

Dear Secretary Becerra and Commissioner Califf:

I am submitting these comments in support of Celiac Journey's FDA Citizen Petition to require the labelling of gluten on all food packages in the United States. You already have all of the supporting documents for this important petition, so I would like to let you know the realities of living with celiac disease and accidental ingestion of gluten by a celiac.

My daughter was diagnosed with celiac disease in 2007 at the age of 16 after having mysterious symptoms for 14 years. Back then, celiac disease was not on a lot of doctors' radars. I founded and helped design the Celiac Disease Program at Children's National Hospital in Washington, DC based on my daughter's needs in a world that lacked adequate information about this disease.

Previously, the FDA issued draft guidance on this topic that indicated that gluten was not in consideration to be added as an allergen to current food labels because it is not associated with an IgE-mediated disease (and by association, does not cause anaphylaxis). This is a short-sighted argument and is dismissive of the very real damage that occurs for people with celiac disease when they ingest gluten. As in IgE-mediated allergies, the body's immune system still reacts inappropriately and still causes damage.

It has been said that gluten free food for a Celiac is akin to insulin for a diabetic. This is true. Gluten-free food is imperative for a Celiac to remain healthy - it is the ONLY medicine available to celiac patients. For most patients, a small crumb of gluten in their meal can set off a terrible reaction that can last for a few hours to a few days. What does such a reaction look like in real terms?

*A student abruptly running to the bathroom in the middle of class because of explosive diarrhea, and then being teased because of it,

*A mortified young adult on a first date spending 20 minutes in the bathroom vomiting because of cross contamination,

*A child missing school because of "mysterious" symptoms: unexplained nausea, vomiting, fatigue

*Food bullying because a child has to eat differently or cannot take part in some classroom activities that involve eating gluten (i.e., birthday parties for students involving cupcakes)

Our program employs a full-time psychologist to address the multiple mental health issues that arise in a world where most people don't understand the disease. Did you know that there are over 30 different ingredients on food labels that contain gluten? That doesn't even cover the dozens more that require phone calls to manufacturers to determine the source of an ingredient (for example, natural flavors, brewer's yeast, and autolyzed yeast extract). Conflict over what should be a simple question - Does this food contain gluten? - causes significant stress to both patients and their caregivers. It can cause stress between parents who have different ideas of what gluten looks like on a label. It can get even more complicated when caregivers of a child are no longer in a relationship. Communication breakdowns can lead to

accidental gluten ingestion. Additionally, poor labeling can stress the relationship between concerned parents and children/young adults who sometimes resist their parents' intrusions into their everyday lives. Lack of clarity in labelling remains a constant source of conflict within many families. A proper label listing gluten as an ingredient will empower kids to make choices without the anxiety of concerned parents.

Over 85 countries around the world require gluten to be listed as an allergen on food labels. The United States has the highest GDP in the world by a longshot – why are we so far behind?

Only the FDA can effectuate a change in labelling. A simple label change will drastically change the lives of our patients and their families.... your fellow citizens. The medical field has finally caught up and celiac programs all over the country have significant wait times. It's time for the FDA to catch up as well and require labelling of all gluten-containing products.