

HOUSE BILL 1438⁶

Hello, my name is Dr. Terri Brown-Whitehorn and I am a pediatric allergist at The Children's Hospital of Philadelphia and an Associate Professor of Clinical Pediatrics at the Perelman School of Medicine, University of Pennsylvania. I have been asked to speak to you by members of the Milk Allergy GI coalition, MAGIC, which has worked long and hard to support the goals set forth in this bill. I am an Academic Physician. I spend most of my time seeing patients, teaching residents and fellows, and doing clinical research. The rest of my days are spent writing, speaking, and raising awareness about food allergies. When most people think about food allergies, they think about immediate or anaphylactic reactions to foods. However, there are other health conditions in which food plays a major role. My goal this morning is to review the different types of food allergies, the role of elemental formulas, and most importantly, how you can help, by supporting the passage of House Bill 1438⁶.

Food allergies affect anywhere from 4 to 8% of the general population (higher in the younger age group) which means, that most likely you either have or know someone who has a food allergy. If we look specifically at The Children's Hospital of Philadelphia over a 12 month period, there were 41,977 patients who came to CHOP and had a food allergy documented, and, of those, 8,300 had a milk allergy! Those numbers are staggering. Thankfully, not all patients with food allergy need special formulas (small percentage). But, for those who do, there is really no other alternative. These non-allergenic formulas contain amino acids (components of proteins), fats, and carbohydrates in special combination to provide complete nutrition for patients who need it, which is why it is imperative for these formulas to be covered by insurers providing health coverage in this Commonwealth. Interestingly, these formulas are already covered by Medicaid and WIC.

What are different types of food allergies? When would an elemental formula be prescribed? There are 5 medical conditions in which elemental formulas may be prescribed in patients with food allergy: IgE mediated food allergy, atopic dermatitis/eczema, food protein colitis, food protein induced enterocolitis, and eosinophilic gastrointestinal disorders (most common being eosinophilic esophagitis).

IgE mediated food allergy: These reactions are the most common type of food allergy. A child will eat a specific food and immediately develop hives, lip swelling, breathing problems, vomiting and/or shock. Epinephrine is given, and the child often improves (although there are deaths). Family is then told to avoid the offending food. Milk, egg, soy, wheat, peanut, tree nuts, fish and shellfish cause 90% of

reactions. If a child has multiple IgE mediated food allergies (milk and soy) or is very young, an elemental formula is prescribed.

Atopic dermatitis/eczema: Approximately 1/3 of babies and toddlers with severe atopic dermatitis, characterized by a very itchy, diffuse, red rash, have food allergies. These allergens can either be ingested directly, through milk or soy formula, or indirectly, through breast milk. When skin rash is really severe and the baby is found to have food allergy, an elemental formula is prescribed.

Food protein colitis: We also take care of infants and toddlers who have a condition known as food protein colitis. These babies, who are otherwise healthy and happy, present to us with blood or mucus in their stools. Milk and soy are the most common culprits. Oftentimes, formulas are switched or a breastfeeding mom's diet is restricted. Although food protein colitis is seen frequently, very few babies go on to need elemental formulas; however, there are times it is necessary to prescribe it. Luckily, most babies outgrow the need for these formulas over time (typically by a year or two of age).

Food protein enterocolitis (FPIES): Another GI food allergy that is seen in known as FPIES. These children present 2 hours after ingesting a food with severe vomiting and lethargy (at times to the point of shock) along with diarrhea. Removing the offending food and treating with IV fluids is helpful. Another subset of children present with irritability, chronic diarrhea and growth concerns. Approximately 5% of these children must avoid multiple foods. These children are often quite sick at presentation. Overall treatment is avoidance of food of concern (which in most cases is milk, soy, and/or grains). We recently published a paper in which we described 380 patients seen in our institution with FPIES: 38% reacted to milk, 24% reacted to soy and 33% reacted to both milk and soy. When we reviewed this data even more closely approximately 1/3 of these patients needed to be on an elemental formula at some point. Most children do outgrow the need for these formulas over time as well.

Eosinophilic gastroenteritis, eosinophilic esophagitis: And finally, we take care of children with eosinophilic gastroenteritis including a condition known as eosinophilic esophagitis. These patients present with severe gastroesophageal reflux not responsive to reflux medications. Babies can present with vomiting, GERD and growth concerns, school age children present with reflux and abdominal pain, and older teenagers and adults, present with difficulty swallowing, food impaction, abdominal pain and heartburn. We have the largest center in the country for children with eosinophilic esophagitis, with over 1,500 patients. A smaller percentage of patients have eosinophilic gastroenteritis. In patients with

eosinophilic esophagitis, the cause of inflammation/symptoms is a hidden food(s) allergy.

Approximately 20% of patients require use of elemental formulas as supplement to their restricted diet and some require for full nutrition.

What are obstacles for getting elemental formulas covered by insurance? Despite the fact that these children are prescribed elemental formulas, some families must struggle to get these formulas covered. Why? These formulas are quite expensive and one's insurance may not cover the needed formula. However, one needs to weigh the risks vs. benefits to coverage. The risks are ill children without proper nutrition, concerns with slow brain development, chronic symptoms and costs of hospitalizations. The benefits: children who are growing, developing normally, and thriving.

However, stipulations remain and insurance companies state they:

- will only cover infants until 12 months of age
- will only cover certain diagnosis (which may include a metabolic condition but not a food allergy or GI food allergy)
- will only cover formula if the child is fed through a tube
- will only cover a formula if it encompasses a certain percentage of the child's nutritional needs
- will not cover a formula because it is not a "real" medicine

As a physician, neither myself nor my colleagues can just write a prescription and the child gets the formula. Letters need to be written to insurers, prior authorization forms need to be completed, and peer to peer reviews sometimes need to occur. We are lucky to have a nutritionist, a medical assistant and other office staff to help. But, what about the patients who do not have help from their physicians? What if the insurance company decides to say "no" and there is no one to help them appeal? What if appeals are rejected? Families pay and may go into debt without insurance back up. After all, what is the alternative? A sick child who isn't growing or developing normally?

How can you help? We need help from you, the Children and Youth committee to ultimately support the passage of House Bill 1438. As physicians, we do our part. We are judicious in prescribing these formulas. We know that they are costly but we see the benefits. We take care of these patients. We see the before and after. We see the improvement in symptoms and quality of life. There are similar

bills in other states that have passed and are now law. I see no reason why this cannot happen in the Commonwealth of Pennsylvania.

Please contact me if additional questions: brownte@email.chop.edu

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