

June 21, 2001

Dear Sirs:

Enclosed for your review is information I recently received from the Food Allergy and Anaphylaxis Network regarding food labeling, legislation regarding the use of epinephrine by EMTs, physician education and research. I urge you to review it and do whatever you can to make these actions happen.

My 6-year old daughter is allergic to milk and eggs. We discovered this as soon as she began eating baby food when we noticed she would sneeze constantly after eating macaroni and cheese or custard-based fruits and puddings. The allergy only became apparent then because after breast-feeding, we started her on soy formula rather than a milk formula, simply because Isomil had sent us free soy formula. Had she started on milk formula, it may have been discovered sooner. It is also very possible that she would have had more severe reactions and become very ill.

When our family doctor sent us to a Columbus allergist, we left without a lot of vital information. We received no information regarding nutrition; only the suggestion that we boil soy beans to make our own soy milk and avoid food with milk and egg in it. We were not educated on how to read a food label. We were not initially told about the use of Benadryl or epinephrine (EpiPens) in case of a reaction. She could not be tested by skin pricks for allergies until she was at least one-year old, so for at least six months, we were pretty much on our own on how to care for her. Fortunately, the doctor did hand us a list of agencies to contact that specialized in food allergies. On that list was FAN (then Food Allergy Network, now Food Allergy and Anaphylaxis Network (FAAN)). If not for this organization, we would still be stumbling in the dark about food allergies. With their monthly newsletters, we learn about reading labels, new research, obtain food recipes, get ingredient warnings from manufacturers who work with them on improving the methods of keeping children safe from ingesting allergens,

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suggestions from other parents on how to handle certain situations and much needed support.

Because of the lack of thorough food labeling, my daughter is still exposed at times to milk and egg. This is because of cross-manufacturing of products and unlabelled items in food. We are fortunate that we have never had to use an EpiPen on her. Benadryl, up to this time, has been sufficient in diffusing her reactions. But, her allergies have changed and become more intense over the years. It began with the sneezing, increased to coughing and wheezing and now is at a stage where her tongue and mouth immediately itch when exposed to an allergen. It is entirely possible that her allergy could progress to a stage where epinephrine will have to be the FIRST course of action. With many children, it is.

This is why it is SO IMPORTANT that manufacturers list ALL ingredients and indicate that there is cross-manufacturing of their products and that EMTs be allowed to carry epinephrine to treat allergies. In the time that it takes to get an ambulance on the way to a hospital, a child could die. (This could also pertain to anyone with allergies to insect stings or bites.)

Regarding the importance of physician education, that was apparent to us when we first went to our Columbus family doctor. He had no information to give us so sent us to the Columbus allergist where we also did not receive adequate information. Through FAAN, we found a pediatric allergy and asthma doctor in Indianapolis. He is familiar with FAAN and has a membership so he receives all updated materials from them. We feel much more comfortable in his knowledge of allergies. The education of physicians also became doubly apparent to me last week when I happened to run into a woman I had met several years ago when our children were in pre-school together. She has a new baby (5 months old). His face was covered with a red rash and I wondered what the problem was. She exclaimed, "Oh, I can't believe I ran into you. I just remembered that Paige has allergies. Does she still?" I said yes, and she said her baby


appears to have an allergy to milk. (You see, at this age, it's mostly a process of elimination to determine what is causing a reaction since they can't be tested this young.) When he began having the rash and patches of eczema, the allergist they went to recommended a special formula because going on soy formula did not help eliminate his rash. (It's possible that he's also allergic to soy.) I can't at this moment recall the name of the formula, but the front was labeled for milk allergic and "food sensitive" infants. She said the rash was continuing to get worse and the doctor attributed that to his drooling. I read the ingredients label of the formula and it contains casein hydrolysate. This is a milk protein, so her child is still ingesting an allergen. I told her she should go back to the doctor and ask if he knows this and if he knows how to read ingredient labels. I provided her with information from FAAN to have with her when she did. It is very possible that he doesn't even know that this formula contains milk protein since the front label indicates otherwise. Hopefully, she will also join FAAN and receive more information from them. Dealing with food allergies, especially when you're not informed, is frightening and overwhelming because your child's life depends on you.

Please give these issues your attention and do all you can to make life safer for children with allergies and easier for the parents and all involved with allergic children. I am now in the process of having to pave the way for my daughter's school to create a safe environment for her. It is a challenge when we travel, go out to eat and simply to provide meals at home. Clearly marked labels and education to all is VITAL as well as the assurance that our children can be treated on the way to the hospital.

I thank you for anything you can do on behalf of my daughter and the millions of children who suffer from allergies.

If you have any questions, please feel free to contact me or FAAN. Their address and phone number is on the information enclosed and mine is below.

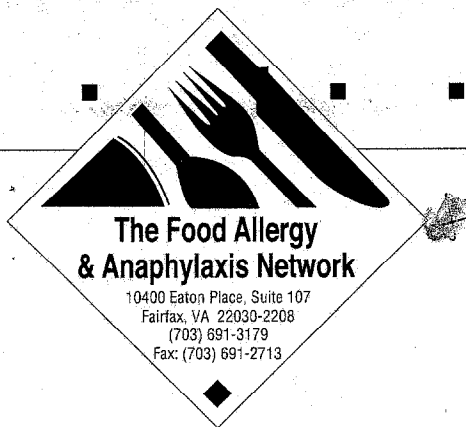
Sincerely,



Kim A. Miller
P.O. Box 12
Hope, IN 47246
(812) 546-4364

Encls.

cc: Senator Robert Garton
Representative Mike Herndon
Congressman Mike Pence
Senator Evan Bayh
Senator Richard Lugar
Dockets Management Branch (FDA)
FAAN



Dear FAAN Member,

A recent investigation of dozens of food companies by the Food and Drug Administration found that as many as 25% failed to list common ingredients that can cause potentially fatal allergic reactions.

This alarming finding underscores our need to be ever more vigilant in the foods we serve food-allergic individuals. It also means we must redouble our efforts to ensure that clearer and more uniform labeling standards are adopted by the food industry.

Food labeling is one of four critical areas that FAAN has placed on its "most urgent" list. The other three are EMT/epinephrine, physician education, and research. As detailed below, we are making significant strides in each of these areas.

But our efforts are limited by the funds we receive. You should know that your financial support in the past has been largely responsible for many of the safety improvements food-allergic individuals are enjoying now. For example, last year your generosity helped us exceed our fundraising challenge and raise enough money to distribute the *Special Edition of the School Food Allergy Program* to 20,000 schools, affecting hundreds of thousands of students nationwide.

Now, your contributions can have a direct impact on the success of these four urgent initiatives:

Food Labeling At FAAN's urging, a large number of trade associations and food manufacturers developed and signed a consensus statement for improvements in labeling—including the listing of all major allergens. We're also working with the FDA to inform them of misleading and potentially dangerous labeling. Additional funds will allow us to speed up our work and strengthen the impact of these campaigns.

EMT/epinephrine FAAN is leading the way to promote new legislation or revise policies and regulations in all 50 states allowing all levels of Emergency Medical Technicians to carry and administer epinephrine. That way, no matter where you are when a reaction occurs, emergency help will arrive with appropriate medication.

FAAN is also funding development of a series of presentations to educate Emergency Physicians on the latest research in the treatment of anaphylaxis. Your donations can help significantly in furthering these causes.

Physician Education Pediatricians and family practitioners receive little or no training about allergy. FAAN is convening a summit meeting of the leading food allergy experts with the objective of creating a definitive publication on food allergy to be distributed free to physicians across the country. Your contributions will lead to faster diagnosis and treatment.

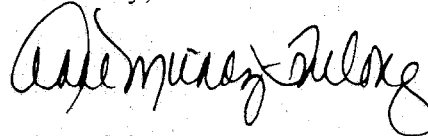
Research FAAN is working on research to better understand how many people are affected by food allergy, who they are, how they cope, what they think about food labeling, how they handle dining at restaurants, and how it impacts child care and schooling. This information is vital in convincing legislators, educators, regulators, and heads of major corporations to change laws, regulations, policies, practices, and marketing strategies to accommodate the needs of the food allergic. Donations will help us find these answers and bring about meaningful change faster.

All of these efforts require countless hours of staff time, printing and production costs, postage, research time, and more.

It takes money to change policies, to educate industries, to help save lives. So please be as generous as you can. Remember, your donations are tax-deductible. Please use the postage-paid envelope to mail your contribution.

And thank you so much for helping to keep the millions of children and adults who suffer from food allergy safe.

Sincerely,



Anne Munoz-Furlong
Founder



Legislative and Advocacy Update

FDA Labeling Workshop

The FDA will host a workshop August 13 to discuss food allergen labeling, including precautionary labeling, and the best ways to improve ingredient statements. The meeting, open to the public, food industry, and trade associations, will be held at the Voice of America Auditorium in Washington, DC.

If you cannot attend, you can submit your comments/concerns to Dockets Management Branch, HFA-305-EDA, 5630 Fishers Ln., Room 1061, Rockville, MD 20852. Note Docket OOP-1322 on the envelope. Please send a copy of your letter to FAAN.

Food Allergen Consumer Protection Act

FAAN attended a recent press conference, where Representative Nita Lowey (D-NY) announced her plans to introduce the Food Allergen Consumer Protection Act. The bill as proposed will:

- Require that food statements list in common English, what, if any, of the eight main food allergens (peanuts, tree nuts, fish, shellfish, eggs, milk, soy, and wheat) are contained in the product;
- Close the additive loophole by requiring ingredient statements to take into account if any allergens were used in the spices, natural or artificial flavorings, additives, and colorings;
- Require food manufacturers to include a working telephone information number on food labels;
- Require manufacturers to better prevent cross-contact between

products produced in the same facility or on the same production line;

- Allow the FDA to assess civil penalties against processors and plants that are in violation of the Act; and
- Require the Center for Disease Control (CDC) to track food-allergic related deaths.

Representative Lowey says, "You shouldn't have to be a scientist to determine what you and your family are eating. I hope the Food Allergen Consumer Protection Act will end the tedious process food-allergic consumers suffer through day after day, label after label, to determine what they are eating."

Food Allergen Labeling Guidelines

FAAN has served as a member of the Food Allergy Issues Alliance (FAIA), a group of 18 food trade associations including flavors, chocolate and candy, snack foods, dairy, and frozen foods and other organizations in the food industry, to develop a consensus document, Food Allergen Labeling Guidelines. These guidelines are similar to the labeling sections of NFPA's Code of Practice and the Lowery bill. These guidelines were adopted by the FAIA in May and presented to the FDA and the USDA:

1. Identify the Major Food Allergens: Crustaceans (such as crab, crayfish, lobster, and shrimp), eggs; fish; milk; peanuts; soy; tree nuts (almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts,

pecans, pine nuts, pistachios, and walnuts); and wheat.

2. Advocate the use of terms commonly understood by consumers (i.e., "plain English") for Major Food Allergens within, or in immediate proximity to, the ingredient declaration, to provide clear communication with the food allergic consumer.
3. Call for manufacturers to disclose the presence of Major Food Allergens when they are an intentional part of the food, regardless of source. Thus, Major Food Allergens would be disclosed regardless of the fact they may otherwise be exempted from declaration (e.g., as part of a flavor, or as an incidental additive or processing aid).
4. Establish guidelines for conditions when the use of supplemental allergen statements is appropriate.

Emergency Medical Services: Where Do We Stand?

As you may know, rapid administration of epinephrine could mean the difference between life and death to an individual suffering an anaphylactic reaction.

One way to expand the safety net to such individuals is to allow all levels of Emergency Medical Technicians (EMTs) to carry epinephrine aboard their vehicles, and be trained to administer this life-saving medication during an emergency.

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Most rules and regulations governing EMTs are developed at the state level. Typically, EMTs are divided into three classes: Basic, Intermediate, and Paramedic. In the majority of states, only Paramedics (EMTs with the highest level of training) are authorized to carry and administer epinephrine. EMT-Basics, on the other hand, are generally not permitted to do so. Rather, EMT-Basics are only allowed to assist a patient in administering the patient's own epinephrine auto-injector device.

This is troubling for the following reasons. First, an individual suffering an anaphylactic reaction may not be in possession of his or her own epinephrine prescription or may never have had it prescribed. Second, EMT-Basics typically outnumber all other

classes of EMTs combined and are often the first to arrive at the scene.

Therefore, it is crucial that all EMTs responding to an emergency call be equipped with this life-saving medication and be permitted to administer it.

When we first reported results on our findings regarding this initiative in June 1999, only eight states allowed all levels of EMTs to carry and administer epinephrine.

As you will see in the table below, 11 states now allow all levels of EMTs to administer the medication, however, several others are expected by summer.

If you live in a state where no legislative or regulatory action is

planned, you can work to make a difference. Undoubtedly, state legislators pay close attention to letters, telephone calls, and e-mails from their constituency.

FAAN would like to thank its members for their effort in getting EMT/epinephrine legislation introduced in Illinois and Louisiana. Congratulations to all!

For further information on how you can get involved, please contact Christopher Weiss, Director of Legislative and Regulatory Research by phoning the FAAN office, or by e-mail at legisl@foodallergymail.org.


EMS Epinephrine Policy Status Report				
All EMTs May Carry & Administer Epinephrine	Legislative or Regulatory Changes Pending	Needs Your Involvement		
		Legislative or Regulatory Changes Projected	Action Pending	
Connecticut	California	Colorado	Alabama	Maine
Florida	Illinois	Georgia	Alaska	Mississippi
Massachusetts	Louisiana	Kansas	Arizona	Nebraska
North Dakota	Maryland ¹	Kentucky ³	Arkansas	Nevada
New York	Massachusetts ²	Michigan	Delaware	Ohio
Oregon	New Jersey	Minnesota	District of Columbia	Oklahoma
Rhode Island	Pennsylvania	Missouri	Hawaii	South Carolina
Tennessee	Texas	Montana	Idaho	South Dakota
Washington		New Hampshire ³	Indiana	Vermont
Wisconsin		New Mexico	Iowa	
Wyoming		North Carolina		
		Utah		
		Virginia		
		West Virginia		

¹ Legislation withdrawn, but new regulation goes into effect January 1, 2002.

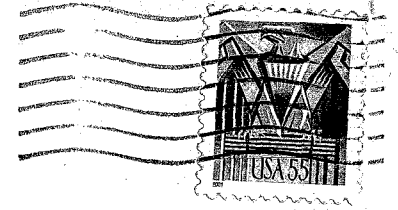
² Revision to existing law.

³ Legislation introduced but not passed during the 2001 legislative session. Similar legislation to be reintroduced in 2002.

Note: This information was accurate at press time. Due to the nature of the legislative/regulatory process, however, the information may change on short notice. See the FAAN website for the latest information.

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