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News and Views

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Gluten-free Food Labeling in the United States

The newly diagnosed patient with celiac disease, and the patient's family, face many challenges. After the initial shock and relief of receiving the diagnosis, the primary concern becomes ''What can I eat safely?'' In the United States, two recent developments in the world of food labeling will greatly impact those with celiac disease, dermatitis herpetiformis, wheat allergy and gluten intolerance. The first is the passage of the ''Food Allergen Labeling and Consumer Protection Act of 2004''. The second is the creation on August 19, 2005 of the Gluten-Free Certification Organization (GFCO) by the Gluten Intolerance Group of North America (GIG). This organization will identify qualifying foods with a new Gluten-Free (GF) certification mark (Fig. 1). That these two events should occur just shy of a year of each other is remarkable, and represents a great step towards improving the lives of children and adults with gluten-sensitive conditions.

Celiac disease is an immune-mediated condition resulting from the ingestion of gluten. In the food industry, the term ''gluten'' refers to the storage proteins of grains. The glutens in wheat, rye and barley stimulate a complex immune response in the celiac patient, leading to villous atrophy, malabsorption, and other nutritional, autoimmune, and malignant complications. At present, the only treatment for celiac disease, dermatitis herpetiformis and gluten-sensitivity is a strict, lifelong, GF diet. However, food labeling in the U.S. has presented a significant barrier to compliance with this diet.

FIG. 1. The new Gluten-Free certification mark. Reprinted with permission from the Gluten Intolerance Group.

The term ''gluten-free'' has only recently appeared on the radar of food manufacturers. Historically, celiac disease has been considered rare in the U.S., despite the presence of the HLA genes and dietary grains that put patients at risk. There was also a misconception among U.S. physicians that celiac disease was a ''European disease'', unusual outside of British, Scandinavian and Mediterranean countries. The perception that celiac disease was rare became a self-fulfilling prophecy, as lack of awareness of the disease led to lack of interest in looking for both typical and atypical symptoms and a low rate of diagnosis. The absence of ''classic'' manifestations of the disease in the U.S. was likely affected by infant feeding practices, age of gluten introduction and the quantity and quality of wheat gluten in commercial food products (1). In the U.S., children are often put on milk, egg and wheat-free hypoallergenic diets by primary care practitioners and pediatric allergists to treat a both gastrointestinal and non-gastrointestinal disorders (2,3). These changes in dietary practice do not prevent celiac disease, but merely delay the age of onset and alter the clinical presentation to a more atypical form (4).

Two studies published in the past decade indicate that celiac disease is just as common in the U.S. as it is in Europe. The first screened 2000 healthy blood donors for anti-endomysial antibodies and found that 1:250 were not only seropositive, but also had very low serum ferritin and HLA consistent with the disease (5). These preliminary results gave the impetus to study the American population on a larger scale for the prevalence of the disease in 13,145 subjects belonging to both at-risk and not-at-risk groups in 32 states. This landmark study showed that the overall prevalence of celiac disease in the ''healthy population'' was 1:133, similar to that reported in Europe. In the at-risk groups, the prevalence was 1:56 patients with classic symptoms, and 1:22 and 1:39 in first and second-degree relatives, respectively (6).

The year 2004 was a landmark year for raising awareness of celiac disease in the U.S. for two main reasons:

1. The National Institutes of Health Consensus Development Conference Statement on Celiac Disease, held June 28–30, 2004 (7) brought much needed public awareness and media attention to the prevalence of celiac disease in the U.S. This was the first time that the NIH addressed the issues of the protean manifestations, epidemiology, diagnostic testing and therapy for celiac disease.
2. The ''Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282)'' signed on August 2,

2004 (8,9), requires that food manufacturers, by January 2006, clearly state on the label if a product contains any of the top eight food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soybeans and wheat. It also charges the Food and Drug Administration (FDA) in the next 2 years to issue rules defining and permitting the term ''gluten-free'' on food labeling and then to implement a plan for GF labeling within four years.

The Food Allergen Labeling Act, while primarily passed for the benefit of those sensitive to the top 8 food allergens, is also of tremendous value to those with celiac disease. Wheat is often considered a ''hidden'' ingredient on labels, and may fall under the nomenclature of ''starch'', ''flavorings'', ''seasonings'', or ''hydrolyzed vegetable protein'' (10). Wheat can also go by many other names, such as couscous, farro, farina, filler, kamut, semolina, spelt and triticale (a wheat-rye hybrid). It is estimated that the average celiac shopper spends an additional 10 to 20 hours per month clarifying food labels for gluten content (11), often relying on uninformed customer service representatives. By clarifying the source of ingredients, and identifying wheat by name, gluten-sensitive patients can be better assured if wheat is present in a product, or is made in a facility that processes wheat (inadvertent cross contamination).

While the FDA debates how to define ''gluten-free'', GIG has formed the GFCO (12), partnering with Food Services, Inc., a subsidiary of the Orthodox Union. The Orthodox Union (OU) is the world's oldest and largest kosher certification agency, with nearly 500 field representatives worldwide (13). The GFCO has an advisory board that includes physicians, food scientists, food manufacturers, and dieticians, who will establish the standards and testing methods used to determine if a food product can be certified as gluten-free. Certification will be reconsidered yearly by ingredient review, on-site inspection and product testing. Inspectors, who are already proficient in modern food production techniques and chemical processing, will perform in-house, rapid, qualitative testing for gluten in plants at different points in production, including the cleaning of machinery and storage of the end product. Plants will be re-inspected based upon a risk assessment. Higher risk plants would include plants that also manufacture gluten-containing products on the same line, and use ingredients which have a high risk for contamination, such as oats. Once certified, the end products will be retested through testing of product directly from the shelves of stores.

According to Cynthia Kupper, RD, Executive Director of GIG, this new labeling will ''identify a confidence in a product for a consumer with a high standard of testing''. Products which bear the GF mark will contain less than 10 ppm of gluten (5 ppm of gliadin) and similar proteins from rye and barley as measured by testing methods approved by the Association of Analytical Communities. The GFCO hopes that their approach will be complimentary to those of the FDA. Applying for gluten-free status is thus far voluntary. At present, five food manufacturers are certifying products for the GFCO launch: Enjoy Life Natural Brands, Gifts of Nature Inc., Montina, PureFit Nutrition Bar, and Miss Roben's.

The success of organizations such as the GFCO will depend largely on the perception of food manufacturers as to whether there is a market for GF products. It is difficult to predict whether ''gluten-free'' will attain the same preferred status as ''sodium-free'', ''low fat'' or ''low carb'' with consumers. At present, there are over 2,000 products in the U.S. with GF label claims, with over $600 million in sales last year (14). GF product sales are growing at 14.6%, rapidly outpacing other key food categories (14). Even some large department stores are hopping on the gluten-free bandwagon. Walmart, a retailing giant, is requiring suppliers to indicate whenever gluten is used in its private-label products, with 982 of the company's 1,254 products identified thus far as ''gluten-free'' (15).

As pediatricians, we advocate for safe medical therapies for our patients. For those who require medical nutritional therapy, whether special formula or prescribed diet, ensuring the quality of commercial food items can be difficult. As gastroenterologists, we are obligated to increase the general practitioner's awareness of celiac disease and other gluten-sensitive conditions. In this way, our patients may be referred and diagnosed earlier, before the onset of complications, and lead more healthy and productive lives. Only by accurately diagnosing patients, who in turn will demand better food labeling, can we address these issues in the U.S. and the world arena.

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