



## DISCLOSURE OF GLUTEN IN MEDICINE

People with celiac disease must be vigilant to avoid ingestion of gluten-containing products. There is an urgent need to help people, especially children with celiac disease, avoid the risk of inadvertent ingestion of gluten. The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) believes medication labels should clearly disclose whether the product contains gluten and is why it endorses the "Gluten in Medicine Disclosure Act" (H.R. 2003).

### WHAT IS CELIAC DISEASE?

Celiac disease is a life-long sensitivity to gluten – a protein from wheat, rye, and barley. When affected individuals eat food containing gluten, it leads to damage of the fingerlike projections, or villi, lining the small intestine. If left untreated, celiac disease has the potential for multiple long-term adverse effects, including an increased mortality rate. Celiac disease commonly results in a number of serious medical problems including growth failure, chronic diarrhea, abdominal pain, and other problems outside the gastrointestinal tract, such as liver disease.

Celiac disease is one of the most common chronic conditions affecting the general population. It is estimated there are between 2-3 million people in the United States with celiac disease, many of whom are undiagnosed. The prevalence of celiac disease in children is thought to be between 3 and 13 per 1000 children.

### HOW IS CELIAC DISEASE TREATED?

The only acceptable treatment of celiac disease is complete avoidance of gluten. Evidence shows that avoiding the ingestion of gluten resolves symptoms common with celiac disease and reduces other medical consequences, including the risk of gastrointestinal cancer in adulthood.

### AVOIDING INADVERTENT INGESTION OF GLUTEN

Adhering to a gluten-free diet imposes a considerable burden on individuals with celiac disease. Because gluten is not always easily identified in commercial products, people with celiac disease have to be constantly vigilant and oftentimes must go to extraordinary lengths to confirm a product does not contain gluten.

### WHY MEDICATION LABELING IS NEEDED

For those with celiac disease, the knowledge that ingestion of gluten carries the potential for adverse health consequences is a source of significant anxiety. As a result, many people with celiac disease choose to avoid ingesting any product they are unable to confirm is gluten free, including medications. This is why NASPGHAN believes there is an urgent need to help people with celiac disease, especially children, avoid the risk of inadvertent ingestion of gluten through medication labeling.

It is not known precisely how often gluten is incorporated in the production of prescription and non-prescription medicine. The knowledge of whether a drug contains gluten is critically important for those living with celiac disease. H.R. 2003 would require the label of drugs intended for human use contain a parenthetical statement identifying the source of any ingredient constituting or derived from a grain or a starch-containing ingredient. NASPGHAN strongly supports passage of this bill and action by the Food and Drug Administration to help celiac patients avoid gluten in drug products, including regulations prohibiting the inclusion of gluten in new oral drug products when non-gluten alternatives can be used in the manufacturing process. NASPGHAN also believes the removal of gluten from existing drug products would benefit children with celiac disease, but further study would likely be needed on the pharmacologic effect of reformulating existing drugs to remove gluten when it is an inactive ingredient.

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