

**For Immediate Release**



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## **NFCA Receives FDA Grant For Gluten In Medications Research**

*Food and Drug Administration award to fund landmark study conducted by the National Foundation for Celiac Awareness*

**Ambler, PA (November 16, 2011)** - The National Foundation for Celiac Awareness (NFCA) is proud to announce that the organization has been awarded a \$50,000 grant from The Food and Drug Administration (FDA) to fund the first scientific research in the area of gluten in medication.

The project entitled, *"Gluten in Medication: Qualifying the extent of exposure to people with celiac disease and identifying a hidden and preventable cause of an adverse drug event,"* will characterize the problem of unlabeled gluten in medication and raise awareness of the potential harm that can occur to patients who ingest medications that they do not recognize as containing gluten, a protein found in wheat, barley, rye and their various derivatives.

Although gluten may be included in excipients used in medications, there currently are no regulations requiring drug manufacturers to label the source of excipients used in their prescription or over-the-counter (OTC) medications. To date, there has been no scientific research conducted to determine if the amount of gluten that is in medication results in harm to people with celiac disease or gluten sensitivity, although there are reports of significant patient reactions to gluten in medication.

This critically needed preliminary research aims to validate or nullify the anecdotal adverse experiences associated with gluten in medications that are reported by the celiac and gluten sensitive patient population. Findings from this project will provide a foundation for future investigation within the FDA and scientific communities, through which additional research, labeling, and safe use guideline initiatives can advance.

"This is a major milestone for the celiac disease and gluten sensitive community," said NFCA President and Founder, Alice Bast, "A central part of NFCA's mission is improving the quality of life for the diagnosed population. Keeping patients safe is an integral part of this undertaking."

In June 2011, the FDA issued a Request for Applications (RFA) in the area of *"Novel Interventions and Approaches to Improving the Safe Use of Medications,"* through which NFCA's proposal was granted funding. Information about this grant can be found on the FDA website: <http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm277720.htm>

"This award is especially gratifying because it represents the next step in a field that NFCA has dedicated a lot of attention to," said Loretta Jay, consultant to NFCA and Primary Investigator directing the research project, "That the FDA has recognized the importance of this work and has elected to partner with NFCA to conduct this research is a significant move toward understanding the effect of gluten in medications and furthering national standards for improvements in the quality of healthcare for this patient population."

Partnering with NFCA on this research is Dr. Robert Mangione, Dean and Professor of Pharmacy at St. John's University, NFCA Scientific/Medical Advisory Board Member, and

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co-Primary Investigator, along with research associates Dr. William Zito, Professor of Pharmaceutical Sciences, and Dr. Somnath Pal, Professor of Pharmacy Administration. Dr. Mangione and his team will conduct examinations of both over the counter (OTC) and prescription drugs reported to cause adverse effects in patients with celiac disease to determine gluten content. Investigators will employ Veratox® for Gliadin R5 testing and analyze for parts per million (ppm) and milligrams per dose.

Research will be underway in November 2011. A national survey distributed to the celiac disease patient population, which will help researchers identify the adverse interactions patients experience and the types of medications that may have caused them, is set to begin in early 2012.

This major achievement is one of several efforts NFCA has spearheaded to raise awareness of the issue of gluten in medication within the pharmaceutical industry and on a national scale. The Foundation has worked with several leading organizations and corporations since launching this campaign including: The Food and Drug Administration (FDA), Digestive Disease National Coalition (DDNC), National Council of Patient Information and Education (NCPPIE), American Society of Health-System Pharmacists (ASHP), American Pharmacists Association (APhA) and Perrigo Company. Earlier this year, NFCA launched GREAT Pharmacists with ProCE, a Continuing Education (CE) program for pharmacists dedicated to the topic of celiac disease.

For more information on NFCA's Collaborations & Actions in the area of Gluten in Medication, visit [www.CeliacCentral.org](http://www.CeliacCentral.org).

#### **About the National Foundation for Celiac Awareness (NFCA)**

The National Foundation for Celiac Awareness (NFCA) is a non-profit organization dedicated to raising awareness of celiac disease in order to gain prompt and accurate diagnoses for those suffering, supporting the health and wellbeing of those with the disease, and facilitating research that will better understand the disorder and find a cure. NFCA is a leading resource for celiac information, offering free information and support materials for celiac patients and families, as well as accredited training for food industry professionals and healthcare providers. Visit [www.celiaccentral.org](http://www.celiaccentral.org) for information.

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