

Butler, Jennie C

From: Mary Thorpe [mthorpe@Peds.umaryland.edu]
Sent: Wednesday, August 01, 2001 1:37 PM
To: 'FDADOCKETS@oc.fda.gov'
Subject: FW: Docket No. 00P-1322



Gluten testimony.doc

Below is my intention to register for the hearing on "Presence and Labeling of Allergens in Foods."

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Please indicate the type of organization you represent:

Industry
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Other (specify) clinical research at UMB Do you wish to make an oral presentation? Yes No If yes, you must also submit the following:

1. A brief written statement of the general nature of the views you wish to present. (attached)
2. The names and addresses of all persons who will participate in the presentation. Depending on the number of people who register to make presentations, we will limit the time allotted for each presentation (from 3 to 5 minutes). (just myself from the CFCR: Mary Thorpe, 2402 Erdman Ave., Baltimore, MD 21213).

Thank you-
Mary Thorpe/CFCR

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Celiac Disease is a condition that is much more common in this country than many physicians know (now estimated to affect between 1/150 to 1/250 in this country, much the same as in Europe), and much underdiagnosed. I myself suffered a myriad of symptoms most of my life, including depression and migraine which were the most debilitating, along with anemia, hair loss, heart palpitations, muscle spasms (to name a few other symptoms) which could have been avoided by elimination of gluten, the storage protein of wheat, from my diet. I am doing that to the best of my ability now, but think a moment how difficult it is to avoid gluten in this country. It's hard enough to avoid the obvious sources. But it shows up in the most unlikely places. Let me name a few:

Wheat is found in some tomato paste. What if tomato paste is an ingredient in another product? One doesn't know if it contains wheat or not. The same is true for soy sauce and products containing soy sauce. Sometimes the manufacturers put the ingredients in parentheses, but sometimes not.

Modified food starch is a common constituent of many foods. The starch may be made from corn starch but it might be from wheat starch. One can't tell. Some manufacturers are beginning to specify that, for instance, their product contains modified corn starch, which we applaud. But this is still in the minority.

Then there are the myriad things that may be made from wheat: citric acid, distilled vinegar, caramel coloring and natural flavors, to name a few.

And there is the use of flour as a processing aid, to keep things from sticking together. Dates might be floured, for instance. Conveyer belts for candies might be floured. Spices may contain flour for anti-caking properties. There is currently no requirement for labeling in these cases, but you can see that these practices are a hidden source of gluten and dangerous for celiacs.

Celiac disease is not an allergy but a different kind of immune response to gluten that progresses to an autoimmune attack on the intestinal lining. New research is elucidating that the immune response also turns, in some cases, on the central and peripheral nervous system: epilepsy, ataxia, peripheral neuropathy, depression and migraine (as in my case) are some of the forms it can take. Gluten is implicated in M.S., fibromyalgia, autism and ADHD, though there is no solid evidence as yet. There is increase risk for other autoimmune disorders and an increased risk of lymphoma. It is a serious condition. It does not result in sudden death as with anaphylactic shock as with allergies, but in a decreased quality of life and risks of more serious disorders. Data us being gathered by the Center for Celiac Research, and other programs elsewhere, to show that gluten intolerance is behind many disorders that plague countless Americans.

We would hope that the legislation would include gluten in all its forms: from wheat (be it wheat protein or wheat starch, or by-products) and from barley and rye as well. These are close relatives of wheat, and the storage proteins are similar in structure. Barley is found in many places, usually as barley malt. But again, the labeling is often not clear.

Europe is way ahead in labeling and even to the extent of including the amount of gluten in products. It is possible to test for the amount of gluten in foods, and our greatest wish would be for this to happen here.

Oatmeal is avoided by celiacs though it is more distantly related to wheat than barley and rye and shouldn't be a problem in and of itself. But cultural practices (growing in the same fields, using the same trucks) cause contamination of oatmeal. Testing of the level of contamination by gluten would enable celiacs to make informed choices about including oats in their diet.

I suggest labeling along the following lines:

gluten free ingredients, using dedicated lines, in a gluten free environment
gluten free ingredients, non-dedicated lines or gluten contaminated facility
contains gluten (mg/100g).

I recommend against allowing labeling "gluten status unknown." This would be an easy way out for manufacturers and it would leave us in the same unknowing situation that exists now. Manufacturers should be aware that this would lose them customers, and more than 1/200 celiac customers, because it will in many cases extend to the families of celiacs who cook for them and share their meals.

Thank you.