DIFFERENCES IN RESPONSE BY THE FEDERAL AND STATE GOVERNMENTS TO THE NEEDS OF INDIVIDUALS WITH CELIAC DISEASE

BY: JASON JANOSKI

APRIL 2010

PREPARED AS AN ACADEMIC REQUIREMENT FOR THE AGRICULTURAL LAW COURSE AT THE PENNSYLVANIA STATE UNIVERSITY'S DICKINSON SCHOOL OF LAW

SPRING SEMESTER 2010

The work product contained in this paper is entirely that of the student author.

Overview

Celiac Disease is a chronic intolerance to gluten that triggers autoimmune reactions in the digestive system.[1] A comprehensive medical study completed in 2003 estimates that Celiac Disease affects two million Americans.[2] For individuals with Celiac Disease, the most effective treatment is prevention, which requires a diet free from gluten.[3] Gluten, a protein found in grains such as wheat, rye and barley, is present in many processed foods and also many non-food items such as medicines, cosmetics and vitamins.[4]

Prodded in part by the increasingly organized and politically active Celiac community, the United States Congress declared a need for nationally consistent definitions and regulations regarding the use of gluten-free labeling on food packaging. In 2004, with the passage of the Food Allergen Labeling and Consumer Protection Act (FALCPA), Congress ordered that the FDA had two years to create a proposed rule for regulating the term gluten-free in food packaging.[5] Congress required that the FDA establish a final rule within four years of the Act's passage.[6]

---

[1] Mukadder Ayşe Selimoğlu, et al., *Celiac Disease: Prevention and Treatment*, 44 J. CLINICAL GASTROENTOLOGY 4, 4 (2010).

[2] Alessio Fasano, et al., *Prevalence of Celiac Disease in At-Risk and Not-At-Risk Groups in the United States*, 163 ARCHIVES OF INTERNAL MED. 286, 286 (2003).

[3] Selimoğlu et al., *supra* note 1.

[4] National Digestive Diseases Information Clearinghouse, Celiac Disease, http://digestive.niddk.nih.gov/ddiseases/pubs/celiac (last visited Apr. 12, 2010).

[5] 21 U.S.C.A. §343 (2004).

[6] *Id.*

The FDA already has regulations in place that govern the use of the nutrient claim "free" in food packaging. One regulation regards the necessary relationship between a type of food and the nutrient at issue.[7] Generally, a food cannot be called "free" of something unless the type of food, in its natural state, possesses the nutrient and it must be processed to remove the nutrient.[8] The FDA also has nutrient-specific requirements for the threshold levels necessary for products to bear claims such as "free," "low," and "reduced."[9] Though the FDA has no specific requirement for using the term gluten-free, it has suggested, for the time being, that the term "can be used in the labeling of foods, provided that when such claim is used, it is truthful and not misleading."[10]

The FDA laboriously proceeded with its directive to establish a regulatory labeling scheme for the term gluten-free. It held hearings, solicited comments, recorded

---

[7] The FDA is concerned, for example, that consumers would be misled by a producer labeling its product as "fat-free" when all varieties of that product are "fat-free." The relevant portion of the law is as follows:

> (e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").
>
> (2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

Food Labeling; Nutrient Content Claims - General Provisions, 63 Fed. Reg. 26,978, 26,980 (May 15, 1998) (to be codified at 21 C.F.R. § 101.13).

[8] 21 C.F.R. § 101.13 (e)(1),(2).

[9] U.S. Food and Drug Administration, Appendix A: Definitions of Nutrient Content Claims, *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064911.htm (last visited Apr. 21, 2010).

[10] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,799 (Jan. 23, 2007).

expert testimony, and conducted independent research and analysis. The FDA came up with a proposed rule in 2007.[11] The FDA has determined that its research thus far has been inadequate. It recently commissioned additional studies and has yet, as of April, 2010, to implement a final rule.

With the lack of food-labeling uniformity, individuals with Celiac Disease have to use themselves as test subjects, trying one gluten-free food at a time and hoping that they will not get sick. Also, absent other regulations, food producers must use careful judgment when labeling foods gluten-free, guiding themselves by the vague legal directive to not be false or misleading.

When individuals with Celiac Disease in North Carolina began getting sick from allegedly eating products that were labeled gluten-free, the state immediately acted. Though the food retailer allegedly acted with intent to deceive, something that a clear rule by the FDA would still be unlikely to stop, the story would be quite similar if the retailer had negligently determined that his products were gluten-free because of an absence of clear guidelines.

The federal government has had six years from the enactment of FALCPA in 2004 to implement a rule. The state of North Carolina received complaints and within two months it had filed charges and secured a preliminary injunction prohibiting the defendant from selling any more bread labeled as gluten-free. Food safety needs quick attention and agile action. Where should Americans place their trust and resources in order to best ensure their safety?

---

[11] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795 (Jan. 23, 2007).

I. Celiac Disease

Celiac Disease, also known as celiac sprue and gluten-sensitive enteropathy,[12] is a permanent intolerance to the ingestion of gluten.[13] Gluten triggers the atrophy and flattening of the villi in the small intestine, resulting in, among other things, inadequate digestion and absorption of nutrients.[14]

A. Gluten.

The FDA has found that the term "gluten" has no single definition, but rather the definition differs based on the context.[15] The technical meaning of the word is "a specific complex of proteins that forms when wheat flour is mixed with a liquid and physically manipulated, such as in the kneading of bread."[16] However, proteins in other grains have also been found harmful to individuals with Celiac Disease.[17] Therefore, when used in discussions about Celiac Disease, the term "gluten" is meant to include gluten in wheat as well as the proteins found in rye, barley, any hybrids of these grains, and possibly oats.[18]

---

[12] *Id.* at 2,796.

[13] Howard E. Bostwick, et al., *Celiac Disease Presenting With Microcephaly*, 138 J. PEDIATRICS 589, 589 (2001).

[14] Michella M.P. Kolsteren, MA et al., *Health-Related Quality of Life in Children With Celiac Disease*, 138 J. PEDIATRICS 593, 593 (2001).

[15] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,797 (Jan. 23, 2007).

[16] *Id.*

[17] *Id.*

[18] *Id.*; *See also*, MayoClinic.com, Celiac Disease: Treatments and Drugs, *available at* http://www.mayoclinic.com/health/celiac-disease/DS00319/DSECTION=treatments-and-drugs (last visited Apr. 24, 2010).

Other cereal grains differ in protein structure from the grains previously listed and they are believed to pose few problems to individuals with Celiac Disease.[19] The most common of the celiac-safe grains include: rice, wild rice, corn, millet, buckwheat, and sorghum.[20]

Regarding oats, it should be noted that there is no consensus among medical experts as to the threat that oats pose to individuals with Celiac Disease. Though the studies generally have been inconclusive and contradictory, it seems that the older studies are more likely to suggest oats are harmful. While some recent studies have found little to no symptomatic increase in celiac sufferers after consumption of oats, oats are still potentially comingled with other grains during production and transport, and it is advised that each individual with Celiac Disease attempt to introduce oats into their diet only when they are asymptomatic.[21]

B. Celiac Disease: Symptoms and Clinical Manifestations.

Celiac Disease is both an immune-mediated and autoimmune disease.[22] Immune-mediated diseases are those in which the immune system behaves abnormally. Autoimmune diseases are diseases in which the immune system actually recognizes part of the self as foreign and respond against the self.[23] In individuals with Celiac Disease,

---

[19] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,797 (Jan. 23, 2007).

[20] *Id.*

[21] *Id.* at 2,798.

[22] Selimoğlu et al., *supra* note 1.

[23] National Institute of Health: MediPlus, Autoimmune Diseases, *available at* http://www.nlm.nih.gov/medlineplus/autoimmunediseases.html (last visited Apr. 14, 2010).

"the consumption of gluten stimulates the production of antibodies and inflammatory cells, resulting in an abnormal immune response, which damages the tiny, fingerlike protrusions called 'villi' that line the small intestine and function to absorb nutrients from food."[24]

Villi, small projections, and even smaller projections called microvilli, increase the surface area of the small intestine, allowing for greater absorption of fats and nutrients.[25] For individuals with Celiac Disease, dietary exposure to gluten flattens and damages the intestinal villi.[26] Continued exposure can destroy the villi.[27]

The disease manifests itself in many ways. Digestive symptoms are more common in children and infants, but can also be found in adults.[28] These symptoms include: abdominal bloating, cramping, and pain; chronic diarrhea; vomiting; constipation; pale, foul-smelling, or fatty stool; and weight loss resulting from malabsorption of nutrients.[29] If the malabsorption of nutrients remains chronic and

---

[24] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,797 (Jan. 23, 2007).

[25] Merck, Small Intestine, *available at* http://www.merck.com/mmhe/sec09/ch118/ch118d.html (last visited Apr. 20, 2010).

[26] Bostwick et al., *supra* note 10.

[27] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,797 (Jan. 23, 2007).

[28] National Digestive Diseases Information Clearinghouse, *supra* note 4.

[29] *Id.*; National Institute for Health, *supra* note 20.

untreated, children are especially vulnerable to delayed growth, short stature, delayed puberty, dental problems, and a failure to thrive in infants.[30]

For adults, common symptoms include: anemia, fatigue, bone or joint pain, arthritis, bone loss or osteoporosis, depression or anxiety, tingling numbness in the hands and feet, seizures, missed menstrual periods, infertility or recurrent miscarriage, canker sores inside the mouth, and an itchy skin rash called dermatitis herpetiformis.[31]

In both adults and children, the chronic malnutrition can result in osteoporosis, liver disease, tooth decay and loss, and intestinal cancer.

Celiac Disease has no cure. After ingestion of gluten, little can be done, other than the passage of time, to mitigate the effects of the ingestion. The most effective treatment is prevention: avoiding the ingestion of any gluten proteins.[32] The FDA has found that "over time, strictly avoiding consumption of all sources of gluten can resolve the symptoms, mitigate and possibly reverse the damage, and reduce the associated health risks of Celiac Disease."[33]

C. The Prevalence of Celiac Disease in the United States.

---

[30] National Digestive Diseases Information Clearinghouse, *supra* note 4.

[31] National Digestive Diseases Information Clearinghouse, *supra* note 4; Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,797 (Jan. 23, 2007).

[32] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,796 (Jan. 23, 2007).

[33] *Id.* at 2,797.

An estimated 1 in 133 Americans suffers from Celiac Disease.[34] Some estimates place the number of Americans with the disease at 3 million.[35] The estimated number of people with Celiac Disease is roughly equal to the number of people living in Nevada.[36] The prevalence and seriousness of Celiac Disease has led state governments and the federal government to seek ways to help individuals with Celiac Disease protect themselves from ingesting gluten.

D. Development of the Celiac Community.

In the last decade, individuals with Celiac Disease have used the internet to connect with others who share their affliction. Dozens of organizations, involving both experts and the general public, can now be found on the world-wide-web.[37] The Celiac community has taken advantage of available communication tools like web logging and real-time chatting to assist in their sharing of topics such as food advice, doctor recommendations, and general support. The Celiac community was largely responsible for the inclusion of a gluten-free labeling directive in FALCPA.[38]

---

[34] University of Chicago Celiac Disease Center, Celiac Disease Facts and Figures, *available at* http://www.celiacdisease.net/assets/pdf/CDCFactSheets%20FactsFigures%20v3.pdf (last visited Apr. 17, 2010).

[35] *Id.*

[36] *Id.*

[37] *See generally*, Celiac.com, *available at* http://www.celiac.com (last visited Apr. 20, 2010); Celiac Disease Foundation, *available at* http://www.celiac.org (last visited Apr. 21, 2010); The Savvy Celiac, *available at* http://www.thesavvyceliac.com (last visited Apr. 24, 2010); Celiac Central, *available at* http://www.celiaccentral.org (last visited Apr. 24, 2010); Celiac Today, *available at* http://www.celiactoday.com (last visited Apr. 24, 2010).

[38] Scott Adams, *Congress Hears First Ever Testimony on Celiac Disease*, CELIAC.COM, May 25, 2004, *available at* http://www.celiac.com/articles/783/1/Congress-Hears-First-Ever-Testimony-on-Celiac-Disease/Page1.html.

II. The Federal Response

A. Congress Acts.

On August 2, 2004, Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA).[39] The Act, focusing on food allergies at large, also specifically recognized the seriousness of Celiac Disease and the importance of individuals with Celiac Disease being able to actively limit their gluten intake.

In the Act, Congress gave the FDA two years to create a proposed rule on the definition of the term gluten-free and how it should be used in the labeling of food.[40] Congress further ordered that the FDA must enact a final rule regarding gluten-free food labeling by August 2, 2008.[41] As of April, 2010, the FDA has not implemented a final rule.

B. The FDA and the Search for a Proposed Rule.

---

[39] 21 U.S.C.A. §343 (2004).

[40] The Congressional directive states as follows:

> Not later than 2 years after the date of enactment of this Act [Aug. 2, 2004], the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term 'gluten-free' on the labeling of foods. Not later than 4 years after the date of enactment of this Act [Aug. 2, 2004], the Secretary shall issue a final rule to define, and permit use of, the term 'gluten-free' on the labeling of foods.

21 U.S.C.A. §343 (2004).

[41] *Id.*

Armed with its directive from Congress, the FDA began the process of drafting a proposed rule. Although there was no official regulatory definition of the term gluten-free, the FDA had a starting point for its official rule. In 1993, "in the preamble to a final rule on the declaration of ingredients on food packaging . . . the FDA advised that the term gluten-free can be used in the labeling of foods, provided that when such a claim is used, it is truthful and not misleading."[42] The FDA generally considers a food, absent other regulations, to be "free" of something if it does not contain any of the substance. Also, the FDA noted that it may be misleading to label a food gluten-free if it is naturally free of gluten, thereby raising the inference that other products like it may not naturally be gluten-free.[43]

i. Developing a threshold level for gluten.

With this starting point in hand, the FDA moved forward. Though FALCPA did not specifically direct the FDA to establish a threshold level for gluten, the FDA nonetheless decided that it would be necessary to establish the "level below which it is unlikely that an individual with Celiac Disease would experience an adverse health effect."[44] The FDA probably recognized the potential difficulty that food producers would have in eliminating all of the gluten in products like breads and therefore wanted to explore a more workable option.

---

[42] Food and Drug Administration: Food Labeling/Declaration of Ingredients, 58 Fed. Reg. 2,859, 2,864 (Jan. 6, 1993).

[43] *Id.*; *see also,* note 5.

[44] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,799 (Jan. 23, 2007).

After all, if an individual with Celiac Disease is highly unlikely to have a reaction below a certain gluten level, then there is little justification in requiring producers to completely eliminate all traces of gluten when calling their product gluten-free. It is common for a threshold level to be established in nutrient-free labeling guidelines. For nutrients like salt and fat, products are not required to be literally void of the nutrient to be called "free" of it.[45]

The FDA established an internal committee called the Threshold Working Group to review scientific literature and develop a proposal for acceptable gluten levels in gluten-free labeled foods.[46] The Group developed four potential approaches for the FDA and noted that "any decisions on approaches to establish a threshold for gluten likely would require consideration of additional factors not addressed in the report, such as ease of compliance and enforcement, concerns of stakeholders (i.e., industry, consumers, and other interested parties), economics (e.g., cost/benefit analysis), trade issues and legal authorities."[47]

On July 13 through 15, 2005, the FDA's Food Advisory Committee (FAC) held a public meeting to evaluate the draft Threshold report.[48] The FDA invited both experts and the general public. Experts presented information on a variety of topics including: the diagnosis and treatment of Celiac Disease, the quality of life issues that confront

[45] U.S. Food and Drug Administration, Appendix A: Definitions of Nutrient Content Claims, *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064911.htm (last visited Apr. 21, 2010).

[46] *Id.* at 2,800.

[47] *Id.*

[48] *Id.*

those with the disease, the relationship of gluten to the disease, how to measure the amount of gluten in food, their thoughts on existing gluten-tolerance studies, and current national and international standards for gluten labeling.[49] In addition, members of the general public shared their viewpoints.[50] Included among them were members of trade associations, consumers, producers, and individuals with Celiac Disease.

The meeting had about 140 attendees.[51] After all of the comments and presentations, the FAC accepted one of the Thresholds Report's approaches and noted that the proposed report "includes a comprehensive evaluation of the currently available data and descriptions of all relevant approaches that could be used to establish a threshold . . . for gluten in food."[52]

After the comprehensive evaluation of proposals for how to conduct a gluten threshold study, an evaluation that included consideration of "all relevant approaches," the FDA chose to apply a risk-assessment approach. The risk assessment approach "examines known or potential adverse health effects resulting from human exposure to a hazard; quantifies the levels of risk associated with specific exposures and the degree of

---

[49] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,800 (Jan. 23, 2007).

[50] *Id.*

[51] *Id.*

[52] FED. FOOD AND DRUG ADMIN. FOOD ADVISORY COMMITTEE, HEARING ON APPROACHES TO ESTABLISH THRESHOLDS FOR MAJOR FOOD ALLERGENS AND FOR GLUTEN IN FOOD, SUMMARY MINUTES, at 1, July 15, 2005, *available at* http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4160m1_summary%20minutes.pdf.

uncertainty inherent in the risk assessment."[53] Nearly a year after the Congressional directive to implement a gluten-free labeling scheme, the FDA determined, after considerable study and discussion, how they were going to begin to think about the problem of establishing a threshold level.

ii. The FDA moves forward with "gluten-free" labeling considerations.

In mid-2005, having decided upon the appropriate scientific approach to determining the gluten threshold level, the FDA announced that it would be holding a public meeting on August 19, 2005 to "solicit comments from appropriate experts and stakeholders to assist us in developing a proposed rule to define and permit the use of the term gluten-free."[54] The FDA invited the general public and experts to the meeting. The experts were brought in to address issues of food manufacturing, analytical methods, and consumer considerations.[55]

Over 80 people attended the meeting and, in a testament to the political involvement of the Celiac community, the FDA received over 2,400 responses to its inquiry for comments, most of them from individuals with Celiac Disease or their caregivers.[56] Consumers generally indicated in their comments that they "appreciate and

---

[53] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,799 (Jan. 23, 2007).

[54] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, Request for Comments, 70 Fed. Reg. 41,356, 41,357 (Jul. 19, 2005).

[55] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,800 (Jan. 23, 2007).

[56] *Id.*

use gluten-free labeling claims to identify packaged foods they can eat when trying to avoid gluten."[57] They further stated that gluten-free labeling made shopping easier and enabled them to avoid the frustration trying to discern potential gluten inclusion from the ingredients lists.[58] The consumers also expressed a desire for uniformity in labeling, noting that a standard definition would enable them to make healthier choices regarding their diets.

As a result of this public meeting, the FDA independently concluded that "a uniform definition of the term gluten-free would prevent confusion and uncertainty among both consumers and food manufacturers about what this food labeling claim means."[59] The FDA still had to actually develop the proposed rule as directed by Congress, but at least they felt better about doing so, having extensively studied the need for it on their own, in spite of their clear directive.

iii. A gluten-free labeling rule is proposed.

On January 23, 2007, the FDA announced its proposed rule for gluten-free labeling of foods.[60]

---

[57] *Id.*

[58] *Id.*

[59] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,801 (Jan. 23, 2007).

[60] *See generally*, *id*.

First, regarding the definitions of relevant terms, the FDA proposed the following: the term "gluten" will mean "the proteins that naturally occur in a prohibited grain and that may cause adverse health effects in persons with celiac disease;" the term "prohibited grain" means wheat, rye, barley, or any of their crossbreeds.[61] The FDA proposed, based on their assessment of medical literature, that oats not be included as a prohibited grain because they didn't contain a high enough concentration of gluten-like proteins to pose a risk for a significant number of individuals with Celiac Disease.

The FDA proposed in 2007 to define the term "gluten-free" as meaning the food does not contain any of the following:

> (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 of gluten in the food (i.e., 20 micrograms or more gluten per gram of food); or (4) 20 ppm or more gluten.

Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,802 (Jan. 23, 2007).

The rule's application to foods containing prohibited grains is straightforward and is reliant on the definition of prohibited grains. The second part of the rule recognizes that some foods, such as modified food starch, are derived from prohibited grains, but have had their gluten removed. These foods can be called gluten-free provided that they also abide by the third and fourth part of the rule. No food that has more than 20 parts per million (ppm) of gluten can be called gluten-free.

---

[61] *Id.* at 2,801.

Considering the fact that no prohibited grain has less than 20 ppm gluten, and that all foods processed to remove gluten must have less that 20 ppm, it seems that the entire thrust of the rule could have been simplified by stating that in order for a food to be called gluten-free, it must have less than 20 ppm gluten. In light of the final prong of the rule, that all gluten-free foods must have less than 20 ppm gluten, the other prongs of the rule seem redundant and unnecessary.

The FDA further requires that any food, except for oats, that does not inherently contain gluten will be considered misbranded if it claims to be specifically gluten-free.[62] It was concerned that:

> If a single brand of the food inherently free of the substance that is the subject of its 'free' labeling claim . . . consumers may assume that only that particular brand of the food is free of the substance and may not understand that other brands of the same type of food that do not make the 'free' labeling claim are also free of the substance.

Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,802 (Jan. 23, 2007).

iv. Offering alternatives to the proposed rule.

In addition to the proposed rule, the FDA offered six variations, many of them highly detailed, and it thoroughly considered the social and economic impacts of each possibility.[63] Based on their previous research and lengthy

---

[62] *Id.* at 2,802.

[63] *Proposed Regulatory Options:* We considered the following regulatory options:

(1) Take no action;

(2) take the proposed action—do not permit firms to make gluten-free claims on foods containing the prohibited grains or ingredients that have been derived from them and have not been processed to remove the gluten; do not permit firms to make gluten-

discussion sessions with experts, the FDA offered estimations and conclusions about the costs and benefits of each of these plans. However, the information collected up to that point was apparently not enough for the FDA to implement a final rule on the use of the term gluten-free in food packaging, since it has decided to proceed with additional studies.

C. Still conducting studies.

The FDA solicited comments on its proposed plan from January, 2007.[64] The FDA spent the next two years holding hearings, conducting research, and soliciting more comments on issues such as the effectiveness of different food labeling schemes and the

---

> free claims on foods containing ingredients derived from the prohibited grains that have been processed to remove the gluten, if the level of gluten is 20 ppm or greater; do not permit firms to make gluten-free claims on foods containing 20 ppm or more gluten, regardless of how the gluten got into the food (i.e. declared ingredient, undeclared ingredient, contaminant, etc.); and restrict the wording of gluten-free claims on foods that inherently do not contain any gluten;
>
> (3) take the proposed action, except do not permit firms to make gluten-free claims on foods containing ingredients derived from the prohibited grains that have been processed to remove the gluten, if the level of gluten is greater than some specified level higher than 20 ppm, and do not permit firms to make gluten-free claims on foods if the level of gluten is greater than some specified level higher than 20 ppm, regardless of how the gluten got into the food;
>
> (4) do not permit firms to make gluten-free claims on foods containing 20 ppm or more gluten, regardless of the ingredients they use to make them, and restrict the wording of gluten-free claims on foods that inherently do not contain gluten;
>
> (5) take the proposed action, except delete the wording requirements for gluten-free claims on foods that inherently do not contain gluten;
>
> (6) take the proposed action, but also define the food labeling claim "low gluten;" and (7) take the proposed action, except include oats in the list of grains that we propose to prohibit in foods that firms label as gluten-free.

Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,812 (Jan. 23, 2007).

[64] Food and Drug Administration Proposed Rule for Gluten-Free Labeling of Foods, 72 Fed. Reg. 2,795, 2,814 (Jan. 23, 2007).

appropriate threshold of gluten for those with Celiac Disease.[65] Finding the past five years of information gathering insufficient, the FDA announced in March, 2009, that it would be conducting a new study.[66]

The FDA proposed that it would screen 6,000 potential subjects, ultimately conducting a full survey with 5,000 subjects.[67] The survey would be used to better understand the public response to the different proposed uses of the term gluten-free in food labeling.[68] The FDA solicited comments from the public on the effectiveness of their proposed survey to determine the effectiveness of gluten-free food labeling.

On November 17, 2009, the FDA responded to the comments they received regarding the proposed survey.[69] The FDA restated that its purpose in conducting the survey was to help them "learn how consumers react and respond to the gluten-free labeling options presented in the gluten-free labeling proposed rule."[70] The FDA initially

---

[65] *See,* Nancy Lapid, *The FDA Asks: How Would You Improve Gluten Warnings on Food Labels?*, CELIAC DISEASE BLOG, Aug. 18,2008, *available at* http://celiacdisease.about.com/b/2008/08/18/the-fda-asks-how-would-you-improve-gluten-warnings-on-food-labels.htm; Andrea Levario, *FDA's Gluten-free Labeling Information*, DELIGHTFULLYGLUTENFREE.COM, July 19, 2008, *available at* http://delightfullyglutenfree.com/2008/07/19/fdas-gluten-free-labeling-info; Jefferson Adams, *FDA Set to Adopt New Gluten-Free Labeling Standards In-Line with New Codex Alimentarius Standards*, CELIAC.COM, July 23, 2008, *available at* http://www.celiac.com/articles/21617/1/-FDA-Set-to-Adopt-New-Gluten-Free-Labeling-Standards-In-Line-with-New-Codex-Alimentarius-Standards/Page1.html.

[66] Food and Drug Administration: Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 9,822, (Mar.6, 2009).

[67] *Id.*

[68] *Id.*

[69] Food and Drug Administration: Comment Request; Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 59,188, (Nov. 17, 2009).

[70] *Id.*

proposed screening 6,000 applicants to find 5,000 subjects for the survey.[71] They wanted to find these applicants by reaching out to Celiac Disease special interest organizations and by using an online consumer panel.[72] However, after receiving the comments, the FDA determined that it would screen 10,000 applicants to find 7,000 subjects for the survey.[73] It would also decided that it wouldn't be acting neutrally enough by reaching out to special interest groups and instead would obtain participants through the voluntary assistance of major Celiac Disease research centers in the United States.[74]

In mid-April, 2010, the FDA officially launched its new gluten-free research survey.[75] It sought responses from adults with Celiac Disease, other people with gluten intolerance, and their caregivers. The response was overwhelming and within a matter of days, they received the necessary number of responses.[76] The final survey was narrowly tailored to gauge the shopping habits and preferences of the subjects.

i. A final rule on gluten-free food labeling?

---

[71] Food and Drug Administration: Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 9,822, (Mar.6, 2009).

[72] *Id.*

[73] Food and Drug Administration: Comment Request; Gluten-Free Labeling of Food Products Experimental Study, 74 Fed. Reg. 59,188, (Nov. 17, 2009).

[74] *Id.*

[75] The National Foundation for Celiac Awareness, FDA Gluten-Free Research Study, Apr. 15, 2010, *available at* http://www.celiaccentral.org/News/Celiac-in-the-News/161/vobId__2568.

[76] *Id.*

In August, 2004, the FDA received a directive from Congress to produce a final rule on the use of the term gluten-free in food labeling by August, 2008. Nearly two years past its deadline, when can the Celiac community expect a final rule from the FDA?

First, the FDA established a committee to determine what analytical approach it would take to study what threshold level of gluten affected those with Celiac Disease. The FDA held a public meeting on that issue with presentations from experts and individuals with Celiac Disease. Upon deciding what analytical approach to take, it solicited public comments on how to determine the appropriate threshold level and how to proceed with a labeling rule. The FDA held another public meeting with experts and the general public. As a result of that meeting, the FDA determined that its task at hand was truly valuable and it set out with vigor upon drafting a rule.

The FDA proposed a rule, complete with definitions of the term gluten and gluten-free. The proposed rule included seven regulatory options. The FDA solicited for public comments on the proposed rule and spent two years holding hearings and conducting other general research. It then announced plans for a large survey to help it determine the effectiveness of the proposed regulatory option. The FDA solicited the public for comments on the proposed survey. The FDA announced its final plans for the survey and in April, 2010, conducted the survey.

The FDA has failed to meet its deadline from Congress. Individuals with Celiac Disease and other intolerances to gluten still do not have consistent food labeling guidelines they can rely on. Given the FDA's commitment to perfection and its

accompanying disregard for its deadline, it is unclear when the public can expect a final rule to be implemented.

III. A State Responds: North Carolina Protects its Residents

A. Paul Seelig and the State Fair.

Paul Evan Seelig, also known as Andrew Jeffrey ("Jeff") Gleason was the sole proprietor of Great Specialty Products, a business in the state of North Carolina.[77] Seelig sold bread products that he marketed trough his website and in person as being gluten-free.[78] The labeling on the product packaging and the claims on his website all stated that his bread products were gluten-free.[79]

Seelig specifically targeted his advertising efforts toward the Celiac community, knowing that those with Celiac Disease are intolerant to gluten and needed to find gluten-free food products.[80] Seelig set up a concession booth at the North Carolina State Fair in

[77] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 2 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

[78] *Id.* at 3.

[79] *Id*; *see also,* Verified Complaint, Motion for a Temporary Restraining Order and Motion for a Preliminary Injunction at plaintiff's exhibit 9, North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 (N.C. Sup. Ct. Jan. 20, 2010) (showing screen-shots of Great Specialty Product's website, claiming that baked goods are gluten-free).

[80] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 4 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

October, 2009, where he sold food, including bread, which he held out to the public as being gluten-free.[81]

Many of Seelig's potential customers specifically informed him, before they purchased his products, that they either suffered from Celiac Disease or had a different intolerance to gluten.[82] His potential customers informed him that if they ingested gluten, they would become seriously ill and that it was absolutely vital for the products to not contain gluten.[83] Some of these potential customers made it clear that they were caregivers for children with Celiac Disease or gluten intolerance. Seelig repeatedly assured them that he knew much about Celiac Disease, that he knew how harmful it would be if they consumed gluten, and that his products were absolutely gluten-free.[84]

In fact, Seelig told his customers that his primary business was to institutions, such as the United States Armed Forces. He stated that he only attended the fair and sold his products at the retail level to people suffering from gluten intolerance and that he did so out of a sense of benevolence, noting how difficult it is for people with gluten intolerances to find wholesome food that doesn't make them sick.[85]

However, some of Seelig's customers did become very sick:

---

[81] Verified Complaint, Motion for a Temporary Restraining Order and Motion for a Preliminary Injunction at 3, North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 (N.C. Sup. Ct. Jan. 20, 2010).

[82] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 5 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

[83] *Id.* at 6.

[84] *Id.*

[85] *Id.*

> Some . . . experienced painful headaches; some experienced severe and painful stomach aches; some experienced painful and debilitating stomach cramps; some experienced skin rashes over substantial parts of their bodies . . . which bled and turned into large, painful red splotches lasting for weeks; some experienced violent vomiting and nausea and some experienced almost non-stop bouts of diarrhea.

North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 7 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

After becoming ill, many of his customers contacted Seelig and informed him of their illnesses.[86] Individuals with Celiac Disease, especially those who are most sensitive to gluten, often have a difficult time determining which ingested food is responsible for their adverse reaction. Seelig's customers asked again if his products were gluten-free. He assured them that they were gluten-free and even encouraged them to purchase more of his bread.[87] Seelig falsely claimed that he bought some of his bread and raw materials from an Amish farm in Millersburg, Ohio and proposed that there had been cross contamination during shipping, but promised it wouldn't happen again.[88] He even offered gifts of free bread to compensate them for their troubles.

B. Citizens take action.

Having grown suspicious of Great Specialty Products, some of his customers searched the internet, specifically web-logs related to the Celiac community,[89] for information about the company. It was apparent that others were also suspicious of

[86] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 9 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

[87] *Id.*

[88] *Id.* at 10; Andrea Weigel, *Bread Seller Arrested on Fraud Charges*, NEWSOBSERVER.COM, Feb. 3, 2010, *available at* http://www.newsobserver.com/2010/02/03/317697/bread-seller-arrested-on-fraud.html.

[89] *See e.g.*, *Great Specialty Products: Seven Tests Show High Gluten*, JUNO NUTRITION, Dec. 13, 2009, *available at* http://www.junonutrition.com/blog/?p=323.

Seelig's claims. In one case, a child grew increasingly ill, suffering from a painful rash and abdominal cramping, until he stopped eating Seelig's bread.[90]

In December, just two months after the state fair, customers began to contact the North Carolina Department of Agriculture (NCDA) to lodge complaints against Seelig and Great Specialty Products.[91] The NCDA acquired samples of the bread from a consumer and on December 21, 2009, sent them to the University of Nebraska-Lincoln, Food Allergy Research & Resource Program to have their gluten levels tested.[92] Several samples tested off the scale, at over 5,000 parts ppm. The NCDA then acquired additional samples from another consumer who filed a complaint and submitted them for testing in January. The tests again revealed the content of gluten to be over 5,000 ppm. The FDA, in its proposed rule, found that a food had to have less than 20 ppm to be labeled gluten-free.[93]

C. North Carolina steps into action.

The North Carolina Department of Agriculture (NCDA) acted quickly in response to the complaints it received from consumers. Within days of receiving the complaints,

---

[90] Jaclyn Asztalos, *Local Bakery Closes After Gluten is Found in Gluten-Free Bread Claim*, MYNC, Jan. 22, 2010, *available at* http://wake.mync.com/site/wake/news/story/47183/local-bakery-closes-after-gluten-is-found-in-gluten-free-bread.

[91] Telephone Interview with Ray Starling, General Counsel, North Carolina Department of Agriculture, Feb. 29, 2010.

[92] Verified Complaint, Motion for a Temporary Restraining Order and Motion for a Preliminary Injunction at 5, North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 (N.C. Sup. Ct. Jan. 20, 2010).

[93] U.S. Food and Drug Administration, *Questions and Answers on the Gluten-Free Labeling Proposed Rule* (Jan. 23, 2007), *available at* http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm111487.htm.

the NCDA commissioned tests to analyze the gluten content of the baked goods that the complaining customers bought from Seelig. The NCDA "contacted the Defendant beginning in mid-December 2009 (and repeatedly thereafter), requesting permission to inspect his business facility as soon as possible."[94] The NCDA requested that Seelig provide samples of his bread for testing as well as business records detailing the purchase of raw materials from his suppliers.[95]

Seelig refused to provide the requested documents, telling the NCDA that he was out of town or too ill.[96] At one point he actually told inspectors that he was undergoing chemotherapy treatment, that he had swine flu, and that he had a heart attack.[97] When NCDA inspectors arrived, unannounced, at Seelig's place of business, he introduced himself as "Jeff Gleason" and told them that Paul Seelig wasn't at home.[98]

---

[94] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 11 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

[95] N.C. Gen. Stat §106-140 (2009) gave the NCDA extensive authority to inspect the premises and business records of Seelig.

[96] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 12 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction); Andrea Weigel, *supra* note 84.

[97] Id.

[98] *Id.*; Seelig brazenly resisted all attempts by others to investigate or reveal his conduct.

This fact is clearly illustrated by another example: When one of Seelig's wholesale suppliers in New Jersey found out that he was falsely rebranding and selling its bread as gluten-free, the supplier "issued a corrective public statement that its bread products contained Gluten, that it had never advertised or otherwise represented to the public that its bread products did not contain Gluten and that it had never told [Seelig] that the bread products it sold him were Gluten free." *Id.* at 14.

Rather than stopping his activity, Seelig fabricated the names of a law firm and six attorneys. He issued a formal cease-and-desist letter demanding that the supplier withdraw its public statement.

The North Carolina Department of Agriculture pursued false advertising charges[99] and sought a preliminary injunction to prohibit Seelig from selling bread.[100] The NCAD cooperated with the Wake County District Attorney's office who has charged Seelig with the crime of "obtaining property by false pretenses."[101] The Superior Court granted the preliminary injunction, ordering Seelig to refrain from selling any bread products until he indentifies his past customers, indentifies his past suppliers, provides samples of each product he still has on hand, and allows his premises to be inspected.[102] If he does satisfy these requirements and wishes to sell bread again, he must place on the front of his packaging, in bold, capital letters, a disclaimer that "**THIS PRODUCT(S) IS <u>NOT</u> GLUTEN FREE**."[103]

---

[99] N.C. Gen. Stat. § 106-122(5) (2009).

[100] Bruce Mildwurf, Bread Seller Faces Deceptive Advertising Charges, WRAL.COM, Feb. 2, 2010, *available at* http://www.wral.com/news/local/story/6949028.

[101] Below is the relevant part of North Carolina's criminal definition of "obtaining property by false pretenses;"

> (a) *If any person shall knowingly and designedly by means of any kind of false pretense whatsoever*, whether the false pretense is of a past or subsisting fact or of a future fulfillment or event, *obtain or attempt to obtain from any person within this State any money*, goods, property, services, chose in action, or other thing of value *with intent to cheat or defraud any person of such money*, goods, property, services, chose in action or other thing of value, such person shall be guilty of a felony. . .
>
> If the value of the money, goods, property, services, chose in action, or other thing of value is less than one hundred thousand dollars ($100,000), a violation of this section is a Class H felony.

N.C.G.S.A. § 14-100 (emphasis added).

[102] North Carolina Department of Agriculture & Consumer Services v. Seelig, No. 10-CVS-001020 at 25 (N.C. Sup. Ct. Feb. 2, 2010) (order granting preliminary injunction).

[103] Id.

Seelig was recently indicted by a grand jury on nine counts of "obtaining property by false pretenses." He is being held on $100,000 bond pending trial and is not selling bread products to anyone at this time.

IV. Differences in Response

When Congress instructed the FDA to come up with a gluten labeling rule by August, 2008 many in the Celiac community were hopeful that their difficult task of finding safe, healthy, gluten-free food would soon be made easier. Whether one defines the actions of the FDA as being 'deliberate and thorough' or 'redundant and inefficient,' it remains an unavoidable fact that the FDA has failed to meet its Congressional mandate in a timely manner. Because of this failure, individuals with Celiac Disease still have to use trial-and-error, often resulting in sickness to themselves, to find out what they are able to eat.

Additionally, food producers and marketers still have to rely on the unclear legal guidelines that their claims cannot be "false or misleading." What level of gluten must a producer attain in order to claim that their food product is gluten-free? Must a product be entirely absent of gluten in order to call it gluten-free, as is suggested generally by the FDA?[104] Perhaps the FDA would allow a negligible or nutritionally trivial amount of gluten as they do with many other nutrient "free" claims?[105] Will a good faith belief on the part of the producer that its self-decided gluten threshold level is adequate be

---

[104] Food and Drug Administration: Food Labeling/Declaration of Ingredients, 58 Fed. Reg. 2,859, 2,864 (Jan. 6, 1993).

[105] U.S. Food and Drug Administration, Appendix A: Definitions of Nutrient Content Claims, *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064911.htm (last visited Apr. 21, 2010).

sufficient to shield it from liability? Would a food producer be free from liability if they adopted the FDA's proposed threshold level of 20 ppm?

In fairness, the actions of the federal government and that of North Carolina cannot be precisely compared side-by-side. While both governments were responding to the needs of those with Celiac Disease and other gluten intolerances, one situation involves an agency of the federal government tasked with creating a rule and the other situation involves a state and a county going to court to protect their residents.

Additionally, it is almost certain that Paul Seelig would still have falsely claimed his products to be gluten-free, even if there was a clear rule for using the term gluten-free in food labeling. Seelig allegedly had little regard for the law.

However, these two situations, the federal government dragging its feet in creating guidelines and the near-immediate response of the state and local governments to food being mislabeled, can help us compare the general abilities of the state and federal governments to respond to a similar problem: the need for people with Celiac Disease to have knowledge about what they are ingesting.

There is little doubt that the United States Congress sincerely wanted to help people with Celiac Disease. To that end, it gave the FDA four full years to implement a rule, arguably plenty of time. Nearly six years later, the FDA, mired in studies, surveys, and focus groups has failed to create a rule. The FDA has failed to assist people with Celiac Disease, not for lack of trying, and not to intentionally injure people, but because its

desire for a perfect rule has prohibited it from timely establishing a good rule, even if that rule may need refined after any negative consequences become apparent.

On the other hand, the state of North Carolina was made aware in December, 2009 that people with gluten intolerance were being made sick by mislabeled bread. The state Department of Agriculture and the Wake County District Attorney acted. In early February, 2010, two months after receiving the first complain, Seelig was placed under arrest and handed an injunction prohibiting him from selling bread until he met the court's requirements.

A. Laboratories of Experimentation.

America has the asset of fifty independent laboratories for experimentation. These are fifty sovereign entities and through their independent legislation as many as fifty different approaches to a national problem can all be attempted at the same time. With fifty simultaneous approaches, states can look to their neighbors to see what's working and what is not, and adjust their own approach accordingly. It's no wonder that the FDA feels so much pressure to create the perfect rule; if one takes six years to react to a problem and impose a single rule on the entire nation, and if that rule may take another six years to be changed if any problems arise, it better be perfect.

States can solve problems, and then remedy potential errors in the solution, with quickness. Food and food safety need this quick attention and agile action. In this situation, however, both the states and the Celiac community have relied on the promise of a timely rule by the FDA. The states have likely postponed action because any action

they take would be preempted by the promised regulations from the FDA. Since the FDA promised to act, the states have refrained. But, the FDA has not acted, leaving those with Celiac Disease unable to make easy dietary decisions and leaving the states to deal with the consequences.

B. The Consequences of States Having the Freedom to find Solutions?

If states were provided with the freedom to retain jurisdiction over food labeling and product claims, there would be a lack of national uniformity definitely for a time, and perhaps indefinitely. For example, states that set more stringent levels for nutrient claims could face economic consequences if food producers become unwilling to sell within that state. However, perhaps these consequences would accurately decide the necessary balance between protecting people and ensuring economic growth.

Also, states with higher populations would have more economic force, with food producers needing to meet those states requirements in order to do business there. Again, the producers will have the freedom to choose whether it is in their best economic interests. The economic interests of the producer, working against the interest of the states in protecting its residents, could produce the most mutually beneficial outcome.

However, Congress, claiming authority under the Commerce Clause of the U.S. Constitution,[106] has given an administrative agency, the FDA, the authority to create,

---

[106] U.S. CONST. art. 1 §8, cl.3. ("The Congress shall have power to . . . regulate commerce with foreign nations, and among the several states, and with the Indian tribes.")

enforce, and adjudicate rules for the entire nation without a vote or any accountability in Congress. The federal government has sacrificed efficiency, creativity, and accountability all for the sake of uniformity and ease of certain ease of commerce.

Even if the federal government is not willing to relinquish some of the power that it took from the states, it should consider that the states still have a very important role to play. State Departments of Agriculture handle most of the day to day tasks when it comes to food safety. More importantly, the state governments are responsible for picking up the pieces when the federal government says, "Just wait, we'll take care of it," and then fails to take care of it.

Additional federal funding would be helpful for states to accomplish their short-term needs, but it wouldn't be in the spirit of reestablishing the efficient and creative self-determination of the states. What is needed to accomplish that goal would be for the federal government to serve, and therefore tax, the people less, so the states could serve, and therefore tax, people a little more. With the efficiency, creativity, and accountability that rest in the hands of state and local governments, more could get done quickly and at a cheaper cost.