Not Sufficient**

The idea that the Gluten Free diet is all that is needed by the Celiac community to live with this autoimmune disease, versus all that has ever been available (since the concept of treating Celiac with diet was first theorized in 1887, ironically the year that the NIH was founded), has stifled funding for medical research to find any treatment options (other than a GF diet), much less to find a cure.<sup>2</sup>

That said, 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. Additionally, for anyone with Celiac, and certainly so for a child such as Jax, Celiac can be so isolating because of life's daily activities that involve food. At friends' birthday parties, he must decline pizza and cake. At soccer practice, he cannot eat soft pretzels with his team. At school, he cannot eat donuts with his classmates. It is heartbreaking to hear him say that some food smells great, but he can't taste it and moreover that he has no food freedom to enjoy the spontaneity of food.

## **Kids on Capitol Hill at a Congressional Briefing on Celiac Disease, January 14, 2020**

In January 2020, my wife, Jax and I hosted a bipartisan and bicameral Congressional Briefing along with Congressman John Joyce, M.D. (R, PA-13, Altoona) and Dwight Evans (D, PA-3, Philadelphia) to advocate for Jax and the 3 million Americans afflicted with Celiac Disease.

**[“Congressional Briefing - Securing Significant Federal Funding for Celiac Disease Research”](#)**

There were about 75 people in attendance, including representatives from the offices of Senator Pat Toomey (R, PA), Senator Bob Casey (D, PA) and Senator Dick Durbin, (D, IL). Moreover there were about 10 other kids from the Washington, D.C. area who we did not know, but who took time out of school to be on Capitol Hill to support Jax and our mutual goals.

Researchers are finding that Celiac Disease prevalence is doubling approximately every 15 years, making it a public health epidemic. Gluten ingestion for people with Celiac causes permanent immunological scarring, doubles the risk of heart disease, and acts as a carcinogen. 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. Diagnosed patients report that they miss, on average, 23 days of work and school annually, resulting in excess utilization of our healthcare resources.<sup>3</sup>

## **Celiac Research Has Been Historically Underfunded**

In terms of the historical Federal underfunding, out of various Gastrointestinal Disorders, from 2011-2019:

- “Celiac disease consistently received the lowest amount of NIH funding over the 5-year period, at approximately \$3 million per year.” NIH has spent about \$1.00 per American with Celiac per year.
- “Celiac disease consistently received the lowest amount of NIH grants, at approximately eight grants per year.”
- “In conclusion, NIH funding of GI diseases is not proportional to disease prevalence or mortality.”<sup>4</sup>

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<sup>2</sup> <https://celiacjourney.com/2019/09/14/national-celiac-disease-awareness-day-presents-a-call-to-action/>

<sup>3</sup> Dr. Stefano Guandalini and Dr. Bana Jabri of the University of Chicago Celiac Disease Center, Public Witness Testimony, Senate Appropriations Committee, Subcommittee on Labor, HHS, June 3, 2019.

<sup>4</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

In spite of the Herculean efforts and accomplishments by some brilliant, small and under resourced research teams and advocacy groups, the paucity of NIH funding has created a vacuum and stifled innovation in the efforts to treat and cure Celiac Disease. Please see attached for my Congressional Briefing [presentation, specifically pages 17-23](#), regarding the negative feedback cycle caused by the scarcity of NIH funding for Celiac research.

### **Ideas Now for Executive Action**

I welcome any ideas that you have to increase Federal funding for Celiac Disease research. I offer the following suggestions (in no order of importance):

#### **1. Appoint Celiac Specialists to the NIAID Autoimmune Disease Coordinating Committee (ADCC)**

Of the [52 members of the ADCC](#), there are 17 members representing specific diseases. A full one third of the ADCC members come from outside the NIH. There are no representatives of any organization or physician/scientist representing the Celiac Disease community. However, there are 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>5</sup>

I have names of qualified individuals who I could recommend if you are interested.

#### **2. Require NIAID to Submit its Past Due Congressionally Mandated Strategic plan to Congressional Appropriators by January 19, 2021 on the Coordination and Execution of Celiac Disease Research for the Autoimmune Causation Underpinning Celiac Disease**

On December 19, 2019, President Trump signed into law the FY2020 Federal Budget Resolution which included a historic first for Celiac Disease with this language,

“Celiac Disease. The agreement encourages NIH to devote sufficient, focused research to the study of celiac disease, including the autoimmune causation underpinning the affliction. The agreement urges NIAID to better coordinate existing research and focus new research efforts toward causation and, ultimately, a cure of this disease. **NIAID is encouraged to coordinate with other Institutes and Centers as appropriate and to submit its plan for coordination and execution of this research to the [House and Senate Appropriations] Committees no later than 90 days [by March 20, 2020] after enactment of this Act.**” (emphasis added)

On March 20, 2020, NIAID submitted its 41 word “plan” to the Appropriations Committees, which simply included a short statement as follows:

NIAID plans to convene a meeting of the ADCC in late spring 2020 to explore additional opportunities for collaboration in the field of celiac disease research among NIH Institutes and Centers, other federal agencies, professional societies, and patient and advocacy organizations. (“NIAID Plan”)

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Israel Deaconess Medical Center; September 4, 2017; **and** Analysis of Federal Funding for Celiac Disease Research Bari Consulting Group, May 2020.

<sup>5</sup> <https://www.niaid.nih.gov/about/autoimmune-diseases-coordinating-committee>

In other words, rather than submitting its plan to Congressional Appropriators, as mandated by law, NIH informed Congress that it planned to hold a meeting of the ADCC on a Friday afternoon in late May via Zoom. My comment is not so much about holding a virtual meeting given that we are all struggling with COVID-19, but more so how this took more than five months to convene and then to host it on a Friday afternoon in the Summer. I hope that I am wrong, but it felt as if this was just an effort to kick the can down the road.

When Marilyn Geller, the CEO of the Celiac Disease Foundation, completed her presentation to the ADCC, Dr. Annette Rothermel, the NIAID subject matter expert in mucosal immunity, made “a comment to the effect that the [ADCC] audience might have found it surprising that the Gluten Free diet is not a cure and really isn’t working as many think it does. I made this comment to emphasize the point for meeting participants not expert in Celiac Disease, as I thought many would find this surprising. My intent was to hit home that the Gluten Free diet is not a cure as many may think.”<sup>6</sup>

This is really disheartening to me that one of the two leaders of the ADCC meeting was surprised that a Gluten Free diet is not a cure and moreover that she believed that the members of the ADCC would have found this surprising too. This underscores why the ADCC needs direct representation on the ADCC from specialists and advocates for Celiac Disease research.

When the public portion of the ADCC meeting concluded there was no recap, no follow up, no action steps, etc., including no meaningful statement by ADCC Chairperson Dr. Ellen Goldmuntz, even though the [Agenda](#) expressly called for “Wrap up and Discussion of Future Meetings.” Then the ADCC convened a closed door meeting with just the ADCC. To date, I am not aware of any specific or meaningful follow up.

### **3. Help Get the Gluten in Medicine Disclosure Act Enacted**

Advocate for President Trump to support Representative Tom Cole (R, OK-4) and the 52 other co-sponsors of the Gluten in Medicine Disclosure Act so this can get passed out of Committee, voted on by the House and Senate and enacted.

In 2004, the Food Allergen Labeling Consumer Protection Act required packaged food labels to identify all ingredients containing wheat and other allergens. This requirement does not extend to prescription drugs making it nearly impossible to determine the presence of Gluten in prescription medicine.

After repeated efforts to shed light on this issue, the FDA initiated a draft guidance in 2017 (which is still being finalized), encouraging drug manufacturers to disclose the presence of Gluten. While some manufacturers have taken this step, many manufacturers have not. This leads to anxiety of not knowing whether or not medication is doing more harm than good.

On April 3, 2019, Congressmen Tim Ryan (D, OH-3) along with his colleague Congressman Cole introduced the Gluten in Medicine Disclosure Act of 2019, which will require drug manufacturers to label medications intended for human use with a list of ingredients, their source, and whether Gluten is present. A Gluten-containing drug that does not meet these

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<sup>6</sup> Email from Annette L. Rothermel, Ph.D., Chief, Autoimmunity and Primary Immunodeficiency Diseases Section, Autoimmunity and Mucosal Immunology Branch, Division of Allergy, Immunology, and Transplantation, NIAID, NIH, DHHS, to Jonathan Bari, July 20, 2020.

requirements would be considered misbranded under Section 502 of the Federal Food, Drug, and Cosmetic Act. This labeling will allow concerned consumers to know, for example, if the starch in their prescription medicine comes from wheat or corn, an important distinction.

- 4. Create Task Force at the NIH to Dedicate Research on Celiac Disease As Lever to Cure All Autoimmune Diseases** – Celiac Disease may hold the scientific key to be the lever to unlock the cure for all other autoimmune diseases since Celiac Disease is the only autoimmune disease with a known on-off switch -- Gluten.

In the spirit of Thanksgiving, I want to express gratitude for your public service, including your work on COVID. Thank you also for your work with the FDA on Gluten labeling and for publicly sharing about your Celiac Disease. That was meaningful to Jax and our family. Your statements on GMA were inspirational in discussing the journey with the NIH and how the vaccine was engineered on January 13, 2020.

We envision a world where Celiac is curable and Jax can live without Celiac. Celiac can be medicalized in many ways to the benefit of the pharmaceutical industry. In addition to treating those with Celiac Disease, there is larger addressable market for all those who have the genetic markers for Celiac. 30-40% of Americans carry the genes for Celiac Disease. No one knows what causes Celiac Disease to activate in some people, but not others. This is one of the key research areas that needs funding. In other words, pharma could potentially benefit by developing a vaccine if you will that prevents Celiac from activating in patients who carry the genetic markers.

I am hopeful that you will give serious consideration to my ideas expressed herein and join us on our [Celiac Journey](#). I believe that you can further enhance your legacy for the 3 million Americans who suffer from Celiac and their families. Happy Thanksgiving!

Sincerely,

*Jon H. Bari*

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