

# United States Senate

WASHINGTON, DC 20510

August 22, 2025

The Honorable Martin A. Makary, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

The Honorable Robert F. Kennedy Jr.  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Commissioner Makary and Secretary Kennedy:

I write to ask you to give your full and fair consideration to using your existing authority to require the labeling of gluten as a “Major Food Allergen.”

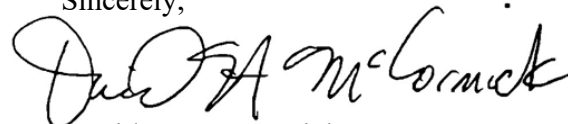
As you may know, approximately 3.3 million Americans live with Celiac Disease, an auto-immune disease for which there is no cure, surgery, or medicine. Of this number, approximately 729,000 Celiac patients are children, which can be overwhelming for parents and caregivers of young children who may be trying new foods for the first time and experience an immune reaction. If not properly diagnosed and managed, Celiac Disease increases the risk for long-term health complications for children including anemia, diabetes, intestinal damage, nutritional deficiencies and more, according to the Children’s Hospital of Philadelphia’s (CHOP) Center for Celiac Disease.

Gluten is a protein found in wheat, rye, barley, and any crossbred hybrids. In addition, gluten can often contaminate oats during harvesting and processing. Research is also ongoing into avenin, a different protein found in oats, and its potential impact on individuals with Celiac disease. Currently, the U.S. Food and Drug Administration (FDA) requires the labeling of wheat but not gluten. “Gluten-free” labeling is a voluntary process, with manufacturers responsible for ensuring their products meet FDA’s requirements. While labeling by many major food manufacturers has been helpful to those living with Celiac disease, many patients still experience regular inadvertent exposure to gluten, leading to immediate symptoms and contributing to long-term health complications.

Under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), the FDA is not precluded from requiring the labeling of gluten as a “Major Food Allergen.” Notably, 87 countries including Canada, Mexico, Australia, and much of the EU already require gluten labeling on packaged foods. I respectfully urge your agency to give full consideration to using this authority to improve the lives of individuals with Celiac disease.

Thank you for your consideration of this important matter affecting my constituents and their well-being. I look forward to your reply.

Sincerely,



David H. McCormick  
United States Senator

702 HART SENATE OFFICE BUILDING  
WASHINGTON, DC 20510-3808  
(202) 224-6324

310 GRANT STREET  
SUITE 2415  
PITTSBURGH, PA 15219  
(412) 803-7370

200 NORTH THIRD STREET  
SUITE 14A/14TH FLOOR  
HARRISBURG, PA 17101  
(717) 231-7540

2000 MARKET STREET  
SUITE 610  
PHILADELPHIA, PA 19103  
(215) 405-9660

329 INNOVATION BOULEVARD  
SUITE 226  
STATE COLLEGE, PA 16803  
(814) 357-0314

17 SOUTH PARK ROW  
SUITE B-150  
ERIE, PA 16501  
(814) 240-5213

840 WEST HAMILTON STREET  
SUITE 301  
ALLENTOWN, PA 18101  
(610) 782-9470

417 LACKAWANNA AVENUE  
SUITE 303  
SCRANTON, PA 18503  
(570) 941-0930