1-1-2010

Balancing Consumer Protection and Scientific Integrity in the Face of Uncertainty: The Example of Gluten-Free Foods

Margaret Sova McCabe
University of New Hampshire School of Law, margaret.mccabe@law.unh.edu

Balancing Consumer Protection and Scientific Integrity in the Face of Uncertainty: The Example of Gluten-Free Foods

MARGARET SOVA MCCABE*

I. OVERVIEW OF ISSUES SURROUNDING GLUTEN-FREE FOOD REGULATION

This article analyzes the regulatory definition of "gluten-free" and gluten-free food labeling requirements. This is an important topic because millions with celiac disease (CD) rely upon gluten-free labels to find suitable foods. Additionally, others with medical conditions not yet proven to benefit from a gluten-free diet also seek gluten-free products. Because consumers seek the medical benefits of gluten-free products for a variety of reasons, it is essential that consumers properly understand the definition of "gluten-free" and the label's limitations. From this article, readers will gain an understanding of worldwide trends in gluten-free regulation, the Food and Drug Administration's (FDA's) action to date, and the challenges of how manufacturers should communicate the meaning of "gluten-free" to consumers. Finally, the article suggests ways to overcome these consumer communication challenges.

A. *The Issues Today*

CD is a serious autoimmune disorder affecting roughly one percent of the world population.[1] CD is characterized by the body's immune response to proteins in wheat and some other grains, commonly referred to as gluten. CD has no cure. To mitigate its symptoms, those suffering from CD must adhere to a gluten-free diet for life. Due to CD patients' demand for gluten-free products, a market for them has developed, and that market is growing rapidly.[2]

To protect the health of those with CD, various definitions of "gluten-free" for use on food labels have developed over the last 30 years. For example, the voluntary international food code, Codex Alimentarius, has a gluten-free standard, and many countries have binding regulations. Additionally, FDA is also close to issuing its final gluten-free rule. All of the regulatory efforts to define "gluten-free" have

* Ms. McCabe is Professor of Law, Franklin Pierce Law Center, Concord, New Hampshire.

[1] "Celiac disease is a chronic inflammatory disorder characterized by mucosal damage to the small intestine leading to gastrointestinal illness, nutrient malabsorption, and a wide range of clinical manifestations." FDA, Center for Food Safety and Nutrition (CFSAN), Threshold Working Group, *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food* (Mar. 2006), *available at* http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryinformation/ucm106108.htm [hereinafter Threshold Working Group]; *see also*, Alessio Fasano, *Surprises from Celiac Disease*, SCIENTIFIC AMN., Aug. 2009, at 32, 35 (providing worldwide prevalence statistics, and noting more than 2 million Americans suffer from CD).

[2] Nick Hughes, *The Rise and Rise of Gluten-free*, FOODNAVIGATOR.COM, Sept. 9, 2009, http://www.foodnavigator.com/Financial-Industry/The-rise-and-rise-of-gluten-free ("Since it was valued at a modest $580m in 2004, the market has grown at an average annual rate of 29 percent and last year was worth $1.56bn, according to Packaged Facts, which estimates the market in 2012 could be as worth as much as $2.6bn."). *But see* Caroline Scott-Thomas, *Gluten-fee Trend Could Fall Like a "House of Cards,"* FOODNAVIGATOR.COM, Mar. 23, 2010, http://www.foodnavigator-usa.com/Financial-Industry/Gluten-free-trend-could-fall-like-a-house-of-cards (reporting "people who have tried adhering to a gluten-free diet for reasons other than celiac disease are drifting back to gluten-containing foods" and that this trend will likely accelerate).

presented challenges to regulators. One key challenge is how to effectively regulate when the scientific landscape changes rapidly. Another challenge is presented by popular press reports of emerging and significant health benefits from gluten-free diets that are unrelated to CD.[3] This is a challenge because all gluten-free regulation is based on CD research, not medical research of other ailments.

B. *Why is a Gluten-free Definition Necessary?*

Americans with CD will benefit from gluten-free rules[4] because they will bring uniformity to the gluten-free industry. For years, CD patients have sought safe manufactured food products only to find a maze of confusing labels and varying interpretations of the term "gluten-free," which adds stress to coping with an already difficult condition.[5] Congress recognized this issue in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALPCA), which mandated FDA to define gluten-free.[6] In 2009, there was worldwide activity concerning gluten-free foods. For example, Codex Alimentarius and European Union (EU) both issued updated gluten-free standards.[7] Together, these regulations are important to those with CD, but also to the gluten-free industry, which is anticipated to grow to $2.6 billion in the next two years.[8] However, this growth is not entirely attributable to CD consumers, a fact that presents additional health-related issues that regulators must consider.[9]

These health-related issues, which are likely relevant to any specially formulated food, may be difficult to address without additional label provisions. For example, such foods often have strong consumer demand, but limited scientific evidence to support the best formulation for consumers seeking the products' medical or health benefits. Gluten-free foods will not be required to be completely gluten-free in the EU, or in countries that follow Codex, and probably also in the United States. Rather, the foods may contain up to 20 parts per million (ppm) of gluten.[10]

---

[3] Caroline Scott-Thomas, *Health issues back continued gluten-free growth*, FOODNAVIGATOR-USA.COM, Mar. 18, 2009, http://www.foodnavigator-usa.com/Financial-Industry/Health-issues-back-continued-gluten-free-growth ("Despite a lack of current medical evidence connecting gluten with autism, ADHD, irritated bowel syndrome and various other conditions, it does not deter a public seeking self-help ... The hard lines that medical professionals draw between a valid reason for a gluten-free diet and a fad do not exist among these patients and consumers.")

[4] Gluten-free Labeling of Foods, Proposed Rule, 72 Fed. Reg. 2795 (Jan. 23, 2007) (to be codified at 21 C.F.R. Part 101).

[5] Tiziana Fera, et al., *Affective Disorders and quality of life in adult coeliac disease patients on a gluten-free diet*, 15 EUROPEAN J. OF GASTROENTEROLOGY & HEPATOLOGY 1287, 1291-1292 (2003) (discussing CD patients' difficulties in adjusting to the diagnosis); *see also* National Foundation for Celiac Awareness, GREAT Mental Health Program, http://www.celiaccentral.org/Education/GREAT-Healthcare/Mental-Health/247/ (last visited Dec. 24, 2009) (describing training program for medical care providers that work with CD patients to help them cope with stress of managing diet and disease).

[6] FALPCA, Title II, Pub. L. No. 108-282, 118 Stat. 891 (2004) [hereinafter FALCPA or cited as appropriate to the *United States Code*].

[7] Commission Regulation No. 41/2009, Concerning the Composition and Labeling of Foodstuffs suitable for people intolerant to gluten, 2009 O.J. (L16) 3 (Jan. 21, 2009; Codex Alimentarius Commission, Standard for Special Dietary Use for Persons Intolerant to Gluten, Stan. 118-1979 (as amended 1983, 2009) *available at*: http://www.codexalimentarius.net/web/standard_list.jsp [hereinafter Codex Stan. 118-1979]; *see also* Codex General Standard for the Labeling of Prepackaged Foods, Stan. 146-1985, *available at*: http://www.codexalimentarius.net/web/index_en.jsp.

[8] Hughes, *supra* note 2.

[9] *Id.* ("In the United States, a recent report from New Nutrition Business entitled 'Organic and All Natural Kids Snacks and Baby Foods' claimed that 15-25 per cent of American parents actively seek gluten-free food and drink. *'The driver is a belief among people that they, or their children, may have a gluten sensitivity—even though they are not diagnosed as having an allergy,'* said the report. *'It's an example of how belief can be a more compelling reason to purchase than rational science.'*").

[10] *See* Gluten-Free Labeling of Food, Proposed Rule, 72 Fed. Reg. 2795; Commission Regulation No. 41/2009, Concerning the Composition and Labeling of Foodstuffs suitable for people intolerant to gluten, 2009 O.J. (L16) 3 (Jan. 21, 2009); Codex Stan. 118-1979 *available at*: http://www.codexalimentarius.net/web/standard_list.jsp.

By contrast, Australia and New Zealand mandate that gluten-free products have no detectable gluten. While this approach may seem common-sense to the average consumer, the term is problematic. It is problematic because "free" is actually a measure dependent upon scientific testing methodology.

Therefore, FDA's gluten-free rulemaking produces two key issues, regardless of the final rule's text. First, there will be scientific uncertainty about what constitutes a "safe" threshold amount. While current science reveals what may be optimal for many with CD, the 20 ppm standard may not beneficial to all.[11] Thus, communicating this uncertainty to those with CD remains an issue. How consumers understand labels based on thresholds is important as food allergy research continues and the possibility of thresholds emerge there, especially as manufacturers expand the use of terms such as "dairy free," "peanut free," "nut free" and "wheat free."

Second, the rules may raise misbranding questions if manufacturers use the "gluten-free" term in a way that implies health claims beyond appropriateness for a CD patient's diet. This is a particularly vexing problem for gluten-free regulations because the legislative history of the FALPCA establishes that, "[t]he claim 'gluten-free' is not intended to be a claim for special dietary use, a nutrient content claim, or a health claim, with their associated requirements for use."[12] Even though the FALPCA clearly sets "gluten-free" outside of the Federal Food Drug and Cosmetic Act's (FDCA's)[13]provisions for health claims, the greater issue is to ensure that "gluten-free" is not communicated in a misleading way.

What are the possible solutions to these two issues? First, readers should make no mistake—FDA's careful approach to meeting the requirements of the FALCPA provides an excellent example of policymaking carefully focused on scientific certainty and integrity. However, scientific certainty is a complex concept. When science appears to achieve certainty, it often reveals that earlier conclusions were wrong or inaccurate.[14] The question might be posed whether there is any such thing as scientific certainty when it comes to nutrition and health, given that expert advice in that arena seems to change frequently.[15] When viewed this way, the crux of the first challenge—that of "safe" threshold rulemaking—is revealed: what science tells us is a safe amount today may be revised by future study. One possible solution is a label that communicates the degree of scientific certainty.

More specifically, the gluten-free rules could be an opportunity for FDA to propose disclaimers for use on gluten-free foods. For example, disclaimer language could be: May not be suitable for all consumers. Consumers following special diets should ask their medical care providers if this product is appropriate. This alternative is similar to disclaimers originally proposed for "qualified health claims." The purpose of those disclaimers was to illustrate the strength of science connected to a health claim, and the same could be considered for gluten-free foods. [16] For ex-

[11] Carlo Catassi, et al. *A Prospective, Double-blind, Placebo-controlled Trial to Establish a Safe Gluten Threshold for Patients with Celiac Disease.* 85 AM. J. CLIN. NUTR. 160, 164 (2009) ("The gluten microchallenge disclosed large interpatient variability in the sensitivity to gluten traces.").

[12] S. Rep. No. 108-226, at 11 (2004).

[13] 21 U.S.C. Ch. 9 (2006); 21 U.S.C. § 343(r) (2006).

[14] *See, e.g.,* Fasano, *supra* note 1, at 32 (tracing the discovery of CD to the ancient Greeks, and noting Dr. Samuel Gee is the "modern father of CD," but that he suggested treating children with CD with "thinly sliced bread, toasted on both sides.").

[15] Examples of "fad diets" that have been recommended and then criticized include "fat free" and "no carb." *See e.g.* CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CSPI), Press Release, CSPI Urges Crackdown on Carb Claims, Feb. 2, 2004, http://www.cspinet.org/new/200402021.html.

[16] FDA, Consumer Health Information for Better Nutrition Initiative Task Force, Final Report (Jul. 10, 2003) *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/QualifiedHealthClaimsPetitions/ucm096010.htm.

ample, a gluten-free label could reflect an "A" rating for CD and a "C" for irritable bowel syndrome. While FDA understands that communicating scientific information to consumers is difficult, its regulation of the term "gluten-free" provides an opportunity for clearer labeling.[17]

C. *Will consumers trust gluten-free labels?*

FDA gluten-free rulemaking has two debated issues: how to treat oats and what testing methodology to use. First, oats are controversial because in the past, medical care providers counseled CD patients to avoid oats as part of a gluten-free diet. Today, many consider the oat avoidance advice outdated because oats now can be produced free of wheat cross-contamination. Thus, FDA must decide whether to allow oats in gluten-free products. If FDA decides in favor of oats, then some will argue the CD population does not benefit from the label because it is too broad. If FDA decides against including oats, then some will argue the rule is too narrow and not in keeping with modern research.

Consumer trust in gluten-free products is, in part, dependent on the testing methodology required by FDA. The Codex standard adopts the enzyme-linked immunosorbant assay (ELISA) methodology as the most reliable for gluten detection, and FDA will likely follow suit. An example of the importance the testing methodology may have for consumers is illustrated by Bob's Red Mill product labels, which include the statement: "We use an ELISA gluten assay test to determine if a product is gluten-free."[18] FDA should consider whether this type of label information is valuable to consumers and will promote trust in the label.

Finally, one way to think about the challenges outlined above is through the precautionary principle. Consumers want efficient, effective, and accurate labels to help them select food products based on the product's benefits. One way to improve the accuracy of the information conveyed by specialized food labels is a precautionary approach that requires additional information where the science is uncertain.[19] This approach would allow FDA to monitor science until it develops certainty, while also providing relevant label information to consumers.

Though FDA's deadline for final gluten-free rules has passed,[20] the agency is responsibly reviewing the available data on both "safe" threshold amounts of gluten

[17] Brenda Derby and Alan Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims*, 34 (FDA, CFSAN, Office of Regulations and Policy, Division of Social Sciences, Working Paper No. 1, 2005) ("None of the different ways tested to communicate the strength of the science supporting a food label health claim performed very satisfactorily. The ways that the different disclaimers failed, however, may help us understand why it is so difficult to communicate strength of science to consumers.").

[18] Bob's Red Mill, Wheat Free/Gluten Free/Dairy Free Brownie Mix, back panel (on file with author).

[19] BERNDT VAN DER MEULEN and MENNO VAN DER VELDE, EUROPEAN FOOD LAW HANDBOOK 269 (2009)(quoting the EU's articulation of the precautionary principle: "In specific circumstances, where following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management is necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."). For the purposes of this article, when the term precautionary principle is used, it means the adopted EU standard, though there are many different iterations of it; *see* Cass Sunstein, *Beyond the Precautionary Principle*, 151 U.PA.L.REV. 1003, 1011 (2003)("But what does the precautionary principle mean or require? There are numerous definitions, and they are not compatible with one another. We can imagine a continuum of understandings. At one extreme are weak versions to which no reasonable person could object; at the other extremes are strong versions that would appear to call for fundamental rethinking of regulatory policy.").

[20] FALCPA §206, 21 U.S.C. § 343 (2009)("Not 4 years after the date of enactment of this Act, the Secretary shall issue a final rule to define, and permit use of, the term 'gluten-free' on the labeling of foods.").

and reliable testing methods.[21] This is laudable, and a prudent step for an agency that must make its policy decisions based on scientific evidence.[22] However, what happens when scientific evidence is lacking, but consumer demand is strong? And how will consumers, especially those who rely on gluten-free labels, understand the new rules? This is especially important as gluten-free product marketing is on the rise.

The remainder of this article examines scientific certainty and administrative regulation of products intended for consumers with special medical or health needs using gluten-free products as an example. Section II provides analysis of the reasons consumers demand gluten-free products. Section III provides an overview of how various world entities and governments have regulated gluten-free labels to date. Section IV examines the American approach. Section V analyzes the tension between consumer demand and regulation where scientific uncertainty exists and proposes that consumers receive greater label information in these circumstances.

II. WHY GLUTEN-FREE?

"Why go gluten free? Not long ago, two of our co-workers found themselves in the gluten-free world. Linc was diagnosed with Celiac disease, and Colleen's family switched to the diet for her son's well-being."[23]

Gluten-free products are gaining in popularity. For example, the quote above is from a Betty Crocker brand dessert mix that was introduced in 2009. Retailers are not hiding these mixes on the bottom shelf of a special dietary section of a health food store. These mixes and similar products are in prime grocery store space—the middle shelf of the conventional baking goods aisle. In addition to new products, manufacturers are adding the term gluten-free to existing product packaging. Examples include cheese, rice cakes, and ketchup. New products and amended existing product labels illustrate consumer demand and the manufacturers' response. The next section explains reasons behind consumer demand.

A. *Health Overview*

CD is a "chronic inflammatory disorder of the small intestine triggered by ingesting certain storage proteins that occur in natural grains."[24] In 2004, Congress estimated that between one-half and one percent of Americans suffer from the disease,[25] though recently released studies have suggested that the number is higher.[26] The disease is an autoimmune response to gluten which causes injury to the "mucosa of the small intestine [specifically targeting] the fingerlike projections, called villi, where absorption of key nutrients takes place."[27]

CD is serious. Symptoms of CD fall into two categories: classic gastrointestinal and non-gastrointestinal.[28] The classic symptoms include abdominal bloating and

[21] Gluten-free Labeling of Foods, Proposed Rule, 72 Fed. Reg. at 2803.

[22] 21 U.S.C §403(j)(2009).

[23] Betty Crocker, Gluten Free Cookie Mix, Chocolate Chip, Right Information Panel (2009)(on file with author).

[24] Gluten-Free Labeling of Foods, Draft Report, 70 Fed.Reg. 35,258 (Jul. 14, 2005); Threshold Working Group, *supra* note 1, at Pt. III (A), Introduction.

[25] FALCPA § 202(6), 21 U.S.C. § 343 note (2006); *see also* Fasano, *supra* note 1, at 35 (quantifying the number of Americans with CD at more than 2 million).

[26] Fasano, *supra* note 1, at 34 ("In 2003 ... the largest hunt for people with CD ever conducted in North America ... found that one in 133 apparently healthy subjects was affected ... meaning the disease was nearly 100 times more common than we thought.").

[27] Threshold Working Group, *supra* note 1, at Pt. III (B), Mechanism of Pathogenesis.

[28] *Id.* at (C), Range of Adverse Effects

chronic diarrhea resulting in weight loss, poor growth in children, and nutrient deficiencies.[29] Non-gastrointestinal symptoms are wide ranging and include: anemia, infertility, developmental delays, epilepsy and many others.[30] CD patients' long-range prognosis includes higher intestinal cancer and mortality rates.[31] Recent studies also show that latent CD may affect even more people and has just as serious a prognosis.[32]

CD occurs most frequently in North Americans and Europeans, who share wheat as a food staple.[33] Wheat contains storage proteins that are referred to generally as "glutens."[34] Glutens more specifically refer to a combination of "prolamin proteins called 'gliadins' and the glutelin proteins called 'glutenins' found in wheat."[35] Therefore, scientifically "glutens" occur in wheat only. Other cereal grains such as wheat relatives (durum, kamut, spelt, and rye), barley, and triticale have similar storage proteins.[36] As a result, the regulatory term "gluten" includes all of the above.[37] Additionally, some with CD are sensitive to oats, while others are not. As noted above, historically, doctors have advised oat avoidance, though this has now fallen out of favor.[38] The only treatment for CD is strict avoidance of gluten.[39] Therefore, consumers with CD must trust gluten-free labels with their health, and ultimately, their lives.

Wheat is also a major food allergen.[40] Though wheat can cause fatal conditions such as cancer in CD patients, wheat may be deadly for those with life-threatening allergies to it. As with CD, the only way to manage a life-threatening food allergy is strict avoidance of the allergen. Therefore, many people who are wheat allergic seek the gluten-free label to help them avoid wheat or products that are likely cross-contaminated with wheat.[41] These consumers (including parents of allergic children) also trust their health, and in severe cases, their lives, to the accuracy of food labels.

Beyond CD and food allergy are other medical conditions that may or may not respond to a gluten-free diet. Autism is the best example. Autism's cause is unknown.[42] Autism has no cure.[43] Some believe that, like CD, it is an autoimmune disorder.[44] Many autistic children's parents attest that a gluten-free (and casein-free)

---

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*; *see* Jonas F. Ludvigsson et. al, *Small-Intestinal Histopathology and Mortality Risk in Celiac Disease*, 302 J. OF THE AM. MED. ASSOC'N 1171, 1178 (2009).

[33] Threshold Working Group, *supra* note 1, at (C), Range of Adverse Effects.

[34] *Id.* at (E), Celiac Foods of Concern.

[35] *Id.*

[36] *Id.*

[37] Codex Alimentarius Commission, General Standard for the Labeling of Prepackaged Foods, Stan. 1-1985; General Standard the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses, Stan. 146-1985, *available at* http://www.codexalimentarius.net/web/index_en.jsp.

[38] Threshold Working Group, *supra* note 1, at (E).

[39] *Id.* at (A) Introduction.

[40] FALCPA §203(c); 21 U.S.C. §321(qq)(1)(definition of major food allergen).

[41] Food Allergy and Anaphylaxis Network (FAAN), *Wheat Card: How to Read a Label*, https://www.foodallergy.org/shoppingcart/cgi-bin/msascartlist.dll/ProductInfo?productcd=CWHE (last visited Oct. 6, 2009).

[42] National Institutes of Health (NIH), *Autism*, http://www.niehs.nih.gov/health/topics/conditions/autism/index.cfm (last visited Oct. 6, 2009).

[43] *Id.*

[44] *E.g.*, Paul Ashwood and Judy van de Water, *Is Autism an Autoimmune Disease?* 3 AUTOIMMUNITY REVIEWS 557 (2004).

diet improves their child's behavior.[45] Defeat Autism Now (DAN) and Talk About Curing Autism (TACA) are two organizations that help parents find physicians who will support use of "the diet."[46] However, there are no accepted scientific studies that correlate gluten-free diets with improved behavior in autistic children.[47] While there are skeptics of the diet's role in improving autism, acceptance of a gluten-free diet as having benefit for people on the autism spectrum is growing—and is one reason for the increase in demand for gluten-free products.[48]

Beyond autism, some consumers believe a gluten-free diet will alleviate other health conditions.[49] These conditions include irritable bowel syndrome, acid reflux, and diabetes. Others believe a gluten-free diet will help those with "gluten intolerance" (a condition not diagnosed as CD or wheat allergy but that suffers believe is responsible for weight gain) lose weight. Regardless of whether gluten avoidance eases these health concerns, the fact is that some consumers believe it does. As a result, they are seeking gluten-free products. However, these consumers were not considered when Congress passed FALCPA, indicating that "gluten-free" has a broader meaning to consumers now than it did in 2004.

B. *Regulatory Overview*

In 2004, Congress passed the FALCPA in response to the increased number of Americans diagnosed with food allergies and CD.[50] Its overarching purpose is to provide clear disclosure of ingredients on food labels to protect consumer health. The FALCPA required FDA to adopt a final rule "to define, and permit use of, the term 'gluten-free' on the labeling of food."[51]

While FDA continues to study the best approach to gluten-free labels, Codex Alimentarius and other countries have adopted regulations. In 2009, the Codex Alimentarius defined "gluten-free" to mean foods that would not contain more than 20 ppm.[52] Similarly, in 2009, the EU also adopted regulations that mirror the Codex Alimentarius standard.[53] However, in 2003, Australia and New Zealand's regulation took a different approach. There, "gluten-free" means *no gluten*, to the extent that

---

[45] JENNY MCCARTHY, LOUDER THAN WORDS (2008) is a particularly well-known testament to the effects of the "diet," with some popular press characterizing its use as a "cure."

[46] TACA, Gluten-free Casein-free diet, http://gfcf-diet.talkaboutcuringautism.org/index.htm (last visited Dec. 26, 2009); DAN, Doctor Listing, http://www.autismwebsite.com/practitioners/us_lc.htm (last visited Dec. 26, 2009).

[47] *In re McDonald's French Fry Litigation*, No. 06-C-4467 (N.D. Ill. – E. Div.) (May 6, 2009) presents an interesting legal source for this proposition. The plaintiffs sought national class certification for all consumers who purchased McDonald's french fries and who had a medical diagnosis of celiac disease, autism, and wheat, gluten, or dairy allergies. The plaintiff's alleged McDonald's claimed their fries were gluten-free when they were not. The court summarized one of the defendant's experts testimony (by affidavit) as "most people with autism eat products containing milk, wheat, gluten, casein, and that there is no reliable evidence that any of these products contribute to or make worse a person's autism." *See also Gluten Free Casein Free Diets for Autism*, http://www.webmd.com/brain/autism/gluten-free-casein-free-diets-for-autism (last visited Dec. 9, 2009).

[48] Scott-Thomas *supra* note 3.

[49] *E.g.*, Adam Voiland, *Gluten-Free Diet: a Cure for Some, a Fad for Most*, US NEWS AND WORLD REPORT (Oct. 31, 2008) *available at*: http://www.usnews.com/health/family-health/digestive-disorders/articles/2008/10/31/gluten-free-diet-a-cure-for-some-a-fad-for-most.html.

[50] FALCPA, §202, 21 U.S.C. § 343 note (2006).

[51] FALCPA, §206; 21 U.S.C. § 343 note (2006).

[52] Codex Stan. 118-1979 *available at* http://www.codexalimentarius.net/web/index_en.jsp.

[53] Concerning the Composition and Labelling of Foodstuffs suitable for people intolerant to gluten, 2009 O.J. (L16) 3 (Jan. 21, 2009) (Commission Regulation No. 41/2009).

scientific testing can detect.[54] Though FDA is aware of these approaches, it rejects the Codex and the EU's approach as based on anecdotal science.[55] Further, in response to a citizens petition to adopt an approach similar to Australia's, FDA stated that it would "respond to this issue ... in our final rule that defines the food labeling term 'gluten-free,'"[56] though the proposed rule does not seem to favor this approach.[57]

III. INTERNATIONAL PERSPECTIVES ON THE MEANING OF GLUTEN-FREE

A. *The Codex Standard*

Since Codex Alimentarius' goal is to harmonize international food standards, this section begins with its provisions.[58] Codex Standard 118-1979 (the Standard) governs foods for people "intolerant to gluten."[59] This international standard first addressed food formulated for those with gluten intolerance in 1979, with subsequent amendments in 1983 and 2008. The key issue in the standard is the acceptable levels of gluten in products labeled as "gluten-free" or "reduced gluten." Closely related to the acceptable gluten levels is the type and accuracy of product testing methods.

The 2008 Standard divides gluten-free foods into two categories. First are those that can be considered gluten-free by composition, defined as those "consisting of or made only from one or more ingredients that do not contain wheat[60]... rye, barley, oats[61] or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or as distributed to the consumer."[62] Next are products that are gluten-free through special processing. These are defined as "consisting of one or more ingredients from wheat, rye, barley, oats or their cross-bred varieties" that have been "specially processed to remove gluten."[63] The specially processed foods' gluten levels also cannot exceed 20 mg/kg in total.[64]

The Codex Standard also recognized "reduced gluten content" foods. These are defined in the same way as gluten-free foods, but can contain between 20 mg/kg and 100 mg/kg of gluten as sold or distributed to the consumer.[65] The regulation of foods labeled "reduced gluten content" is left to individual nations.[66] The Standard also notes that gluten-free foods should strive to "supply the same amount of vitamins and minerals as the original foods they replace."[67] Under this guidance,

[54] Australia New Zealand Food Standards Code 1991, Stan. 1.2.8 (16) (prohibiting gluten in products labeled "gluten-free," but permitting up to 20 ppm in foods labeled "low gluten"). *available at* www.comlaw.gov.au/comlaw/Legislation/.../FoodStandANZ91.pdf.

[55] Threshold Working Group, *supra* note 1, at IV(D), Gluten Threshold: Evaluation and Findings, Finding 9 ("The levels being considered by Codex seem to be based on anecdotal evidence ...").

[56] FDA Docket 2005-N-0404, Doc. Id. FDA 2005-N-404-0124 (Carolyn Smith Pet'n Dec. 26, 2007 and FDA response June 27, 2008).

[57] Gluten-free Labeling of Foods, Proposed Rule, 72 Fed. Reg. at 2801 (option two).

[58] "The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme." For further information about its history and purpose, *see* http://www.codexalimentarius.net/web/index_en.jsp (last visited Dec. 9, 2009); *see also* WORLD HEALTH ORGANIZATION (WHO), CODEX ALIMENTARIUS FOOD LABELLING (5th ed. 2007).

[59] Codex Stan. 118-1979.

[60] Codex Stan. 118-1979, 2.1.1(a). The standard identifies wheat as all *Triticum* species, including durum wheat, spelt and kamut.

[61] Codex Stan. 118-1979, 2.1.1(a), Fn.1.

[62] Codex Stan. 118-1979, 2.1.1.

[63] Codex Stan. 118-1979. 2.1.1(b).

[64] *Id.*

[65] Codex Stan. 118-1979, 2.1.2.

[66] *Id.*

[67] Codex Stan 118-1979, 3.3.

manufacturers should fortify a gluten-free breakfast cereal such as corn flakes in the same manner as its conventional counterpart.

The Standard has three specific gluten-free food labeling requirements, which are in addition to the Codex's general labeling standards for prepackaged foods and those for special dietary uses.[68] First, manufacturers must place the term "gluten-free" in the "immediate proximity of the name of the product."[69] Next, manufacturers may not label "reduced gluten content" foods "gluten-free."[70] Finally, manufacturers may not claim that foods naturally gluten-free or with "reduced gluten content" are special dietary foods.[71] Manufacturers are permitted to claim "this food is by its nature gluten-free" if a consumer would not be misled by such a statement.[72]

Finally, the Standard sets out six guidelines for quantitative and qualitative analytical and sampling methods. First, manufacturers must test their products using an immunological method or a different method that provides at least the same sensitivity and specificity as the immunological method.[73] The testing method must react with the prolamins that are toxic to CD patients, without cross-reacting with ones that CD patients can tolerate. Additionally, the Standard suggests validation and calibration with a certified reference material (a control). Next, the Standard requires any method to be "state of the art and the technical standard." Currently, the Standard elucidates that state of the art means detection levels at10 mg gluten/kg or lower. Finally, the Standard specifies qualitative methods as ELISA or DNA methods.[74]

The legislative history of the Codex Standard illustrates participating nations' efforts over 30 years to define foods that are safe for those who cannot tolerate gluten. The history reveals that the current issues concerning thresholds and reliable testing methods have existed from the start. In 1978, the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) reported that, while progress had been made towards a threshold, various nations had differing opinions on an optimal level.[75] At the same meeting, participants recognized the ELISA method for its potential to test for gluten contamination. By 1983, the proposed threshold of 5 g of gluten per 1000 grams had been referred to member governments for approval.[76] In the intervening years, Codex has continued to monitor the science, as well as the consumer demand, for gluten-free foods. Its continued efforts are to be lauded for their contribution toward the goal of international harmonization of gluten-free standards.

The 30-year history of the development of the Standard reflects the differences of opinion that exist from country to country as to ideal gluten-free standards. This is illustrated by the varying worldwide standards for the use of the term "gluten-free" and the fact that some nations continue to debate how to label and define these foods. Additionally, because "reduced gluten" and "naturally gluten-free" food regulation is left to individual nations, there is likely even wider variation on the

---

[68] *See* Codex Stan. 1-1985, General Standard for the Labeling of Prepackaged Foods; Codex Stan. 118-1979.

[69] Codex Stan. 118, 4.1.

[70] Codex Stan. 118, 4.2.

[71] Codex Stan. 118, 4.3.

[72] *Id.* The standard acknowledges that nations will likely need more detailed rules regarding naturally gluten-free food labeling.

[73] Codex Stan. 118-1979, 5.1.

[74] *Id.*

[75] CODEX ALIMENTARIUS COMMISSION, Report of the 11th Session of the CCNFSDU, ¶ 55-70, (Oct. 23-27, 1978).

[76] CODEX ALIMENTARIUS COMMISSION, Report of the 15th Session of the CCNFSDU, Appendix III, (July 4-15, 1983) (noting progress made on thresholds but consensus still not reached).

meaning of these terms. These national variations, despite the Standard, illustrate the difficulty CD patients, or those with other medical reasons for avoiding gluten, encounter in a globalized economy.

The next section compares several recent gluten-free regulations to the Codex Standard and explores how variations in those regulations affect consumers.

B. *The European Union, 2009*

Following the 2009 update of the Codex Standard, the EU adopted its own regulation "concerning the composition and labeling of foodstuffs suitable for people intolerant to gluten."[77] The Commission Regulation (Regulation) recognized the growing number of products marketed for people intolerant to gluten and noted wide variation in labeling practices. As a result, one purpose of the Regulation was to offer clarity for consumers and for manufacturers.[78] Further, because gluten intolerance varies from person to person, the EU also sought to "enable individuals to find on the market a variety of foodstuffs appropriate for their needs and for their level of sensitivity."[79] As a result, the Regulation, similar to the Codex Standard, recognizes two types of products as suitable for special labeling, and two terms ("gluten-free" and "very low gluten") which can be used to describe them.[80]

"Very low gluten" foods are those that manufacturers specially process to reduce the gluten content from "ingredients made from wheat, rye, barley, oats or their crossbred varieties." These specially processed grains must not exceed 100 mg/kg of gluten in the food sold to the consumer.[81] Manufacturers may label these specially processed ingredients "gluten-free" when the gluten content does not exceed 20 mg/kg in the food when purchased by the consumer.[82] When manufacturers substitute ingredients for gluten-containing grains, the food labels can state "gluten-free" so long as the food meets the no more than 20 mg/kg gluten standard. A product that contains *both* specially processed grains and substitutes for grains is treated as a specially processed food.[83]

Like the Codex Standard, the Regulation specifically addresses oats. Not only must oats meet the standards, manufacturers must take steps to ensure that the oats are "specially produced, prepared and/or processed in a way to avoid contamination" by other gluten-containing grains.[84] Oats, while included in the general rule for "very low gluten labeling" for specially processed grains, must first be confirmed to not exceed the 20 mg/kg gluten-free standard.[85] Therefore, manufacturers using oats must ensure that they are gluten-free before they are used as an ingredient in another "very low gluten" or "gluten-free" product.

The Regulation also allows gluten-free labeling on products that are "for normal consumption" (meaning those naturally gluten-free) as well as specially prepared dietary foods for conditions other than gluten intolerance, so long as those foods meet the 20 mg/kg standard.[86] However, unlike the Codex Standard, the Regula-

---

[77] EC Reg. No. 41/2009 (Jan. 20, 2009).
[78] EC Reg. No. 41/2009 (1).
[79] *Id.* at (6).
[80] *Id.* at (7); Art. 3.
[81] *Id.* at Art. 3 (1).
[82] *Id.* at Art. 3 (2).
[83] *Id.* at Art. 3 (5).
[84] *Id.* at Art. 3 (3).
[85] *Id.*
[86] *Id.* at Art. 4 (1).

tion does not require manufacturers to note that all like foods are also gluten-free. However, the Regulation does prohibit the use of "very low gluten" in labeling naturally gluten-free foods or those prepared for other dietary needs that may meet the very low gluten standard.

As with the Codex Standard, the Regulation is intended to help gluten-intolerant people find suitable products, while limiting the chance that labels may mislead this class of consumers. The Regulation is effective January 1, 2012, though manufacturers may voluntarily comply before that date.

The Regulation interrupted some EU member states' efforts to regulate gluten-free labeling. For example, in 2008 Ireland's Food Safety Authority issued a report with recommendations to manufacturers.[87] The Irish recommendations originally suggested labeling foods containing 20 to100 mg/kg gluten "Reduced Gluten, suitable for most celiacs" rather than "very low gluten."[88] The Irish report also recommended that manufacturers begin labeling in accordance with its recommendations by June 17, 2009, but now acknowledges the later EU date of January 1, 2012.

C. *Canada, 2008*

In 2008, Canada began "Project 1220" for the "enhanced labeling for food allergens and gluten sources and added sulfites."[89] This initiative is not aimed solely at gluten-free foods; rather it includes the issue as a subset of allergen labeling. Like the Codex and the EU, Canada is taking this action to "minimize the risks associated with inadvertent consumption" of gluten and to "maximize the choice of safe and nutritious foods."[90] Health Canada's response to public comments on these regulations also indicates that this review is a first step in the process of updating "gluten-free" and related claims.[91]

The Canadian proposed regulation defines gluten as "any gluten protein or modified protein, including any protein fraction derived from the grains of the following cereals: barley, oats, rye, triticale, wheat, kamut or spelt."[92] This definition departs from the Codex Standard in that it is not directly linked to a 20 ppm threshold for gluten. Unlike the EU, the regulation does not specify special handling of oats. This omission drew suggestions that Health Canada revisit the oat issue before issuing final regulations, which Health Canada has said it will do.

Project 1220's focus is not necessarily gluten-free labeling, but rather special notice to consumers of the presence of gluten with the words "Allergy and Intolerance Information Contains: ... ."[93] For gluten, manufacturers would then list the gluten source such as spelt, wheat, or barley. Because this focus is slightly different from

---

[87] Food Safety Authority of Ireland [hereinafter FSAI], Report on Gluten-free Foods (2008) *available at* www.fsai.ie/assets/0/86/204/4a70f71b-7c15-4e72-bd6f-c85deba481de.pdf.

[88] FSAI, Update on Labeling Gluten-Free Foods (Mar. 2009), *available at* http://www.fsai.ie/.

[89] *Canada Gazette,* Part I (July 26, 2008); *see also,* The Bureau of Chemical Safety, Food Directorate, Health Canada, *Health Canada Reviews Comments Received on Regulatory Project 1220, available at* http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/sum-comm-exa-eng.php [hereinafter Health Canada Comment Review].

[90] Health Canada Comment Review at 2.

[91] *Id.* at 4 ("once finalized, Health Canada and the Canadian Food Inspection Agency will aim to develop guidance, and compliance policy that clearly reflects the intent of the amendments with respect to gluten declaration.")

[92] *Id.*; *see also* Canada Food and Drug Regulations SOR/1995-444, s.2 (Can.) ("No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye, triticale or any part thereof.")

[93] *Id.* at 3-4.

the Codex Standard and the European Regulation, the Canadian approach contains other details such as whether waxes should be exempted from gluten disclosure.[94]

Finally, the Canadian comments raise the thorny issue of scientific standards. Scientific method for gluten detection will likely improve over time, and the Canadian regulation is currently silent on a gluten threshold amount. While the threshold question remains under review in Canada, Australia and New Zealand have adopted a zero-gluten standard.

D. *Australia and New Zealand, 2003*

The Australia and New Zealand Food Standards Code prohibits "gluten-free" claims unless the food contains "no detectable gluten; and no oats or their products; or cereals containing gluten that have been malted or their products."[95] "Low gluten" claims can be made on foods that contain 20 mg/kg. This standard does not specify the testing method that should be used by manufacturers. While this standard predates the Codex reference to specific qualitative and quantitative testing methods, its silence on this point makes it difficult to hold it as a model. However, its approach of "no detectable gluten" for a gluten-free label is likely the one preferred by consumers.[96]

IV. REVIEWING THE GLUTEN-FREE SCIENCE: THE AMERICAN APPROACH

As noted above, the 2004 FALCPA[97] mandated FDA adopt final rules "to define, and permit the use of, the term 'gluten-free' on the labeling of foods."[98] While that deadline has passed, FDA has made significant strides in fulfilling the mandate. However, the delay in the rulemaking raises important questions about the appropriate balance between consumer protection and scientific evidence. Based on the growing demand for gluten-free products and the Congressional mandate to develope a definition of the term, one could ask whether FDA should have quickly adopted the Codes standard as an interim measure that would have been harmonized with international standards. Then, FDA could have revised the interim measure as scientific advances are made in the treatment of CD and testing of gluten. Another key question is whether FDA will restrict or qualify the use of the term "gluten-free," since the marketplace is already beginning to imply that this attribute may provide benefits beyond the management of CD and/or wheat allergy.

A. *The FALCPA*

The major thrust of the FALCPA was to require simplified food allergen labeling for major food allergens,[99] The following example illustrates the need for regulation to help CD patients find safe foods.

---

[94] *Id.* at 7.

[95] Australia New Zealand Food Standard Code, 1.2.8 (2003).

[96] *See supra* note 56, discussing citizen's petition to FDA requesting zero gluten for gluten-free product label use.

[97] FALPCA §201, 21 U.S.C. § 301 note, 343 note. *See generally* Laura E. Derr, When Food is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004, 61 Food & Drug L.J. 65 (2006).

[98] *Id.* at §202(6); 21 U.S.C. § 343 note.

[99] *Id.* at §202; 21 U.S.C. § 343 note; FALPCA § 203(c) amends the FDCA, 21 U.S.C. 321 (qq) by adding the term "major food allergen."

In late 2008, the *Chicago Tribune* investigated whether several Whole Foods products labeled "gluten-free" truly were.[100] The reported results were stunning: Wellshire Kids gluten-free products—primarily processed meat products like chicken bites and corn dogs—contained between 116 and 2,200 parts per million of gluten.[101] Initially, Whole Foods refused to remove the products. However, the *Tribune* reported that after its story ran, the company received complaints "including from those who thought 'gluten-free' meant zero-gluten."[102] Referring to the delay in removing products from shelves, the parent of a wheat allergic child who had an allergic reaction to the products said, "It's shameful that it wasn't done sooner because they were knowingly putting customers in jeopardy."[103]

By contrast, in August 2009 a gluten-free product manufacturer, Van's, voluntarily recalled its gluten-free and wheat-free pancakes (labeled with those terms) because they contained gluten. Van's press release acknowledged the special responsibility it felt towards its consumers who rely on its label to eat safely.[104] Yet, since recalls are voluntary, whether and how quickly a product is recalled depends on corporate ethics. A regulation can simplify the recall decision by informing the corporate decision with uniform standards.

B. *The FDA Proceedings*

FDA's gluten-free rulemaking proceedings have been thorough and all-inclusive. In this sense, FDA has developed an excellent public record of the gluten-free food industry, medical literature and treatment options, scientific testing for gluten methods, and, of course, consumer concerns. In another sense, these proceedings have been lengthy. Five years may not be long for a federal rulemaking proceeding, but is likely perceived as an eternity for those who in 2004 urged Congress to pass the FALCPA. Additionally, there is no anticipated adoption date.[105] The following sections summarize three key portions of FDA's action to date: the Threshold Working Group process; the public meetings; and the proposed rule.

---

[100] Sam Roe, *Whole Foods Pull "Gluten-free" Products from Shelves after Tribune Story*, Chicago Tribune, Dec. 31, 2008, http://www.chicagotribune.com/news/nationworld/chi-whole_foods-dec31,0,4055580.story.

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] Van's Voluntary Product Recall, *http://www.vansfoods.com/home/voluntary-product-recall* (last visited Dec. 23, 2009); *see also* Van's International Foods issues voluntarily product recall, Chicago Gluten-Free Food Examiner (Aug. 31, 2009) http://www.examiner.com/x-13312-Chicago-GlutenFree-Food-Examiner~y2009m8d31-Vans-International-Foods-issues-voluntary-product-recall (last visited Dec. 23, 2009).

[105] Email to author from Rhonda Kane, noting "As discussed on page 2803 of the FDA's proposed rule on gluten-free food labeling, the agency committed to conducting a safety assessment on gluten exposure in individuals with celiac disease. FDA has completed that assessment, which has undergone an expert peer review. FDA is now in the process of reviewing the comments of the peer reviewers to make whatever changes in the safety assessment are appropriate before its availability is announced in the *Federal Register* (FR). The agency expects to publish an FR notice in the near future to reopen the comment period on the proposed rule and to share the safety assessment. FDA will consider the comments received in response to this notice and on the proposed rule as well as the findings of the safety assessment and the other factors (i.e., ease of compliance and enforcement, stakeholder concerns, economics, trade issues and legal authorities) also mentioned in the proposal to develop a final rule. When the FR notice on the safety assessment is published, a link to it likely will be posted at FDA website http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/default.htm under the subheading "Gluten-Free;" therefore, interested parties may wish to check that website periodically for updates. The final rule will be published sometime after the comment period closes for the FR notice on the safety assessment and FDA has had a chance to review the public comments it receives. At the present time, FDA cannot predict the publishing date of the final rule." (July 16, 2009) (copy on file with author).

1. *Starting with Science: the Threshold Working Group*

As the lengthy Codex Standard's history illustrates, the threshold amount of gluten tolerated by CD patients has been the subject of both medical debate (the diagnosis and best treatment for patients) and testing methods debate (effective and accurate methods for detecting gluten). FDA's process continued these themes.[106]

In May 2005, FDA announced a meeting of the "Food Advisory Committee" (FAC), to be held in July of that year.[107] The FAC's principal task at this meeting was to evaluate the FDA's Center for Food Safety Nutrition (CFSAN) Threshold Working Group's draft report.[108] The Threshold Working Group was "an interdisciplinary group of scientists" from CFSAN.[109] The FAC's task was to determine whether the report was "scientifically sound in its analyses and approaches and adequately considers available relevant data on allergens and gluten."[110]

At its July 2005 meeting, the FAC received and conveyed many comments for the Working Group, most of which were incorporated or otherwise addressed in that Group's final report issued in March 2006.[111] At the outset, it is important to understand that the Working Group considered four different approaches to gluten standards. The approaches were: analytical methods-based approach,[112] the safety assessment-based approach,[113] the quantitative risk assessment-based approach,[114] and the statutorily-derived approach.[115] As a result, many of the comments addressed which analytical method was most appropriate for setting a gluten threshold for foods labeled "gluten-free."

For example, several industry association representatives urged FAC to avoid the analytical-methods based approach because it could result in a threshold that was lower than medically necessary for most with CD.[116] Industry comments also reflect that a zero tolerance standard is an "unnecessary and unachievable burden on the industry."[117]

Others spoke to scientific uncertainty surrounding CD, noting that "[t]he strict definition of a gluten-free diet remains controversial due to the lack of accurate

---

[106] FDA rulemaking addressed requests for gluten-free label regulation as early as 1993. At the time, FDA decided to allow the use of the term "when as used it is not false or misleading." It further indicated its willingness to consider more specific rules if "petitioned with sufficient information, including analytical methodology for food analysis." 58 Fed. Reg. 2850, 2864 (Jan. 6, 1993). As we now know, that analytical methodology remains an issue.

[107] 70 Fed. Reg. 29528 (May 23, 2005).

[108] *Id.*; *see also* Threshold Working Group, *supra* note 1.

[109] Food Advisory Committee, Notice of Meeting, 70 Fed. Reg. 35,258 (June 17, 2005).

[110] FDA Response to Pubic Comments on the Draft Report "Approaches to Establish Thresholds for Major Food Allergens and Gluten in Food" *available at* http://www.fda.gov/Food/LabelingNutrition/FoodAllergens.

[111] *Id.*

[112] An Analytic Methods-Based Approach establishes a "regulatory threshold' by using the sensitivity of the analytic method(s) that can be used to verify compliance to determine the threshold. Threshold Working Group, *supra* note 1, at III (D).

[113] *Id.* The Safety Assessment-Based Approach uses the degree of certainty and an assumption of negligible risk to assess public health issues and issues related to substances in food.

[114] *Id.* A Risk Assessment approach evaluates systematic, scientific examination of possible negative health effects from exposure to a hazard and decides its severity by 1) hazard identification, 2) exposure assessment, 3) hazard characterization, and 4) risk characterization.

[115] *Id.* The Statutorily Derived Approach establishes a threshold by extrapolating from an exemption established by Congress for another purpose.

[116] Threshold Working Group, *supra* note 1, at Table 1 at 1; 12.

[117] *Id.* (though it is not clear whether this comment was directed at food allergens, gluten, or both).

method [sic] to detect gluten in food products and the lack of scientific evidence of what constitutes a safe amount of gluten ingestion."[118] This comment prompted the response that labeling issues were outside the scope of the Threshold Working Group report—though these issues were raised again later in public meetings with FDA. Numerous other comments noted the lack of scientific evidence of "safe" gluten thresholds, which the final report addressed.

2. *Inviting Comments by Manufacturers, Scientists, and Consumers: Public Meetings*

In August of 2005, FDA convened a public meeting to gather the comments of three groups (manufacturers, scientists and consumers) on the gluten-free concept.[119] The industry perspective covered important topics such as how grains are cross-contaminated. Scientists focused on gluten testing methodology, while consumers spoke overwhelmingly in support of FDA defining "gluten-free." Among the questions on which FDA sought input were: how manufacturers were defining and certifying "gluten-free," production methods (including methods to avoid cross-contamination), and whether there was research data or findings on what consumers believed "gluten-free" meant.

Grain cross-contamination is a major issue for gluten-free products and, in particular oats. Cross-contamination begins in farm fields. For example, oats may be sown in a field where barley grew the year before.[120]Some barley seed may then grow with the oat crop which begins cross-contamination. The potential for oat cross-contamination continues at almost every stage as harvesting, storage, transportation, and packaging processes all pose the potential for gluten-free grains to come into contact with gluten-containing grains. As the North American Grain Millers' Association (Millers) representative explained, U.S. grain grading and inspection standards account for cross-contamination by permitting up to four percent of "admix" (foreign grains).[121]

From a manufacturer's perspective, grain testing is helpful to purity but still a developing technology. Though optical scanning and ELISA are used by millers, both have drawbacks. Optical scanning is a developing technology, while ELISA tests a small percentage of grain and may not be reliable for certifying whole shipments.[122] Finally, the Millers offered that "... . without a threshold, "gluten-free" means zero... . [and] [123][f]or the oat millers, zero is, frankly, not achievable both due to presence of gluten in oats and because of the small presence of other gluten-bearing grains."

Bob's Red Mill (BRM), a manufacturer that for the past 10 years has been milling and retailing gluten-free products, discussed how its process is meeting CD consumers' needs.[124] Specifically, to avoid the cross-contamination issues discussed

---

[118] FDA Response to Pubic Comments on the Draft Report, *supra* note 113, at Consumer Association Comment.

[119] Gluten-free Labeling of Foods, Public Meeting, 70 Fed. Reg. 41,356 (Jul. 19, 2005); Tr. Of Public Meeting on Gluten-free Food Labeling (Aug. 19, 2005) [hereinafter Tr. of Public Meeting].

[120] Comments of Jane DeMarchi, Coordinator of Technical and Export Programs, North American Millers' Association, Tr. of Public Meeting, *supra* note 119, at 48.

[121] *Id.* at 50-51.

[122] *Id.* at 56-57.

[123] *Id.* at 58.

[124] Comments of Dennis Gilliam, Executive Vice President, Bob's Red Mill Natural Foods, Tr. of Public Meeting, *supra* note 119, at 68-69.

by the Millers, the company has stand-alone milling and packing rooms for its gluten-free products.

The BRM representative explained the company's extensive procedures for gluten-free products. BRM begins with purchasing gluten-free grains from "specialty growers" who are familiar with how to avoid the cross-contamination described by the Millers. Dedicated machinery combines with frequent ELISA testing to ensure purity (BRM measured purity at 10 ppm).[125] BRM also maintains separate storage locations for finished products. Finally, the manufacturer noted that it interpreted the Canadian standard at the time to mean "zero"—but that this was an impossible measure given the limitations of the ELISA test. BRM's representative also noted the "zero" standard was undesirable "because there are no tests that take it down to zero. Beyond being impractical and impossible, it may ... eliminate so many foods if it were [taken] to zero."[126]

Finally, another dedicated gluten-free manufacturer, Miss Roben's, offered its view.[127] Keeping in mind that the testimony was five years ago, it illustrated the wide variety in gluten-free manufacturing and testing processes. Miss Roben's primary method of ensuring gluten-free products was to rely on a "dedicated sole source ingredient supplier, straight from the farm that makes their own product and does all aspects of the production."[128] At the time, Miss Roben's did not use ELISA testing, but planned to implement it later in 2005.

In the end, the manufacturers showed that gluten-free products require multiple methods to ensure their purity. All manufacturers use some combination of dedicated facilities, supplier certification and tracking, ELISA testing, and education of their employees and consumers to detect problems with these processes. The discussion ended by exploring the rigor of manufacturer testing compared to their reliance on supplier certification, with particular concerns about oats. Obviously, the manufacturers' statements illustrated their belief that they were taking the best possible precautions to ensure their products were suitable for consumers who need gluten-free products.

Next, scientists discussed various testing methodologies, with primary focus on ELISA . One scientist noted that while ELISA does detect wheat, barley and rye, it cannot distinguish between them. Therefore, a manufacturer would only know that the product was contaminated with gluten, but not by what or by how much.[129] Significantly, the scientist noted that the method could *not* detect oat prolamins. He also drew FDA's attention to Codex's temporary endorsement of ELISA testing (which was permanently endorsed in 2009, as noted above).

Next, the panel heard specific information about types of test kits available and their reliability.[130] In 2005, the bottom line was that there were many different manufacturers using slightly different tests. Threshold measuring capabilities were as sensitive as 3 ppm, but there were questions about the costs, reliability, and necessity of such measures.[131] This is a key issue that FDA continues to study. Given its complexity, it may be the main reason that final rules have not been adopted.

---

[125] *Id.* at 81.

[126] *Id.* at 83.

[127] Comments of Ms. Berger, Miss Roben's, Tr. of Public Meeting, *supra* note 119, at 86.

[128] *Id.* at 88, 97.

[129] Comments of Dr. William Hurkman, Tr. of Public Meeting, *supra* note 119, at 145-146.

[130] Comments of Dr. Yeung, Tr. of Public Meeting, *supra* note 119, at 155 - 174. (This summary cannot do justice to the scientific expertise offered by Dr. Yeung regarding the various commercial test kits, and readers are encouraged to review Dr. Yeung's complete testimony for a full description.)

[131] *Id.* at 160, 164, 179.

However, without including a consistent and reliable threshold testing methodology, the final rule would be functionally meaningless.

While the technical information regarding manufacturing and testing is fascinating, the consumer perspective cannot be overlooked. If consumers do not trust the gluten-free label, the regulatory effort will be wasted. The Celiac Sprue Association representative offered that its members wanted "gluten-free" to represent the absence of gluten.[132] Specifically, when its members were polled about the gluten threshold, the representative summarized their response as "don't tell me the parts per million, I want it absent of wheat, barley, rye, and oats. I don't know what these numbers mean."[133] To illustrate the group's concerns, the representative offered the specific example of a "gluten-free" gravy mix that tested at 3,630 ppm.[134]

Continuing the consumer theme of plain language, easy-to-read, and reliable gluten-free labels, a nutritionist with the Celiac Disease Center offered a diet survey to help the panel understand how CD consumers make purchases.[135] She noted that the CD patients rely on gluten-free packaging to find safe foods. She also noted, with concern, that CD patients in the study tended to over-consume snack foods, because those foods were clearly labeled "gluten-free." An additional concern was that even naturally gluten-free products, such as canned tomatoes, gain some market advantage with CD patients if the label says "gluten-free."[136] To summarize, consumers and their representative groups spoke about the need for consistent labels, but disagreed on whether oats should be included in the "gluten-free" definition. Based on the data and information generated by the Threshold Working Group and the public meetings, FDA next released its proposed rule.

3. *The Proposed Rule*

On January 23, 2007, FDA released its proposed rule for gluten-free labeling of food.[137] The rule proposes definitions of "prohibited grains," "gluten," and "gluten-free."[138] These definitions would form the basis for evaluating whether a gluten-free food was misbranded.[139]

First, "prohibited grains" is proposed to mean "any of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye) that have not been processed to remove gluten: 1) Wheat, meaning any species belonging to the genus *Triticum*; 2) rye, meaning any species belonging to the genus *Secale*; and 3) barley, meaning any species belonging to the genus *Hordeum*."[140] Next, the proposed definition of "gluten" is "the proteins that naturally occur in prohibited grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins)."[141] Finally, a "gluten-free" claim will mean that the product does not contain any of the following:

---

[132] Comments of Ms. Mary Schluckebier, Executive Director, Celiac Sprue Association, Tr. of Public Meeting, *supra* note 119, at 183.

[133] *Id.* at 193.

[134] *Id.* at 194-195.

[135] Comments of Ann Lee, Nutritionist, Celiac Disease Center, Tr. of Public Meeting, *supra* note 119, at 215.

[136] *Id.* at 222.

[137] Gluten-free Food Labeling, Proposed Rule, 72 Fed.Reg. 2795 (Jan. 23, 2007).

[138] 72 Fed. Reg. at 2801-2802.

[139] *Id.*

[140] *Id.*

[141] *Id.*

> 1) an ingredient that is a prohibited grain; 2) an ingredient that is derived from a prohibited grain and that has not been processed to remove gluten; 3) an ingredient that is derived from a prohibited grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food (i.e., 20 micrograms or more gluten per gram of food); or 4) or 20 ppm or more gluten.[142]

FDA includes examples such as farina, wheat germ, wheat bran, barley malt extract, and malt vinegar as substances that would be prohibited in a gluten-free product. By contrast, modified food starch and wheat starch, because they are processed to remove gluten, could be included in a gluten-free product.[143] However, all gluten-free foods, regardless of whether they contain specially processed grains, must contain no more than 20 ppm gluten—the same standard adopted by Codex and the EU[144]

Based on these definitions, FDA analyzes seven possible implementation options in its proposal. The first, "do nothing," is included only as a threshold and will not be discussed further here. The second option allows gluten-free labels on products not containing "prohibited grains," while also requiring qualifying language on inherently gluten-free foods.[145] The third option contemplates use of the "gluten-free" claim on foods at a threshold greater than 20 ppm.[146] The fourth option allows the "gluten-free" claim only when the food does not contain 20 ppm or more gluten, regardless of whether it contains prohibited grains.[147] The fifth option would follow option two but eliminate requirements for wording on inherently gluten-free foods.[148] The sixth option follows option two but adds a "very low gluten" category.[149] Finally, option seven also follows option two but adds oats to the list of prohibited grains.[150]

The proposed rule's content is consistent with FDA's current requirements for use of the term "free" in other food labeling requirements. The proposed rule notes that although FDA has never set a maximum permissible level of gluten, it generally regarded a claim "that a food is 'free' of a substance as false or misleading if the food actually contains the substance."[151] Additionally, FDA notes that consumers can generally expect a label that uses the word "free" to mean that the food does not contain the named substance, e.g., salt, sugar, fat, or cholesterol, though "free" rules generally set minimum thresholds.[152] For example, "fat free" actually means not more than .5 grams of fat per serving.[153] However, implementation option two protects consumers by barring prohibited grains from gluten free foods. The rules means that a product that contains wheat (a prohibited grain) cannot be labeled gluten-free, even if it meets the 20 ppm standard. Consumers would then be able to easily verify gluten-free claims by scanning the ingredient list to make sure a prohibited grain was not listed.

---

[142] *Id.*
[143] *Id.*
[144] *Id.*
[145] *Id.* at 2805.
[146] *Id.* at 2806.
[147] *Id.* at 2811.
[148] *Id.*
[149] *Id.*
[150] *Id.* at 2812.
[151] *Id.* at 2805.
[152] 21 C.F.R. §101.60(b)(2009)("calorie free"); §101.60(e)("sugar free"); §101.61(b)("sodium free"); §101.62(b)("fat free"); §101.62(d)("cholesterol free").
[153] 21 C.F.R. §101.62(b)(i).

FDA's proposed rule also addresses the meaning of "free" in cases where the product is inherently gluten-free. Drawing parallels between foods that are naturally fat or salt free, the gluten-free rule would also render misbranded any inherently gluten-free foods that are labeled "gluten-free" without use of a disclaimer.[154] For example, in order to label milk "gluten-free" the product would have to meet two requirements: first, it must contain no more than 20 ppm gluten, and 2) it must indicate all milk is gluten-free with phrases like "milk, a gluten-free food" or "all milk is gluten-free."[155] This rule prevents manufacturers from gaining an unfair competitive advantage from the "gluten-free" claim where all similar products share the same attribute.

Notably, the FDA definition of "prohibited grain" excludes oats, except as noted in implementation option seven.[156] FDA did conclude "there is no general agreement among experts about the extent to which oats present a hazard for individuals with celiac disease."[157] Nevertheless, FDA decided to exclude oats from the definition of a prohibited grain, giving weight to the National Institutes of Health CD statement and the American Dietetic Association's support of allowing oats. However, because there is no scientific agreement about the dangers of oats to those suffering from CD, the proposed rule seeks input of the best treatment of oats.

In the proposed rule, FDA tentatively endorsed ELISA-based methods as the most reliable for detecting gluten.[158] This decision rests on published literature that the test is reliable. ELISA-based methods are also favored by the Codex and EU standards. The one drawback to ELISA-based methods is that other emerging tests may be more sensitive. In fact, FDA notes that methods capable of detecting as little as 5 ppm gluten are being developed. However, other literature questions whether the development of such sensitive testing is necessary because recent research shows the 20 ppm standard is tolerable for those with CD. As a result of the questions surrounding testing methodology, FDA continues its scientific review of threshold science and testing methodology.[159]

To summarize, FDA's proposed rule sets the gluten-free threshold as not more than 20 ppm. The most likely implementation (option two) takes a two-step approach: it bars prohibited grains from gluten free foods and requires specially processed prohibited grains to contain no more than 20 ppm. Though the FALCPA did not require threshold amounts, FDA likely chose this path to be consistent with other standards (both existing FDA regulation and Codex). This approach is also consistent with FDA's historical approach to misbranded products. Similarly, an inherently gluten-free food that is labeled "gluten-free" without noting that all foods of that type are gluten-free would be misbranded. Finally, the proposed rule will further follow the Codex and EU approach by permitting oats to bear gluten-free labels but without any special testing requirements.

Where does the proposal leave consumers? First, those with CD—whom Congress intended to help—should be pleased with the thoroughness of the FDA proposal. The agency has thoughtfully reviewed the current scientific literature and recommendations as well as the current gluten testing methods. As a result, compared to other gluten-free regulations around the world, the American process is likely the most anchored in science. However, for those with food allergy or autism, the gluten-free label may be rendered unreliable. If this is the case, FDA can anticipate that

[154] *Id.* at 2802.
[155] *Id.*
[156] *Id.*
[157] *Id.* at 2797.
[158] *Id.*
[159] *See* Kane email, *supra* note 105.

as science explores thresholds for people with life-threatening allergy to wheat, or the relationship between autism and wheat, additional regulation may be needed.

As with other "free" labels, if the CD consumer assumes that "free" means "zero" and consumes a number of "free" products throughout the day, the consumer may consume medically significant amounts of gluten. Additionally, it is important to understand that a gluten threshold will mean that gluten may be present in "gluten-free" products. This is likely the case with products now on the market. However, in the absence of a rule, consumers can only research individual manufacturer's practices. With a final rule, consumers will gain a clear definition of "gluten-free," even if that definition does not mean "not containing gluten." CD patients who are sensitive to less than 20 ppm gluten, however, will have very few options if they rely solely on the package's label. Those consumers will have to continue to research food ingredients with manufacturers. This may also be true of other consumers such as allergy patients who are trying to avoid wheat (at any level) or autistic consumers who have little to no information on why a gluten-free diet may improve their condition.

V. OPPORTUNITIES FOR LABEL CLARITY AND COMMUNICATING SCIENTIFIC UNCERTAINTY

When law requires the definition of a food label term, it is always helpful to ask: What is the best way to communicate the term's meaning to consumers? From a consumer perspective, Australia and New Zealand might seem to take the most common sense approach to defining "gluten-free" because consumers understand "free" to mean the product does not contain a particular substance. A good example of how this is not always true is the regulatory definition of "fat-free."[160] However, a determination of whether a food is "free" of any particular substance depends on how it is tested and the sensitivity of the test to the substance. Therefore, thresholds tend to be the norm in food regulation.

Gluten-free labels present an opportunity for manufacturers and FDA to improve how consumers understand the meaning of such terms.[161] Consumer trust should be a paramount concern because without it the labels are meaningless to consumers. For example, consumers who do not get enough information about what "gluten-free" means will likely view the term as a marketing ploy that does not convey safety information. Similarly, CD patients who cannot tolerate 20 ppm may develop a similar distrust if gluten-free products make them ill. Labels that more fully describe the science behind the claim can address both scenarios.

A. *Information Disclosure Precautionary Principle: Communicating the Dynamic*

There is scientific certainty that a gluten-free diet improves the symptoms of CD.[162] However, there is not scientific certainty concerning the threshold amount of

---

[160] 21 C.F.R. § 101.62 (b)(1)(2009).

[161] Readers should understand that FDA is researching consumer perception of gluten-free labels. Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 9822 (Mar. 6, 2009); 74 Fed. Reg. 59188 (Nov. 17, 2009).

[162] *E.g.*, NIH, Consensus Development on Celiac Disease Conference Statement, June 28-30, 2004 *available at* http://consensus.nih.gov/2004/2004CeliacDisease118html.htm.

gluten that a person with CD can tolerate.[163] This uncertainty warrants the analysis of gluten-free label regulation with the "precautionary principle."[164] Though it has many forms, at base, the precautionary principle permits government regulation for protection of public health, even where human risk is not established.[165] Here, the precautionary principle is not necessary to protect *general* public health, but its application could be helpful to those consumers who rely on the gluten-free label to address a *specific* health condition.[166]

The precautionary principle need not rely upon regulation alone. In fact, at its most effective, the principle also draws on government funding and promotion of scientific research to resolve risk.[167] This facet of the precautionary principle is already at work because Congress and FDA have allocated funds to CD research. This initiative recognizes that scientific uncertainty impedes manufacturers' ability to produce gluten-free foods that CD patients can consume safely.[168] The goal of the research is to learn more about CD, as well as possible treatment and cure.[169] To date, much of that research has focused on a key issue: threshold gluten tolerance.[170] Scientific accuracy and the reliability of the safety threshold is an essential precursor to useful regulation.

B. *Thresholds and Norms*

As noted earlier, some consumers demand a zero-tolerance rule for gluten-free labels. However, there is a legitimate argument that science does not yet know true zero. For example, what testing today reveals as zero gluten in ppm, testing tomorrow may reveal as gluten in parts per billion (ppb).[171] One could argue that a ppb detection test is unnecessary because those suffering from CD are not sensitized to such minute amounts. On the other hand, this is an example of the limits of current scientific knowledge. Perhaps minute amounts of gluten *do* have some impact that science is yet to discover. The question is how to regulate in the meantime.

---

[163] *Compare* Catassi, *supra* note 11 at 165 ("The threshold of 20 ppm keeps the intake of gluten from 'special celiac food' well below the amount of 50 mg/d, which allows a safety margin for the variable gluten sensitivity and habits of patients) *with* Pekka Colin, Letter to the Editor, *A Safe gluten threshold for patients with celiac disease: some patients are more tolerant than others*, 86 AM. J. CLINICAL NUTRITION 260 (2007) ("Whether the safe limit of gluten contamination should be 0, 20, 50, or 100 ppm remains to be seen. As the study by Catassi ... showed, celiac disease patients respond individually to small amounts of gluten.")

[164] Sunstein, *supra* note 19, at 1014.

[165] *Id.*

[166] For an interesting and informative opinion about the precautionary principle, scientific evidence, and public health *see* David Kriebel and Joel Tickner, *Reenergizing Public Health through Precaution*, 91 AM. J. OF PUB. HEALTH 1351, 1353 (2001) (noting that "[t]he precautionary principle represents a call to reevaluate the ways in which science informs policy, and in particular the ways in which scientific uncertainty should be handled" [and that] "more and better investigation and communication of uncertainties (what we know, what we do not know, what we cannot know) in study results will assist a more open decision-making process.")

[167] VAN DER MEULEN, *supra* note 19, at 271.

[168] FALCPA § 208; 42 U.S.C. §243 note (2006).

[169] *Id.*

[170] *E.g.* Catassi, *supra* note 163.

[171] Hossam M. Nassef, et al., *Electrochemical Immunosensor for Detection of Celiac Disease Toxic Gliadin in Foodstuff*, 80 ANALYTICAL CHEM. 9265, 9266 (2008) (reporting a new testing method capable of ppb with accuracy comparable to ELISA); *see also* Jefferson Adams, *Rapid Gluten Detection Test for Food Products Promises Better Product Labeling, Easier Gluten-free Shopping*, (Nov. 19, 2008) http://www.celiac.com/articles/21695/Rapid-Gluten-Detection (last visited Dec. 29, 2009) (reporting on meaning of Nassaf research for those with CD).

Here, the question of a regulation's norm is relevant. If a regulation incorporates the scientific agreement at the time it is drafted, it is static.[172] A static regulation, such as one that defines "gluten-free" as less than 20 ppm, provides legal certainty, which is good for industry and for consumers. A static regulation is, however, subject to scientific irrelevance. If the threshold's accuracy is revised, the rule becomes outdated. By contrast, a rule that evolves with scientific research is dynamic and allows society to keep pace with the best advice to treat CD.[173] However, the price of scientific relevance is legal uncertainty, which would likely hinder or even discourage manufacturers from investing in gluten-free product lines.[174]

The other norm, and the one frequently implied by "free" or "zero" language on labels, is zero tolerance.[175] This norm, while it may appear to be fixed or static, is not. It evolves with scientific technology to measure zero.[176] For example, the more sensitive the gluten test, the more acute its measure of "zero." As a result, zero is actually a dynamic concept based on testing accuracy. Additionally, as testing becomes more sensitive, its usefulness as a safety predictor may become irrelevant if science reveals the safe threshold is well above the "zero" norm. In a practical sense, the zero norm provides neither legal certainty nor scientific relevance. Thus, it may be the least desirable food law norm for science-based regulation.[177]

From a consumer perspective, the plain language meaning of the term "free" means the product does not contain the substance, which may cause consumer confusion. To consumers, a gluten-free label indicates the product contains no gluten—when in fact, it may contain gluten below levels the tests can detect or up to 20 ppm. As a result, the use of the "gluten-free" and the proposed rule creates a need to educate consumers seeking gluten-free products about the term's meaning. Such education could occur through medical care providers. But at a minimum, key information should accompany the "gluten-free" claims, perhaps as a label disclaimer. Other analysts have labeled this the "information disclosure precautionary principle" because "in the face of uncertainty, those who subject people to potential risks must disclose relevant information to those so subjected."[178] Applied to gluten-free labels, the analysis is then that a safe threshold amount of gluten for CD patients is scientifically uncertain. As a result, FDA through its 20 ppm standard does expose some with CD to risk and, therefore, those risks should be disclosed on the label.

C. *Health Claim Parallels*

The FALCPA did not intend "gluten-free" to be regulated as a health claim.[179] A health claim is any claim "made on the label ... that expressly or by implication ...

---

[172] VAN DER MEULEN *supra* note 19, at 272.

[173] *Id.* at 272-273.

[174] This is not a concern to take lightly. For example, the food industry's reaction to an earlier attempt at allergen labeling requiring gluten declaration resulted in "industry demand[s] that this provision be removed due to concerns about liability given the dearth of scientific knowledge about gluten tolerance levels." Derr, *supra* note 97, at 145.

[175] VAN DER MEULEN *supra* note 19, at 273.

[176] *E.g.* Belen Moron, et. al. *Sensitive Detection of cereal fractions that are toxic to celiac disease patients by using monoclonal antibodies to a main immunogenic wheat peptide* 87 AM. J. CLINICAL NUTRITION 405, 412 (discussing the evolution in gluten testing methodology and noting an emerging test, G12 MoAb, may be particularly well suited to studying oat avenins).

[177] VAN DER MEULEN, *supra* note 19, at 272.

[178] Sunstein, *supra* note 19, at 1015 (offering the conundrum of labeling of GMOs as an example of an "information disclosure precautionary principle").

[179] *See supra* note 12 and accompanying text.

characterizes the relationship of any substance to a disease or health-related condition,"[180] Even though the legislative history clearly shows Congress did not mean for "gluten-free" to fall within the legal definition of health claim, the term still expresses a conclusion about the relationship between the food and a significant health claims. Additionally, consumers who are not CD patients may wonder if there is a health benefit to "gluten-free." As a result, some of the FDA's health claim regulatory history can help anticipate consumer reaction to the "gluten-free" label.

The Consumer Health Information for Better Nutrition Initiative, prompted in part by *Pearson v. Shalala*,[181] recognized that "[i]n order for consumers to make healthy dietary choices across product categories, consistency in health messages is paramount."[182] This sentiment is certainly applicable to those seeking foods appropriate for a gluten-free diet. Yet, the Initiative has shown that it is not easy to consistently convey health information, and in particular, the strength of science information.[183] In fact, 78 percent of those surveyed by FDA as part of its assessment of health claim efficacy could not correctly identify the certainty of the science based on the disclaimer language and a letter grade.[184] The study reveals that "evidence to date suggests that [label claims have] had limited success and in fact may be misleading to consumers with regard to understanding scientific evidence as well as overall diet choices."[185] Because CD patients rely on gluten-free products for their health, it is paramount that they receive accurate information about a gluten-free product. The reality for some CD patients is that it will be risky to purchase gluten-free products. Given this risk, as part of its gluten-free label efficacy research FDA should consider whether disclaimers on gluten-free packaging are worthwhile.[186]

The disclaimer could be simple. Any product labeled gluten-free product could simply state on its label: "This product contains no more than 20 ppm gluten, verified using FDA-approved testing methods." As approved testing methodology improved, the threshold disclaimer could become lower if warranted. The addition of such a disclaimer to "gluten-free" helps make the norm more dynamic than static. For example, if science links a gluten-free diet to improving autism but at a lower threshold, such as 10 ppm, then the disclaimer could help consumers find the appropriate products. Such an information disclosure would allow consumers to take the appropriate precautions with their diets. Furthermore, it would allow individuals to assess risk based on their own sensitivity. Without such disclosure, uninformed consumers will likely rely on the label to assume that they are not consuming any gluten.

D. *Concluding Considerations*

Regulating gluten-free labels provides one example of how scientific uncertainty, coupled with good government intention to protect the public health, presents regulatory challenges and opportunities. The primary challenge is to regulate in a way that is dynamic enough to communicate the right information to consumers,

[180] 21 C.F.R. §101.14(a)(1) (2009); *see* 21 U.S.C. § 343 (r)(3) (2006).

[181] 164 F.3d 650 (D.C. Cir. 1999) (holding the First Amendment does not permit FDA to reject potentially misleading health claims unless the FDA reasonably finds that a disclaimer would not eliminate the potential for consumer deception).

[182] Consumer Health Information Task Force Report, *supra* note 15, at 4.

[183] *E.g.*, Derby and Levy, *supra* note 17.

[184] Clare Hasler, *Health Claims in the United States: An Aid to the Public or a Source of Confusion*, J. OF NUTRITION, S1216, S1218 (further analyzing FDA's working paper from CFSAN, *Experimental Study of Health Claims on Food Packages, report* (May 2007)).

[185] *Id.* at S1219.

[186] Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 9822 (Mar. 6, 2009).

but static enough to provide some baseline legal definition for manufacturers to follow. The information disclosure precautionary principle is one way to meet this challenge. The opportunity is to view labels not as a distilled representation of science, but as a communication tool that helps consumers find appropriate products that the consumer understands. A uniform application of the information disclosure precautionary principle could also help other "zero" or "free" labels include more complete consumer information.

Finally, FDA should also consider how to regulate health claims that might accompany, or be implied by, gluten-free labels. Given CD patients are not the only market for gluten-free products, this is a serious issue. The purpose of the FALCPA was to address CD, not autism or other disorders that the popular press claims a gluten-free diet will improve. The question is whether the definition of "gluten-free" or additional requirements for information disclosure should somehow indicate to consumers that the use of the term is targeted to those with CD, but not others. The "significant scientific agreement"[187] or support of authoritative federal scientific bodies[188] simply does not exist for a gluten-free diet outside of CD. Therefore, any label implication other than for use by CD patients is inappropriate.

FDA has done its job of reviewing the CD science. What remains to explore is consumer interaction with the gluten-free label. The label will likely be susceptible to consumer misunderstanding unless it conveys additional information concerning the meaning of gluten-free. At best, more consumers may find products that they can tolerate. At worst, consumers who will not benefit from "gluten-free" will pay a price premium for no reason. A disclaimer may not be a perfect answer, but it will likely reduce the potential for consumer confusion. This is important for the millions of CD patients who rely on labels for their health and well-being.

[187] 21 U.S.C. § 343(r)(3)(B)(i)(2006).

[188] The Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 303 and 304, 21 U.S.C. § 403(r)(3) and (2)(2006) (permitting published, authoritative statements from NIH or CDC to form the basis of manufacturer's health claim).