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## Letter to the Editor

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### RE: GLUTEN CONTENT OF THE TOP 200 MEDICATIONS OF 2008

The special feature in November's issue of *Hospital Pharmacy* inadvertently epitomizes the significant problem faced by consumers, pharmacists, and drug manufacturers pertaining to gluten in medications. Gluten, the protein in wheat, barley, and rye, is sometimes used as an excipient in medication. A growing number of the approximately 3 million Americans with celiac disease are being diagnosed; their only treatment is the implementation of a strict, gluten-free diet. Small amounts of gluten, even the minute amounts that may be in a medication, can compromise their health.

The Allison R. King, et al published list of medications' gluten-free statuses attempts to provide a much needed resource. Unfortunately there is at least 1 error within: *Prevacid* (lansoprazole) is gluten-free. The authors documented contact with TAP Pharmaceuticals on July 15, 2009, and erroneously reported that this medication contains gluten. Takeda Pharmaceuticals North America Inc, the current manufacturer of *Prevacid*, and 1 of the 2 partners comprising the now defunct TAP Pharmaceuticals, confirms that *Prevacid* has not contained gluten for at least the previous 8 years.

How did this error occur? Did the representative from TAP or Takeda give the wrong information? Was it a documentation error on the part of the pharmaceutical students on Dr. King's team? We don't know. What we do know is that every day hundreds—if not thousands—of patients and pharmacists are calling manufacturers attempting to determine the gluten-free status of needed medications. Without formal guidelines from the Food and Drug Administration (FDA), attempts at ascertaining the inactive ingredients of medications are left in the hands of individuals. Mistakes are inevitable. Consumers' health status hangs in the balance.

Manufacturers routinely field calls about medications' inactive ingredients. Pharmacists, when they have the time, read the package inserts for the source of excipients and spend precious time calling manufacturers. Consumers, often without the resources or education of Dr. King's team, are left to fend for themselves. In the spring of 2008, the National Foundation for Celiac Awareness (NFCA) conducted a survey of people with celiac disease who received services from Philadelphia area hospitals. Seventy-nine percent of respondents report-

ed that neither the pharmacists nor the physicians were able to ascertain if needed medications contained gluten.

There are possible solutions to this problem. NFCA and others are advocating that the FDA establish guidelines requiring gluten to be identified when used in medications. Until this occurs, a list of manufacturers who voluntarily choose to refrain from using gluten as an excipient in the development of their medications can be created. The list, similar to one utilized in Canada, would benefit pharmacists and consumers alike, and could even become a marketing tool for the manufacturers: *Use our drugs: they are gluten-free!* Ideally, the use of wheat as an excipient can eventually be phased out in the formulation of medications.

The aforementioned will not be a rapid fix. In the meantime, NFCA is pursuing funding to develop a training program for pharmacists so they can effectively verify the gluten-free status of a medication.

—Loretta Jay, MA  
Director of Program Development  
National Foundation for Celiac  
Awareness  
215.325.1306 x104  
lorettajay@celiaccentral.org  
www.celiaccentral.org