

External Appeal for Anne

Overview

This medical thesis paper is being provided for External Appeal for **continued healthcare services for Anne for allergy testing, treatment and services from an AAEM Physician** (American Academy of Environmental Medicine). Univera Healthcare does not have a Board Certified Environmental Medicine Physician in the Univera network. If Univera Healthcare did have a Board Certified Environmental Physician in the network there would be no reason for this appeal.

For the purposes of this paper the following terms all refer to the same services: intradermal neutralization testing, intracutaneous provocative food testing (IPFT), provocation-neutralization treatment, provocation-neutralization testing (P/N), provocative food test, as well as symptom-provoking and relieving food test. This paper is authored by Lisa A. Lundy, Anne's biological mother, and as such the reference to "I" in this paper refers to me. The references to "we", "our", and "us" in this paper refer to my Husband of nine years, Randy, and myself. We have intentionally excluded the names of several physicians from this paper as some information in this paper may not reflect those physicians in the best light and we are not out to malign anyone's character or reputation. This paper shall address the following issues:

1. Historical background of food allergy
2. Medical background of the family and of Anne
3. Effectiveness of said allergy services for Anne
4. Dispelling the Myth that there is any real controversy in this field of science
5. The Issue of Medical Necessity
6. Rationale for why these allergy services are not experimental or investigational
7. Rationale for discriminatory reimbursement policies and practices
8. Summary

1. Historical background of food allergy

It is relevant, pertinent, and quite important to provide a brief review of the history of food allergy. For more than two thousand years there has been medical recognition that food can cause illnesses, diseases and health concerns for some people. Hippocrates was a Greek physician who is considered to be the *Father of Medicine* according the Merriam Webster Dictionary. Over two thousand years ago Hippocrates¹ wrote about the negative effects that food could have on different people:

"For cheese does not prove equally injurious to all men, for there are some who can take it to satiety, without being hurt by it in the least, but, on the contrary, it is wonderful what strength it imparts to those it agrees with; but there are some who do not bear it well, their constitutions are different, they differ in this respect, that what in their body is incompatible with cheese, is roused and put in commotion by such a thing; and those in whose bodies such a humor happens to prevail in greater quantity and intensity, are likely to suffer the more from it. But if the thing had been pernicious to the whole nature of man, it would have hurt all."

¹ Adams, Francis. *The Genuine Works of Hippocrates*. Baltimore: Williams, 1939.

Historically, physicians were recognized for being able to treat their patients' illnesses by diet manipulation. An example of this written about 200 years ago and credited to Matthew Baillie² is as such:

"To judge of the true skill and merit of a physician requires a competent knowledge of the science of medicine itself; but to gain the good opinion of the patient or his friends, there is perhaps no method so ready as to show expertness in the regulation of the diet of the sick. Discretion and judgment will, of course, be required; the rules should not be unnecessarily severe or rigid, otherwise they will not be followed; but the prudent physician will prescribe such laws as though not the best, are yet the best that will be obeyed."

Moving into the early 1900's there is a plethora of medical writings that support the fact that foods are a problem for some individuals and can cause a whole host of medical illnesses and diseases. One of the physicians who made substantial contributions to the area of food allergies was Dr. Francis Hare of Brisbane, Australia. In 1905 Dr. Hare wrote a two-volume 1,000 page book titled *The Food Factor in Disease*³ which was a result of his observation in 1889 that migraine headache incidentally was relieved when the patient was put on a special diet that largely excluded fats, carbohydrates, and saccharine alcoholic drinks. Dr. Francis Hare sought to explain that a whole host of diseases were related to food allergies including migraine, asthma, gout, nervousness, epilepsy, mania, dyspepsia, biliousness, headache, bronchitis, eczema, hypertension, gastrointestinal disturbances and other degenerative diseases.

But Dr. Hare was only one of many physicians that were discovering what Hippocrates had written over two thousand years ago. **In 1906, Dr. Clemens Von Pirquet⁴ suggested the use of the word "allergy" to describe an inappropriate reaction to food or other substances not typically harmful or bothersome.** A physician in England, Dr. Alfred Schofield, wrote in 1908 about successfully treating a boy who suffered from angioedema and asthma because of an allergy to eggs.⁵ This egg desensitization was confirmed by Dr. Keston, Dr. Walters, and Dr. Hopkins.⁶ Thus, nearly one hundred years ago physicians were successfully treating patients with food allergies.

New York physician Oscar Schloss reported a similar experience as that of Dr. Schofield in 1912.⁷ In 1917, the *Journal of Urology* published an article by Dr. Longcope and Dr. Rachemann describing six patients who reacted to foods with urticaria and renal insufficiency.⁸ The *Archives of Internal Medicine*, *Journal of the American Medical Association*, and *Annals of Clinical Medicine* would all publish medical articles on the relationship between food and medical illnesses by Dr. W. W. Duke from 1921 to 1923.^{9 10 11}

² MacMichael, William. *The Gold-Headed Cane*. New York: Hoeber, 1926. p. 223.

³ Hare, Francis. *The Food Factor in Disease*. London: Longmans, Vol. I, II, 1905.

⁴ von Pirquet, C. Allergie. *Munch Med Wochenschr* 52:1457, 1906.

⁵ Schofield, Alfred T. *A Case of Egg Poisoning*. London: *Lancet*, 1908, p. 716.

⁶ Keston, B, Walters, I & H, Gardner J. Oral Desensitization to common foods. *J Allergy* 6:431, 1935.

⁷ Schloss, Oscar M. A Case of Allergy to Common Foods. *Am J Dis Child*, 3:341, 1912.

⁸ Longcope, W.T., and Rachemann, F.M. Severe renal insufficiency associated with attacks of urticaria in hypersensitive individuals. *Journal of Urology* 1:351, 1917.

⁹ Duke, W. W. Food allergy as a cause of abdominal pain. *Arch Int Med* 28:151, 1921.

¹⁰ Duke, W. W. Food allergy as a cause of bladder pain. *Ann Clin Med* 1:117, 1922.

A major contributor to the study and advancement of food allergies was Dr. Albert Rowe who in 1931 published a book called *Food Allergy: Its Manifestations, Diagnosis, and Treatment*.¹² Dr. Rowe documented that food allergies can cause a wide range of symptoms affecting any part of the body, and that allergies can show up at any age. Forty-One years later, Dr. Rowe and his son co-authored another book on food allergies titled *Food Allergy: It's Manifestations and Control and the Elimination Diets – A Compendium*.¹³

Dr. Warren T. Vaughan began studying food allergies in 1932. Dr. Vaughan studied an entire village of 508 people who lived in and around Clover, Virginia in 1934. Of the population that he studied, ten percent had allergies severe enough to require medical attention and another 50 percent had minor allergies, which meant that 60 percent of the population studied, had some degree of allergy. Dr. Vaughan took his survey one step further and looked at the possible causes for the allergies. Out of the 60 percent of people who had major and minor allergies who where were able to attribute symptoms to definite causes..."62.6 percent reacted to foods, 23 percent to inhalants, and 14.4 percent to contact allergies."¹⁴

In 1941, Dr. Vaughan published a book called *Strange Malady*¹⁵ in which he presents the multiple manifestations of food allergy and the interplay of food reactions with other environmental exposures and concealed excitants. In *Strange Malady* Dr. Vaughan states three key points: **food allergies or sensitivities are the most common form of human allergy, a person can become sensitized to any food, and it is unusual to be allergic to just one food.** Several years later in 1948 Dr. Vaughan published a book called *Practice of Allergy*¹⁶ further adding to the knowledge of food allergy that already existed.

Also making additional substantial contributions to books published on the topic of food allergies and allergies in general was a Dr. Arthur Coca. Dr. Coca authored *Familial Nonreaginic Food Allergy* in three editions, which were published in 1942,¹⁷ 1945,¹⁸ and 1953.¹⁹ One of Dr. Coca's significant observations was that exposure to food allergens resulted in a change in the pulse of the human body. *The Pulse Test* was published as a tool for the layman in 1956.²⁰

The Pulse Test outlines the direct relationship between food allergies and backaches, headaches, epilepsy, diabetes, ulcers, hemorrhoids, obesity, hives, fatigue, migraine, high blood pressure, depression, and even multiple sclerosis with the most fascinating case histories and references to successfully treated patients.

¹¹ Duke, W. W. Meniere's syndrome caused by allergies. *JAMA* 81:2179, 1923.

¹² Rowe, Albert H. *Food Allergy: Its Manifestations, Diagnosis, and Treatment*. Philadelphia: Lea & Febiger 1931.

¹³ Rowe, Albert H., and Rowe, A. Jr. *Food Allergy It's Manifestations and Control and the Elimination Diets – A Compendium*. Springfield: Thomas, 1972.

¹⁴ Vaughan, Warren T. *Practice of Allergy*. St. Louis: Mosby, 1948.

¹⁵ Vaughan, Warren T. *Strange Malady*. New York: Doubleday, 1941.

¹⁶ Vaughan, Warren T. *Practice of Allergy*. St. Louis: Mosby, 1948.

¹⁷ Coca, Arthur F. *Familial Non-Reaginic Food Allergy* 1st edition, Springfield: Thomas, 1942.

¹⁸ Coca, Arthur F. *Familial Non-Reaginic Food Allergy* 2nd edition. Springfield: Thomas, 1945.

¹⁹ Coca, Arthur F. *Familial Non-Reaginic Food Allergy* 3rd edition. Springfield, Thomas, 1953.

²⁰ Coca, Arthur F. *The Pulse Test*. New York: Arco 1956.

Dr. Arthur Coca was not just any other allergist who discovered that food allergies had a significant relationship to illness, diseases, and health and well being. Dr. Coca had more accomplishments than most medical physicians ever dream of. Dr. Coca was the founder and first editor of the *Journal of Immunology*, which is still the foremost medical publication in its field. He also served on the editorial boards of the *Journal of Allergy*, the *Journal of Investigative Dermatology*, and the *Journal of Applied Nutrition*. He taught at Cornell, the University of Pennsylvania and Post-Graduate studies at Columbia University. He was also Honorary President of the American Association of Immunologists. And he was a member of many other medical organizations like the American Association for Cancer Research, the American Society for the Study of Allergy, and the Society for Experimental Biology and Medicine. Dr. Coca and the other pioneers in allergy were no ordinary physicians; they had more credentials than most physicians had at the time or have now in current day time.

Yet another major contributor to the field of food allergies was a physician by the name of Dr. Herbert Rinkel. In the 1930's Dr. Rinkel described the very nature and cyclic concept of food allergy, the individual deliberate feeding test, and the rotary diversified diet. *Food Allergy* published in 1951 by Dr. Rinkel, Dr. Theron G. Randolph, and Dr. Zeller was a comprehensive book covering the nature and cyclic concept of food allergy, the deliberate feeding test and the rotary diet.²¹

According to Dr. Lawrence D. Dickey²², "Dr. Rinkel's last major contribution had to do with the symptom-provoking and relieving food test which was presented at the First International Congress on Food and Digestive Allergy in 1963,²³ nine days after his death. Dr. Rinkel's presentation was delivered by Dr. Dor Brown." It should be noted that Dr. Rinkel and co-authors work was presented at the First International Congress on Food and Digestive Allergy which speaks to the international recognition that exists for Dr. Rinkel, et al's work. It also speaks to the global recognition that food allergies are a significant problem.

Dr. Rinkel's observations of reactions to 2-closely spaced feedings after at least 4-1/2 days of avoidance can be traced back to Hippocrates who wrote over two thousand years ago:

"Such persons, provided they take dinner when it is not their wont, immediately become heavy and inactive, both in body and mind, and are weighed down with yawning, slumbering, and thirst: and if they take supper in addition, they are seized with flatulence, tormina, and diarrhea, and to many this has been the commencement of a serious disease, when they have merely taken twice a day the same food which they have been in the custom of taking once.".....

Hippocrates also wrote:

"...if a patient fast for the first two or three days and take food of a heavy nature on the forth and fifth, he will be much injured."²⁴

²¹ Rinkel, H.J, Randolph, T.G., and Zeller, M. *Food Allergy*. Springfield: Thomas, 1951.

²² Dickey, Lawrence D., The food factor in disease: its history & documentation. *Clinical Ecology*. Vol. 1, No. 2, pgs 67-68. Fall/Winter 1982-83.

²³ Rinkel H.J., Lee CH, Brown, D Jr. Willoughby JW, and Williams JM. The Diagnosis of food allergy. *Arch Otolaryng* 79:71:, 1964.

²⁴ Adams, Francis. *The Genuine Works of Hippocrates*. Baltimore: Williams, 1939.

An internationally known and renowned allergist who made remarkable contributions to the field of allergy was a Dr. Theron G. Randolph. While Dr. Randolph did not begin in private allergy practice until 1939, his interest in allergy was clearly evident when he attended a national allergy meeting during his senior year of medical school in 1933. During that same time he also attended a national meeting of the American Association of Immunologists, and heard the presidential address of Dr. Arthur F. Coca, a man Dr. Randolph would later become friends with. Dr. Randolph was the third person trained through a Fellowship offered by the Harvard Medical School and Massachusetts General Hospital.

Dr. Randolph's bibliography of published articles and presentations is both extensive and diverse. Throughout the course of his career, Dr. Randolph published and presented over 393 articles, books, or presentations.²⁵ He was internationally known making many presentations to international meetings like the 1st and 3rd International Congress of Social Psychiatry, the First International Congress on Food and Digestive Allergy in Vichy, France, and 3rd World Congress of Psychiatry to name a few. Dr. Randolph was also called upon to provide his testimony to the United States Government on several different aspects of allergy during the course of his brilliant career. A career which incorporated relationships with Dr. Coca, Dr. Rowe, and Dr. Rinkel.

To put the medical research of the early 1900's into perspective relative to life at that time, life was very, very different. At the turn of the century there were no cars zooming around the United States as that would come later. Henry Ford founded the Ford Motor Company in 1903 with the first Model "T" being produced in 1908. The Manhattan Bridge would not be completed until 1910, and the Holland Tunnel and Lincoln Tunnel, two tunnels connecting New York State and New Jersey for automobile transportation would not be completed until 1927 and 1937 respectively. A refrigeration process for meat cargoes was not developed until 1934, which meant that you had to obtain your meat from a place close to where you lived.

In these early days of medicine and allergy, there were no computers, no short wave radio, no Televisions, and no mass transportation systems. But there was also no pollution from automobiles, trains and airplanes, no preservatives or mass produced foods, no chemicals and no pesticides. There was no plastic. Life was radically different in the early days of medicine. A Physician would make an observation in his or her medical practice, from which he or she would develop a theory or hypothesis. The physicians of the time would then test their theories out with the patients that they cared for. Physicians practiced independently prior to the advances of the railways, automobiles and airplanes. Yet, for over two thousand years physicians independently came up with the same conclusions all over the world: food allergies can cause illness, disease and poor health.

There was also a recognition that people react differently to foods, and that a food, which is a problem for one person, may not a problem for another person. In the past physicians were judged by their ability to treat their sick patients by diet manipulation. There was complete medical agreement that food allergies could cause nearly every disease and illness known to

²⁵ Randolph, Theron G. *Environmental Medicine-Beginnings & Bibliographies of Clinical Ecology*. 1987. Clinical Ecology Publications, Fort Collins, CO. Pgs 349-357.

man. But of course, this was all years before the advent of the Food and Drug Administration, the availability of pharmaceutical drugs, pollution, pesticides, and chemicals.

The vast majority of the current medical profession knows little or nothing about food allergy symptoms, the ways that foods can negatively impact an individual's health and the diseases related to food allergies. The current medical profession knows more about dispensing a pharmaceutical drug than they do about food allergies. It is certainly less expensive, not to mention less invasive to rule out food allergies in the course of helping a patient who is experiencing health concerns. However this is never routinely done in the present medical establishment.

Most allergists only test for IgE (immediate and more serious) allergies which accounts for only 5-10% of food allergies. And most people with serious and immediate reactions already know that they have a problem with food and they also usually know which food is the problem. It has been stated that IgE mediated food allergies will present within one hour of food ingestion. Delayed food allergies account for 90-95% of food allergies, and this is the one area of allergy that is sadly lacking in terms of the availability of treatment options, recognition of prevalence, and acknowledgement of the wide variety of illnesses, and diseases that are due to the delayed allergies. Medically it is documented that delayed food allergies are the most difficult to pinpoint because of the cyclic nature of their being and because of a medical phenomenon called "masking".

Some delayed food reactions will not appear for several hours while other delayed reactions to foods will appear only after two or more days. Therefore without a complete elimination diet or medical testing it is nearly impossible for a patient to discern if a reaction experienced from food was from food eaten that day or days prior. Elimination diets are difficult for patients to do and are impacted by noncompliance. Deliberate food tests or challenges are extremely time and labor intensive and have other issues as well. It was because of this exact issue that more precise and comprehensive testing, intradermal neutralization testing, came into being.

A relatively recent study demonstrated that 93% of 88 children with severe, frequent migraine recovered on a special diet.²⁶ Another article reviews 40 children with severe eczema who had not responded to conventional treatment; 100% of these 40 children improved on a hypoallergenic diet.²⁷ These medical conditions have been historically proven to be related to food allergy. Yet, in present day time, it is as if the authors of such studies have "discovered" some new phenomenon.

The list of physical illnesses, diseases and health related problems that can be explained primarily by this type of allergy includes asthma, hay fever, itchy skin, headaches, fatigue, nausea, vomiting, hives, stomach pain, irrational behavior, edema (swelling), hyperactivity, muscle pain, joint pain, reflux esophagitis or acid reflux, back pain, acne, phlebitis, arthritis, anxiety, mood swings, dizziness or tingling sensations, diarrhea or persistent bowel problems, bad breath, constant congestion, irritating twitches, eczema, depression, inability

²⁶ Egger J, Carter CM, Wilson J, Turner4 MW & Soothill JF. Is migraine food allergy? A double-blind controlled trial of oloantigenic diet treatment. *Lancet* 2:865-869. 1983.

²⁷ Hathaway MJ, Warner JO. Compliance problems in the dietary management of eczema. *Arch Dis Childhood* 58:463, 1983.

to concentrate, and behavioral and emotional problems to name just a few. While there is no question that currently there is no mainstream conversation about the importance of and impact of food allergies on health, illness and disease, that fact does not erase over two thousand years of medical literature, research, and proof that food allergies can be a serious problem to many people.

2. Medical Background of the Family and of Anne

Anne's Mothers' Allergy History

Prior to addressing Anne's medical history it is relevant and necessary to discuss the family history of allergies. I, Lisa Lundy, Anne's biological mother, had allergies as an infant and was receiving allergy shots by the time I was 18 months of age. My parents sought allergy treatments when the family physician ruled out all other types of disease and infection for me. From birth I suffered from constant head congestion, wheezing, mucus discharge, and vomiting, as well as other symptoms. Allergy testing revealed allergies to several foods and some environmental factors, which were primarily dusts, molds, animal dander, and feathers.

My parents drove me as a toddler to an allergist more than an hour away since we were living in rural Pennsylvania at the time of my birth. Later when our family moved, my parents found themselves driving more than 1 ½ hours, one way, to see an allergist able to treat me. The field of allergy back in the early 1960's was not as it is today where there is an abundance of allergists.

I received allergy shots for sixteen years until age 18 when my allergist released me from treatment. My allergy treatment has proven to be extremely successful over my lifetime since I have not needed seasonal allergy medication, and am in excellent health. I do however remain anaphylactically allergic to tree nuts and penicillin and allergic to a lesser degree to cats, and feathers, a fact that I had discussed with my allergist at the time of my discharge from allergy treatment at age 18. I come from a family where my Father and 50% of my siblings have allergies of varying degrees. Additionally, several of my nieces and nephews also have food and other allergies.

Luke's Birth

Prior to having children, I had a myomectomy to remove a 19-cm fibroid tumor that weighed nearly 2 pounds and was 8 times larger than my uterus. This myomectomy necessitated that any children born to me and my husband would be born by Cesarean Section and born at or around 37 week's gestation to prevent uterine rupture. My first born son Luke, was born by C-section with perfect Apgar scores, and no health concerns. Luke was exclusively breast fed. By around two months of age, Luke was suffering from constant diaper rash, which no medical measures seemed to help.

We followed all of the medical recommendations for diaper rash including airing out the diaper area and not wearing any diaper at all, which was not an easy feat. It was not until around age 6 months when someone mentioned that the diaper rash could be related to my diet that things improved dramatically with Luke's diaper rash problem. I immediately removed dairy, tomatoes, onions, garlic, and a number of other foods from my diet and Luke's diaper rash resolved right away. When I ate "problem" foods Luke's diaper rash would

reappear immediately, and clear right away if the offending foods were eliminated from my diet. It was the most amazing phenomenon to us knowing very little about food allergy symptoms in a nursing baby.

I began weaning Luke at age 10 months only to find out that the milk-based formula we tried gave Luke diarrhea. Luke was ultimately weaned at one year to a soy formula after several other formulas also produced diarrhea. We avoided milk-based foods for Luke and he thrived.

Noah's Arrival and Medical History

Luke became a big brother with the birth of baby Noah who also arrived by C-section around 37 week's gestation. Both Luke and Noah weighed in at about 7 ½ pounds despite their early arrivals. Noah was in great health and nursed very well from the start. In the hospital Noah only cried if he was hungry or if his diaper was being changed. Due to the C-section, I had been denied solid food while in the hospital until the morning of Noah's discharge when I was finally given pizza and other solid foods. Because it had been three days since I had eaten solid food, I was starving. I ate every morsel of food on the hospital lunch tray as I was waiting for my discharge papers.

Once I got home, I ate again still hungry from my three days of fasting. Several hours after we arrived home from the hospital, Noah cried for no apparent reason. He had been fed, and changed, and he was not tired or over tired. It seemed strange that he would be crying for no apparent reason since he had not done that at the hospital. The more I thought about it I could not believe that our home was the source for his crying. After all our home was quiet compared to the noises at the hospital and was certainly more interesting as far as visual stimulation went, and surely it smelled much better than the hospital. There had to be some other reason for his crying.

What else had changed besides our location? It finally hit me like a ton of bricks. I had not been eating food until just prior to our departure from the hospital. Noah's crying could be related to me now eating food! As an experiment I then began avoiding all spicy foods, foods with onion, garlic, and several other ingredients, and Noah ceased his crying.

When baby Noah was two weeks old we had pancakes for dinner one evening which were prepared from scratch using whole wheat flour, toasted wheat germ, rolled oats, eggs, and soy milk. Several hours later Noah screamed inconsolably for about 4-5 hours non-stop. It was frightening. Noah did not have a fever, did not have any signs of a cold or illness, and except for the screaming everything else seemed normal. He was so upset and nothing would calm him down. Again, I evaluated what could have prompted this outburst of screaming? I suspected that it could have been the pancakes, however that was very difficult for me to believe because whole wheat, toasted wheat germ and rolled oats are very healthy foods, and seemingly so benign. I wondered if it could have been the maple syrup. Later I would notice that Noah's bowel movements were mucus laden, not normal in color, and extremely odorous all of which were extremely abnormal for him.

THE NURSING NIGHTMARE BEGINS

The crying episode prompted a visit to the Pediatrician as soon as it could be arranged. Noah was quickly diagnosed with Gastroesophageal Reflux Disease (GERD) or acid reflux

and we were instructed to give him Maalox, and to keep him upright for 20 to 30 minutes after every feeding. Additionally we were told to elevate the head of his crib a few degrees. We asked the doctor whether Noah's symptoms could be related to my diet to which the pediatrician stated emphatically that it could not be related to what I ate. We had no reason to doubt our pediatrician's knowledge on food allergies or any other medical situation so we complied with the physician's instructions trusting that he knew what he was talking about. As a result of the diagnosis of reflux or GERD, I did not change my diet other than to continue to abstain from the foods that I had already removed. **After all, I had already been reassured that it could not be related to what I was eating.**

At nearly two-months of age Noah began crying at the breast and refusing to nurse. Since we were keeping a nursing log as we had been told to do while we were in the hospital we were able to see how Noah had reduced his nursing time by 50% in one week's time. Alarmed, we again visited the pediatrician who again reassured us that it was a simple case of acid reflux or GERD, and that a stronger medication, Zantac Syrup was in order. We willingly filled the Zantac syrup prescription and after checking with a pharmacist friend to make sure it was harmless, we gave it to Noah.

The Zantac syrup made no noticeable difference in Noah. And our life was getting worse by the minute. Now just two months old, Noah was refusing to nurse at all unless he was asleep at night. Nursing at night was not a problem, but when he was awake he would refuse to nurse. Noah refused to take a bottle making the situation worse. I consulted with a lactation consultant who advised that if I was pretty sure his condition was related to food allergies that his situation could be much worse if he was on formula. I discussed this with our pediatrician who was in complete agreement with the lactation consultant. While no one seemed to be offering us with solutions on what to do or how to fix the problem, there was at least some consensus that it would be in our best interest to continue nursing Noah.

Now worried because Noah was not having enough wet diapers and getting any breast milk into him was a problem except when he was asleep, we devised a scheme to get Noah asleep during the day so he could then be nursed. We would put Noah in the baby swing on the highest speed setting and played moderately loud music. The combination of the music and the fast swinging inevitably put Noah to sleep. Then after Noah was asleep for approximately 30 or so minutes, I would turn off the music and get Noah out of the swing taking extreme caution not to wake him. I would then nurse him on our bed while he was asleep.

While it was not the same type of vigorous nursing that Noah would do while he was awake, it was better than nothing. The plan worked reasonably well unless Noah happened to wake up before I had gotten him on the bed and he was nursing. Then we had a major problem as we had a hungry baby who refused to eat. I would then pump, but getting Noah to drink the milk was always a problem because wanted nothing to do with the bottle. We tried sippy cups, regular cups, and even resorted to using an eye dropper to get the breast milk into Noah on those "failed" occasions when he woke up too soon. With this unreliable feeding plan and several occasions where Noah did not eat, we soon purchased a baby scale that weighed by the ounce so that we could monitor Noah's weight in between doctor appointments and make sure that he was at least maintaining his weight. Noah was barely

producing enough wet diapers during the day so the baby scale provided an additional element of feedback for us.

Life for us as we knew it fell apart. We could not take a trip or even go to the mall or out to dinner because of the feeding problems with Noah. We could not even have people over because the whole entire house had to be drop dead quiet while I got Noah out of the swing or I was sunk. The whole day revolved around getting Noah to sleep in the baby swing just so that I could get him back up and nurse him. It was an emotionally grueling time like I had never experienced. It was a nightmare for the entire family including 2 ½ year old Luke who had to learn very quickly that he had to be quiet and not wake Noah during the swinging/feeding process. We were worried sick about sustaining his weight and wondering what we would use as a formula when I stopped nursing him.

We consulted with the pediatrician again this time being more forceful with the doctor about our observations relative to my diet and Noah's physical disposition, crying, bowel movements, etc. We asked the pediatrician if Noah might have Celiac disease to which the Pediatrician laughed. The pediatrician told us that Celiac Disease was extremely rare in the United States, and there was only a one in 500,000 chance or one in one million chance that Noah could have Celiac Disease. We were at the time quite relieved.

A VERY DANGEROUS DRUG

It would be much later that we would come to find out that Celiac Disease affects 1 out of every 133 healthy Americans, a far cry from the 1 in 500,000 or 1 in 1 million that we had been told by our pediatrician. Noah's pediatrician recommended a hospital scintiscan test and a stronger prescription drug called Propulsid. We were a little leery about both suggestions and told him that we would think about it. In the meantime we called our pharmacist friend to see if the pharmacist could get medical information on Propulsid for us.

Our pharmacist friend called the pharmaceutical manufacturer of Propulsid and was able to obtain concrete information regarding safety and effectiveness relative to adult and pediatric use. Propulsid was associated with cardiac deaths in adults and children, and our pharmacist friend did not recommend it as Noah was not in imminent danger, and the risks far outweighed the benefits given Noah's current state of health. We gave our pediatrician the 20 plus pages that the pharmacist had obtained for us from the drug manufacturer, and declined to put Noah on Propulsid. Propulsid would later be withdrawn from the market by the Food and Drug Administration after having caused over 200 pediatric and adult deaths in the U.S.

With Propulsid dropped as an option, we decided to go ahead and have the hospital scintiscan test done because this test might give us some answers. This 45-minute test which measures acid reflux and stomach emptying time was done when Noah was about 5 months old. Noah screamed for the first 30 minutes to the point that I thought that he was going to stop breathing. The hospital technicians however refused to stop the testing even at my repeated requests. Noah eventually stopped crying, and the scintiscan test provided conclusive evidence that **Noah did not have any acid reflux and that his stomach emptying time was definitely well within normal limits.**

It was only after the scintiscan test that the pediatrician agreed that Noah's problems might well be related to my diet. It was only after acid reflux or GERD had been completely ruled out that we discovered through our own research that the symptoms of food allergy in a nursing baby and the symptoms of GERD or acid reflux are exactly the same! It was a shock to lay the symptoms of both food allergies and acid reflux side-by-side and see them match up perfectly. It made me wonder how many other infants with actual food allergies were being mistakenly diagnosed with acid reflux or GERD.

THE TRIALS OF FEEDING NOAH

Shortly after the Scintiscan test our nursing plan fell apart as Noah would no longer fall asleep in the swing. I then began pumping every daytime feeding and using the sippy cup, occasional bottle and any means possible to get Noah to drink the breast milk. Noah was still nursing at night which is where he got the majority of his calories judging from the wet diapers at night versus daytime wet diapers. At about 6-months of age, Noah weaned himself from the nighttime feedings, and we scrambled around to find a formula that Noah could tolerate.

We began with the most "hypo-allergenic" formulas, which Noah refused to drink. The worst smelling one gave him the dry heaves. When we had exhausted the commercially made formulas, and with no additional suggestions from either the pediatrician or the local Children's Hospital Feeding Clinic, we tried a rice milk beverage. Noah seemed to tolerate this and we quickly added baby rice cereal for added calories and nutrition. At no time did the pediatrician make recommendations for fortifying the rice milk with essential fatty acids, probiotics, or other vitamins and minerals.

The Pediatrician recommended that Noah begin baby oatmeal at his 6-month check up. I, of course, followed the doctor's advice and gave him 1 tablespoon of baby oatmeal mixed in with his baby rice cereal. The first time Noah ate the baby oatmeal he had projectile vomit immediately after he finished eating. Never suspecting the oatmeal I surmised that I must have jostled him when I got him out of the highchair. I decided to pay more attention to how I got him in and out of the high chair. The second, third, and fourth day that Noah had baby oatmeal he had projectile vomit after each meal that contained the baby oatmeal. I had only given Noah the oatmeal one time per day and he only had the projectile vomit once a day immediately following the oatmeal. Noah had no indications of a cold or infection: no fever, no rashes, no congestion, no cough, no sign of illness what so ever. On the fourth day of the projectile vomit, I decided that Noah's vomiting had to be related to the oatmeal because I had been extra careful in getting him in and out of the high chair after meals. The baby oatmeal was stopped and so stopped the projectile vomiting.

From that point forward, I paid much more attention to Noah's reactions to foods both during feeding time, and afterward. I would later learn that some of the foods that Noah absolutely refused to eat were in fact foods that he was allergic to. From ages 7 to 12 months we experimented with foods. We researched allergies to "wheat" and "oats" and learned more about Celiac Disease. A scrap of wheat toast the size of an adult pinky finger would produce an upset stomach in Noah a few hours after ingestion, diarrhea, gas, abdominal pain, and an eczema like rash on his skin primarily on his arms and legs. With that reaction I quickly researched gluten free cooking and began accumulating the necessary gluten free flours to make carbohydrates that Noah would need for his diet.

Around May 2000, Bette Hagman, the premier gluten free cookbook author, came to Buffalo to give a speech to the local Celiac support group. I was lucky enough to find out that Bette Hagman was coming to Buffalo and I went to hear her talk. At Bette's presentation I met another mother who also had her child on the gluten free and milk free diet for therapeutic reasons related to Autism. She invited me to join a local gluten free, casein free diet support group that had recently formed for parents of Autistic children doing the "Diet". Even though I did not have a child with Autism or any other type of delay, I was welcomed into the group. This group was extremely valuable in that it got me out of the house one evening a month and I was surrounded by other mothers experiencing the same food concerns that I had.

It was by and large an enormous learning experience for me because prior to my involvement with this diet support group I had never personally known families with autism, PDD, PDD-NOS, ADD, ADHD, and other global developmental delays. I am truly grateful that I was welcomed into the group as I have learned so much about delays, autism, and other types of labels. It helped to lift my spirits because it is always humbling to realize that other families have bigger problems than you do.

By the time Noah was 14-months old, I was sure that Noah either had Celiac Disease (or was simply gluten intolerant) or that he was allergic to wheat, barley, rye, and oats. Additionally, I was sure that Noah was allergic to soy, eggs, milk, banana, and peanuts because of his reactions to those specific foods. The upset stomach was gauged by Noah lying on the floor holding his stomach and crying, and by his refusal to eat for 24 hours after he had ingested an "offending" food. Typically, an offending food also produced diarrhea, and in some cases stool that was so hard you would consider it to be petrified or rock-like. He would have dry eczema-type patches of skin erupt on his arms and legs. And usually when Noah had eaten a food that he was allergic to he would always wake up at night crying.

We again consulted with our Pediatrician regarding Noah's food allergies. We requested IgG food testing since we were sure that Noah's food allergies were not IgE mediated. The pediatrician stated that there was no such thing as IgG mediated testing, and instead ran the following foods as IgE: wheat, oats, barley, rye, eggs, milk, peanuts, soy, and banana. When the blood test came back the pediatrician called to tell me that I was nuts, that I was wrong, and that Noah could eat all of the foods that we had tested. It was only after we picked up the blood tests that we realized that the test had been for the immediate IgE reaction and not the requested IgG testing (delayed reaction).

I learned how to bake without wheat, oats, barley and rye and without milk, eggs, and soy out of necessity. Part of the reason that I continued to test, retest and challenge Noah's diet to confirm his food allergies is because I am somewhat selfish. If Noah could have store bought cookies, breads and crackers then I would not need to make them. And while I like to bake more than some people, I did not sign up for making all of my children's foods when I had them. Soy, eggs and milk are found in many of the gluten free products. I had other things that I wanted to do with my time than spend all day in the kitchen baking crackers, cookies, breads, rolls, and making homemade non-dairy ice cream.

We did research on allergies focusing on the delayed or Type II, III and IV allergy classes. We called most of the local allergists to see if they did IgG testing. The local allergists that

we contacted did not do IgG testing, nor did they typically see children under three because the skin prick/RAST testing is unreliable for children under the age of three. We needed help in figuring out what to feed Noah, and there seemed to be reasonable information available regarding IgG and delayed food allergies. We just could not find a local source for IgG testing and support.

More Medical Misinformation

Ruling out Celiac Disease was still an issue for us so in the fall of 2000 we were able to get a referral to a pediatric gastroenterologists at our local Children's Hospital. The pediatric GI specialists after taking Noah's medical history and doing an examination recommended that we feed Noah gluten for **two days** and then the GI specialists would do a biopsy of the small intestine. We were stunned and horrified to hear this recommendation because it was completely in error according one of the lead Celiac physicians in the United States.

Prior to seeing our local GI specialists we had consulted with Dr. Peter Green of the Celiac Disease Center at Columbia (Columbia University College of Physicians and Surgeons in New York, NY), who is recognized for his expertise in Celiac disease and leads one of the top three facilities in Celiac Disease in the U.S. Dr. Peter Green had indicated that in a case like Noah, we would have to feed Noah gluten for an extended period of time possibly for three or more months, up to perhaps six months before a valid biopsy could be conducted.

A Ph.D. researcher that I contacted who has considerable expertise in the area of Celiac disease and testing reinforced Dr. Green's evaluation and recommendation. This researcher stated that no one would be able to tell me how long Noah would have to eat gluten to get a reliable biopsy, but it was a certainty that Noah would have to be ingesting gluten on a daily basis for more than three months.

It was therefore obvious to us given our research that the local pediatric GI specialists knew less about Celiac disease than we would have hoped or expected. We chose not to argue with the doctor and simply declined to have the biopsy done for Noah. And we were back to figuring things out for ourselves again.

Getting Noah IgG tested for food allergies

We eventually found a way to get Noah's blood tested for IgG mediated food allergies although it would mean driving out of State to get the blood drawn. New York State is the only State in the U.S.A., which does not allow for IgG blood work to be done by most out-of-state facilities. Every other State in America allows for IgG blood draws for food allergy testing. This has to do with regulatory issues and licensing issues that only New York State has relative to IgG blood testing. Since we were unable to find a way to have the IgG blood work done in New York, and our Pediatrician was not supporting IgG testing we felt that we would have to make other plans to get this testing done.

By Noah's second birthday, we had made arrangements to drive 4 ½ hours one way to Central Pennsylvania and have Noah's blood drawn to have about 96 foods IgG tested. Prior to the trip, I made sure to give Noah as many of the foods that bothered him as I could since we believed that this might provide better test results. Two days before the trip, Noah was waking up at night crying. The night before the trip he could hardly sleep because he was up crying half of the night.

Noah's IgG blood test results showed that he was allergic to: wheat, oats, barley, rye, milk, eggs, soybeans, bananas, peanuts, coconut, pumpkin, mustard, tomato, rice, canola, and sesame. At long last, we had some technical test results that confirmed our suspicions. Interestingly enough, there was no way for the lab to influence the test results because the testing lab had no prior knowledge as to what foods we suspected were a problem.

We were shocked to see that rice and tomatoes were on the list and later we speculated that Noah's problem with rice showed up because rice had been 85% of his diet for the past 18 months. Noah had eaten rice every single day, 3 to 4 times a day for the last year and a half. Noah had also eaten a fair amount of ketchup on a regular basis. When all the allergenic foods were removed from his diet, Noah was a happy, well-adjusted child who slept well at night and was thriving. If Noah ate a small amount of food that he was allergic to he turned from a sweet and easy child into a high-maintenance, unhappy, irritable child that would cry for no apparent reason. It was like the difference between an angel child and a monster.

It has been suggested that one of the reasons that I was able to make all of these observations regarding Noah and food allergies is because I am a stay-at-home Mother who also happens to have a food allergy myself. There is no doubt that those two factors were at play, however Noah is probably much more reactive than many children experiencing IgG food allergies. Even the most oblique of individuals as he became a toddler could not miss the change in his demeanor and personality that would occur after he had eaten an offending food.

Ruling Celiac Disease in or out

In the spring of 2003 I spoke to the Program Director at the University of Chicago Celiac Disease Program relative to Noah and his long-standing problem with gluten with the hopes that she could provide some insight as to what we might do. Basically I wanted to rule out Celiac disease if I could from the perspective that a small amount of gluten would not hurt Noah if he only had gluten intolerance or allergies to the foods. On the other hand, if Noah had Celiac Disease, ingesting gluten would put him at some risk for other autoimmune diseases, cancer and neurological problems. Thus, it was important to us to rule Celiac disease either in or out. The Program Director was interested in what I had to say, and indicated that Noah was the perfect candidate for Celiac genetic testing, something that is not typically recommended because the highest majority of patients with the Celiac gene (93-95%) *never actually get Celiac disease*.

We took the necessary steps to have Noah genetically tested for Celiac using an in-network laboratory. The lab test results however tested for different genes than the genes that the University of Chicago Celiac Disease Program states are the Celiac genes, so this issue is at present unresolved. The test results along with a research paper from the laboratory are being sent to the University of Chicago Celiac Disease Program office. The Program Director did state that if Noah **had the Celiac genes** then they would consider him a "confirmed" diagnosis.

Now as a 4 ½ year old, Noah's physical demeanor and disposition changes radically if he has rice, apples, grapes or any juices containing apples and or grapes, and cheese to name the biggest offenders. There is no doubt whatsoever that if Noah was not on a diet that excludes

foods that he is allergic to that he would have some medical “label”, and not a good one. With a restricted diet he is a happy, thriving child with no disorders or problems other than that of food allergies and the possibility of Celiac Disease.

Anne’s Birth & History

Had we trusted our original OB-GYN, Anne would have been dead before she was even born. Our first daughter, Christina died in utero when I was about 6 months pregnant. We had an autopsy done which revealed that Christina was perfectly normal and healthy from a DNA/genetics standpoint, as was the placenta. Thus, from Christina’s death we learned that things can go wrong in an otherwise normal pregnancy. Anne stopped moving at nearly 30 weeks gestation, and we were of course scared to death. Were we going to lose this baby as well? Our original OB-GYN, knowing full well my OB-GYN history checked ‘s heartbeat and sent me home stating that there was nothing to worry about.

But I had not gone to the doctor because Anne’s heart wasn’t beating, I had gone because SHE HAD STOPPED MOVING. I went home and cried to my husband who in turn called the doctor’s office back and requested to be seen by a specialist. We were sent immediately to The local Children’s Hospital where we spent the next four or five hours. The hospital specialists could not induce movement in Anne with the “cattle prod” device nor by filling me up with juices and soda. They saw Anne’s heart was beating, but the physician’s seemed baffled about her lack of movement. The specialist ultimately sent us home with no resolution.

We called our OB-GYN back and requested to be seen somewhere else as we were not satisfied with the lack of resolution, diagnosis or explanation. That evening Randy and I did research into possible explanations for a change or decline in movement which included malfunction of the umbilical cord, malfunction of the placenta, twisted umbilical cord, and lack of amniotic fluid to name just a few possible causes. The next morning we went to a different Neonatology Department. I asked over what period of time would it typically take for a malfunctioning placenta, or malfunctioning umbilical cord to show up on ultrasound. The technician indicated that it could take a few weeks to show up depending on the scope and nature of the problem.

When I returned to my OB-GYN for follow-up the doctor felt it was completely unnecessary to have repeat ultrasounds to rule out any of the above mentioned problems. The doctor told me not to worry and that nothing was wrong. We switched to a physician who would support the care we needed to rule out any problems. Much to our surprise, ultrasounds over a period of a few weeks showed a steady decline in amniotic fluid until an immediate delivery was necessary.

Anne showed up nearly two months early arriving just before Christmas 2001 with a due date of February 8, 2002. Her birth weight, however, did not match her prematurity, as she weighed in at a hefty four pounds 14 ½ ounces, which made her the largest baby in the neonatal intensive care room that she occupied. Anne was on a ventilator for a day and required some surfactant. She was in the neonatal intensive care unit for 12 days before being discharged.

Due to her prematurity, Anne was unable to nurse. I pumped every feeding and we bottle-fed for the first two months. There was no indication during the first two months that food allergies were even a possibility. The first food issue that showed up after Anne's birth showed up with me. By February 2002, I was unable to eat even the smallest amount of gluten. A minute amount of gluten made me double over in pain, and needless to say I began avoiding gluten completely. It is interesting to note that, because Celiac Disease is one issue that we have been trying to rule out for Noah since his birth, and because Celiac disease frequently manifests in women *after* a pregnancy.

FORCED TO NURSE

By March 2002, however things with were changing. Anne began to cry when it was time to nurse exactly in the same way that Noah had. I felt sick to my stomach. Here we go again I thought. But this time, I wondered if I played around with my diet then perhaps I might be able to avoid the terrible time that we had experienced with Noah. There was just no way that I could do the "swing/nurse" ordeal again.

So I quickly began trying to change my diet to see if that would help. There were however many diet related things that we did not learn via Noah because I had never done any real extensive diet manipulation due to the fact that I was constantly being reassured that it was not what I was eating. As a result I never learned until we had Anne that if you only eat salty foods all day, then your breast milk will taste salty, and be quite unappealing to a baby used to normal breast milk which is typically sweet. Nursing had become a very real problem so we devised a "play with the baby" routine to get Anne to nurse. Anne would nurse for limited time periods so long as I had a toy or book that completely held her attention.

Therefore every single nursing session save for the night time feedings, I had to have an array of toys on the sofa ready and waiting for Anne to play with. On those occasions where the toys did not pass muster, I would call out to my husband or the boys to please bring me another toy. It was a nightmare. A far, far cry from what nursing Luke had been. This nursing set up also meant that I was again tied down to the house because she would not nurse in a strange environment which was exciting and stimulating.

We resorted to additional nighttime nursing while we sorted out the issues related to my diet. In April 2002, I became determined to figure out the foods that were bothering Anne, so I picked corn as the food to try thinking that very few people were allergic to corn. After all, neither Luke nor Noah were allergic to corn. It seemed like a safe bet. So I ate corn all day long; dry corn flakes, Fritos corn chips, corn pop cereal, tortilla chips, and popcorn, all the while making sure that I did not eat too much salt.

That night Anne was the worst we had ever seen her. She was crying nonstop and she was inconsolable. By the next day Anne had eczema on the right side of her face and on the tops of her hands where the forefinger and thumb meet. She rubbed it until it bled. She woke up crying at night something that she had never done, and she was miserable. We bandaged her up and went to the pediatrician's office looking for help.

The medical advice we got from the pediatrician was to use dye-free Benadryl systemically for the itching as well as topical creams and lotions like Calamine lotion, hydrocortisone, and anti-itch creams. We began giving Anne a low dose of Benadryl to help reduce the itching

and eczema outbreaks. The pediatrician had no recommendations for how to figure out what was the problem in my diet. We had changed pediatricians with Anne's birth, and at least we were comforted by the fact that the new office was generally more agreeable that food allergies can present in young babies.

By the time Anne was five-months old, I had figured out that corn and soy were big problems for her. The smallest amount of corn or soy in my diet would cause Anne to have eczema, diarrhea, and sometime hives. The removal of corn from my diet was difficult at first because while I had read in my research about corn allergies, I did not realize all of the foods that contained corn, nor did I realize that corn was not always listed as "corn" on a food label. Corn could be labeled as maltodextrin, sucrose, fructose, dextrin, dextrose to name just a few of the corn names. Out went my coffeemate light, which meant no decaffeinated coffee at all, all candy, jelly, sauces, and even lunchmeats. It was an education to find out the volume of foods that contained some type of corn, corn syrup or corn by-product.

Shortly after the removal of corn and soy, came the removal of any type of dairy in even a minute quantity. Each time a food was removed from my diet, Anne improved. I was however unprepared for the physical shock of having no sugar in my diet. I felt completely out of sorts for the first time in my life. I kept telling my friends that I didn't feel like myself, but that I wasn't sure what was wrong. I had never in my life felt this way, and therefore it scared the heck out of me. I just felt off balance. Then I had a huge revelation when I realized that a little sugar might be what was missing. Sure enough, once I devised some gluten free, corn free, soy free, egg free and milk free cookies that I could eat, I felt like my old self again.

Life however was nothing like my former life. I could not eat any of the foods that bothered Anne. And I must say I was becoming increasingly agitated that I had to deprive myself of the foods that I loved. I'm not embarrassed to say that I am reasonably selfish, and I felt that I was being forced to nurse Anne for lack of another option. None of which made me very happy. Depressed about all the foods I couldn't eat, I suggested that we might as well try a formula for Anne.

This was both an exciting and frightening proposition. If a formula worked then I would be off the hook, which was so exciting. On the other hand, if no formula worked then where would we end up? So around our about 's 5th month, we gave her one-ounce of a hypoallergenic formula. The most hypoallergenic formula that we could find. Anne drank the one once and did not throw up. We were elated and wondered if we should give her another ounce in an hour or so. We decided not to give her another ounce and see how she faired for the rest of the evening.

It was not long until Anne let us know exactly how much the formula bothered her. It was one of the most memorable moments of my motherhood, and not a pleasant one. Anne cried for more hours, nonstop than Noah ever had. We contemplated taking her to the hospital to have her stomach pumped, but by the time we had that brilliant idea we figured we were at the tale end of the screaming. She screamed for nearly 6 straight hours. Randy and I took turns holding her and walking around. It was the most heart breaking night I have had with a baby so young. It only takes allergies to about 6 or so foods to rule out all commercial formulas: corn, soy, milk, coconut, safflower, sunflower, rice and tree nut oils.

With that formula fiasco under our belt we felt forced to make our nursing situation work out until we had some type of formula or other foods to feed her. Forced primarily of the fear of what would happen to Anne if we did not nurse her, which was fueled by our own very personal experiences with Noah. Unless we would find better medical understanding and help with Anne, there was no hope for her. Thus we felt that there was no other option than to try to nurse her until we would find the foods she could tolerate.

By August 2002, I had determined a few more allergenic foods that bothered Anne, namely carrots, rice, chocolate, sorghum, grapes, strawberries, and sunflower seeds or oil. Each food that I dropped from my diet brought improvement in Anne's skin, diarrhea, and physical condition. With the removal of rice and sorghum, I had only potato and tapioca starches to use to make any sweet "sugar-fix" carbohydrates for myself.

Already making homemade milk-free, dairy-free ice cream, gluten free/allergy free rolls and bread, cookies and crackers for Luke and Noah, it was too much for me to try to make gluten-free, milk-free, egg-free, soy and corn-free, rice-free, foods for myself. So I went on a primarily protein diet with the limited exceptions of a few special cookies that I made to keep my sugar level properly in tune. As I would joke, I need sugar to keep my normally sweet disposition. The removal of almost all carbohydrates from my diet, save for my sugar fix, caused me to lose weight which was a thrill. I believe however that it also meant that my milk content was nearly 100% protein, and Anne stopped gaining weight as she had been earlier in the year.

Anne's Low Muscle Tone causes Delay

In October 2002 when Anne was 10 months old I expressed serious concerns about Anne's gross motor skills. While she could sit if you put her in a sitting position, Anne was unable to get herself into a sitting position and she was not propping herself up on her forearms something that is a 4-month milestone. Additionally, she could not bear weight on her legs, and she could not hold her head level when pulled to a sitting position. I told the pediatrician that I believed that Anne had low muscle tone and that she needed physical therapy. I also stated that if I could just be instructed on what to do with her, I would be happy to do the exercises with Anne on my own.

The pediatrician told me flat out that there was no way that Anne needed physical therapy and that we would check her at her one year visit and see if things had improved. Because I had two other children who had excellent muscle tone, I was not convinced that I was wrong. Nevertheless, I did not argue with the pediatrician, and at home I began trying to do exercises with Anne to help her build muscles. In November 2002 I happened to speak to a woman who works for the Easter Seals Society in a different State about Anne's need for physical therapy. When I told the woman all of the basic things that Anne could not do, she directed me to immediately contact the local early intervention program. While I thought that was good advice, I did not heed the suggestion immediately as I had been reassured by my pediatrician, whom I trusted, that physical therapy was not needed at this time.

Anne turned one in December 2002 and I cried. I cried because I was just so happy that we had made it to her first birthday. And I cried too because I was so tired of nursing her and I just wanted to know what foods she was not allergic to. What foods could I feed her that would not give her diarrhea and eczema? What foods would allow her to grow, gain weight

and thrive? I was growing frustrated at the lack of information I was being given and I became more determined to start resolving 's allergy issues and what I thought were her physical delays.

In December 2002 I finally called the Erie County Early Intervention Program and they came out just after Christmas and signed the paperwork which would allow for a Core Evaluation of Anne in January 2003. The Physical Therapist, Speech Therapist, and Service Coordinator who conducted the Core Evaluation stated that it was a good thing that I had not waited any longer because Anne was measuring at a 6-month delay in her gross motor skills and definitely qualified for physical therapy. The Erie County Early Intervention Program representatives were clearly not pleased with Anne's speech evaluation, however I felt that was no further behind in speech than her two siblings had been at the same age.

For speech, Anne would have a visit every so often where the speech therapist would check in and provide suggestions relative to Anne's speech. This way, Anne would not get further delayed in the area of speech. The initial goal for 's 6-month evaluation was that she be able to get up on all fours and be able to rock back and forth. Anne began receiving Physical Therapy twice a week for a minimal time period because of her age. I worked with her on a daily basis doing all of the exercises that the PT showed me during the sessions at our house. I was committed to getting Anne back on track with her gross motor skills because I knew first hand how much cognitive learning goes on for toddlers when they are able to walk and explore on their own.

During this time we purchased a baby walker so that Anne had some independence and mobility that was self-directed. We also felt that this might help strengthen her legs. The idea for the walker also had its roots in addressing another serious problem in the household. I needed Anne to be somewhat occupied for short periods of time so that I could get all of our gluten free, milk free, soy free ad infinitum foods whipped up and in the oven. There weren't any foods that we had found that she could eat in the high chair, and since she wasn't walking, or crawling, there was nothing to do with her but carry her around all day. The walker provided just enough time for her to move around the house and investigate her surroundings that I could get something in the oven. Almost every day I have to make some food from scratch for our household which normal families would purchase at the grocery store.

Low on the Growth Chart

Also in January 2003 I had decided that Anne was not nursing enough to maintain her body weight and needed more calories. She was so low on the growth charts that she was as close to zero as you can get and still be on the charts. She weighed only 16 pounds 14 ounces, which meant that **she had literally not gained any weight in 5 months!** It was very upsetting to see her so tiny and frail looking. Equally disturbing was that our pediatrician seemed unconcerned. Anne was not crawling or walking at this time, so she was not burning the amount of calories that a typical one-year-old would, yet she had not gained an ounce in five months.

I began making homemade tapioca breadsticks that were free of gluten, eggs, milk, corn, soy, nuts, and rice. Every single morning before she got up I had to get the breadsticks made because the breadsticks had no shelf life. Because the breadsticks lacked any

preservatives, and lacked milk and eggs, they would become stale very quickly and lasted only one day. While she seemed to tolerate the breadsticks, she had only her front teeth which meant that she could not bite off pieces and chew them up. Therefore we had to break the breadsticks into little bird-size breadcrumbs and feed them to her while she was otherwise occupied.

We decided that we would also forge ahead and try new foods in the hopes of finding other foods that Anne could eat. This proved to be a nightmare. Without exception, Anne gobbled up every single food that we offered her: raisins cut up into fourths, tater rounds, craisins, and other homemade carbohydrates free of egg, milk, gluten, soy, and corn. However, without exception Anne would get diarrhea, skin rashes and eczema, and seemingly have an upset stomach shortly after eating the new food. So as a result of trying new foods, Anne lost more weight. It was most typical that she could lose anywhere from 3-4 ounces a day from the upset a new food caused to her system. We decided to stop trying new foods and concentrate on the breadsticks which were helping with the weight and spend our time working within the medical community to find an answer to this problem.

By mid January I was completely frustrated and crying over the whole issue of feeding Anne. Our Pediatrician had no advice other than to call a registered dietitian, which I did. The registered dietitian which came highly recommended by our doctor had absolutely no suggestions whatsoever for me. The RD did say however that once I figured it out I could come in and she would tell me if I was doing it right. Undaunted, I called the local Children's Hospital Feeding Clinic and asked them for help as I had done with Noah several times. They indicated that they were unable to help me because of the large numbers of foods that Anne was allergic to and that I was "on my own" which was the same response I had gotten when Noah was little.

In tears, I called Univera Healthcare and asked for their recommendations. While they had none, they did state that if I found a physician who could help and that physician was out of the Univera network, then according to New York State Law, Univera would be obligated to pay for the out-of-network physician as long as Univera did not have the same kind of specialist in the network. After networking with various families in the area that had food concerns, it was recommended that we contact a physician outside of the Univera network who was supposed to have expertise in food and nutrition.

We received an out-of-network authorization to see this physician for Anne, and saw the doctor almost immediately. The doctor recommended a large panel of tests to eliminate problems with Anne's body organs like the liver, kidney, pancreas, etc. The doctor also recommended vitamins and probiotics. Unsure about this doctor's recommendations, we met with our pediatrician to see if the pediatrician concurred with doctor's protocol. Our pediatrician wholeheartedly agreed with the out-of-network doctor's recommendations. Our Pediatrician then wrote out a script for the blood work which we had done within the Univera network.

Because of Anne's tiny veins, we had three failed attempts at a blood draw. Thus it was March 2003 before we finally had a successful blood draw. 's blood tests for her body organs came back normal, but the testing did show that she was anemic. We purchased Tri-Vi-Sol with iron hoping that she would not react to it. The Tri-Vi-Sol turned her lips black, and gave

her physical distress. We then ended up getting a script from the pediatrician and paid for iron capsules that we emptied into her water.

With the probiotics, iron and homemade tapioca breadsticks Anne began to gain weight. However the out-of-network physician did not help me in determining what she could eat and made no recommendations for feeding her. I kept a follow-up appointment with that physician, but felt that he was not helping me with my primary problem, which was what liquids, and what foods could I feed her. The “play with the baby” nursing routine was so old that whenever my husband was home, he would stand behind the sofa and play with Anne with a toy or a book to give me a break. Anne didn’t want to nurse and neither did I. We were hostages in a nasty game of food allergy.

In May I felt that I needed a prison break, and we decided to take a trip to Pennsylvania to see my family. I spent the week before the trip baking and packing all of the food that our two boys would need to eat since their allergies to gluten and milk, soy, etc. ruled out most of the foods that our hosts would have on hand. The next issue was what would we do with Anne when we stopped at a restaurant to eat? Our plan was that my husband and I would take turns walking around the restaurant with her while the other of us ate very fast. This trip proved conclusively that we needed to get this problem solved because soon Anne would be old enough to demand sitting at the restaurant table to eat with the family and then what would we do.

While on the trip our “play with the baby” nursing plan fell apart. Anne just drank water and ate the tapioca breadsticks that I made fresh each day. When we returned Anne was down to one nursing a day and one feeding at night. She began losing weight since there was no liquid with calories to replace the breast milk that she was not getting any more. Within a week of our return home, Anne was down to one feeding in a 24-hour period. To continue that we would wake her at around 5:00 a.m. and nurse her, and then put her back to bed. This we did in an effort to help her with some liquid calories.

By June 2003 I was getting pretty desperate. Water and homemade tapioca breadsticks are not nutritionally sound for a baby of 18-months. The medical community was not helping me at all, so I decided that IgE and IgG blood testing might provide us with the information on what to feed Anne. When I initially called our local Children’s Hospital Blood Lab to see if we could do a food allergy panel of 90-100 foods and gave them an idea of the foods I was looking to test for, I was told that the Blood Lab was unable to accommodate my needs. The technician was quite interested in why I would want to do such testing and I explained about Anne’s allergies. To my surprise the Technician from the Blood Lab called back the next day and told me that she had done some research and that the Blood Lab would indeed be able to do many of the foods.

The technician and I spent the next week and a half or so passing testing lists back and forth until we came to a consensus of what foods Children’s Hospital would actually be able to do. In early July we had Anne’s blood drawn for the IgE and IgG testing. I had cautioned the Blood Lab about the special New York restrictions in the area of licensing and certifications relative to IgG blood work, which went unheeded. Two weeks later’s blood work came back with only the IgE portion completed.

The IgG blood tests had been sent out of New York State and the receiving out-of-state Laboratories refused to do the testing because the blood originated in New York State. While I was extremely disappointed, I had realized that by using a lab that had never before done IgG testing that botched results were a possibility. I asked if there was perhaps any old blood in frozen storage that could be used to do at least a few foods. There indeed was, and we received IgG testing for 7 foods instead of the intended 34 foods. Anne's test results demonstrated that she was IgE allergic to egg whites, egg yolks, cow's milk, peanuts, and three tree nuts. Anne's IgG testing showed that she had IgG reactions to all of the foods tested which were apple, banana, casein, onion, tomato, grape and orange.

With the blood draw done, we would now have to wait six to eight weeks to have more foods tested, and based on Anne's declining health we did not have that many weeks to wait. So we began feeding Anne mashed potatoes to add calories to her diet. While she was reacting to them, at least she was getting calories. It became a calorie battle each day where the total goal was just to get enough calories into her to stop the weight loss. I got an "Allergy" cookbook and looked for suggestions. The Allergy cookbook recommended trying non-mainstream foods like venison, ostrich, goose, duck, rutabaga, and other foods that I had never purchased, seen or eaten in my life.

During this period Anne amazed the Physical Therapist and all of the Erie County Early Intervention personnel involved with her case by walking! Anne was walking well before our scheduled 6-month review. We were ecstatic. While Anne was walking with a very wide base of support, she was at least walking all by herself. It was a huge success that helped to offset the declining food situation.

We decided that we would take a trip in August 2003 to see my family in Pennsylvania at a lake. My mother lives in the mid-west, and once a year she comes east to Pennsylvania. It was my one chance for the year to see her, and despite all of the troubles with Anne, I wanted to go. While we discussed me going alone, I could not deprive my other children of seeing their grandmother, grandfather, cousins and aunts and uncles. We decided that we would all go. I spent two weeks before the trip packing and planning for our food issues. The trip went well, and Anne ate mashed potatoes for the majority of the time there.

Anne's physical condition seemed to deteriorate quickly once we returned from the Lake vacation. The mashed potatoes and homemade tapioca breadsticks seemed to be causing visible symptoms that began as soon as she started eating the foods. It looked like pink streaks as in the "tears of a clown" appeared on her face the minute she began eating. Anne had chronic diarrhea, and was losing weight. Frantic, I began looking for the venison, ostrich and other exotic foods that I had read about in the allergy cookbook. I was stunned when the meat store told me that I could not purchase venison, squirrel, or other foods that were considered game. I was told that I would have to find a hunter to get those foods.

I went to Wegman's to purchase Rutabaga's only to find that they were not in season yet. It was almost too painful to bear to watch Anne starving in front of our eyes. I was as desperate as I have ever been in my life. We went on-line and found some gluten free really exotic flours that were extremely pricey at \$32.00 a pound! So with all faith and hope we ordered malanga flour, lotus flour, white sweet potato flour, and some other flours to try. We spent \$170.00 on 5 little bags that would fit into an empty half-gallon container.

Since I had been active in the preceding two years in the Western New York Gluten Free Diet Support Group, I had access to two women who are Registered Dietitians and Registered Nurses. They tried very hard to be helpful, but there are only so many foods available and we were quickly eliminating all of them. Two women from the WNY Gluten Free Diet Support Group went on rutabaga hunts and found some for us to try. We were all out of options and could do nothing but try food after food in hopes of finding something that would not give her diarrhea. At this point we were completely unconcerned about the eczema, and only concerned with stopping the down hill slide.

No foods were working for Anne. Crying and exhausted we turned to our pediatrician and begged him for help and direction. During the month of August before and after our vacation I had spent all of Anne's naptime hours which was about 2- 2 ½ hours a day on the phone calling local allergists. I also called nationally renowned allergy facilities like the National Jewish Medical and Research Center which bills themselves as "Global Leader in Lung, Allergic and Immune Disease." I spoke at length with a R.N. from their nurse line who extolled the virtues of the center. When I began asking very specific questions about Type II, III, and IV or delayed food allergies the nurse got very quiet. The National Jewish Medical and Research Center did not do IgG mediated food testing I was told. But they would be more than happy to see Anne if we would just bring her out to Denver, CO. The nurse made sure I understood that there was no treatment for food allergies which was interesting because I was not looking for a treatment for 's food allergies I was simply looking to find what foods I could feed her that would not give her diarrhea.

I also contacted almost all of the in-network with no exception, all of the allergists represented to the parents that they (a) did not do IgG food testing, and (b) there was no treatment for food allergies other than avoidance.

On September 1, 2003 desperate for foods to sustain Anne's life, we tried buckwheat groats which a member of the rhubarb family and can be purchased in fine, medium and coarse groats. We cooked this like rice and flavored it with chicken broth. Anne ate a bowl full of it late that afternoon with no apparent reaction. All out of foods to feed her, we decided to give Anne some more of the buckwheat with chicken broth. She again ate it right up and we felt relieved for the first time in a long time that we had found one food that Anne could eat. Our sense of euphoria was however short-lived as the next morning when I went to get Anne from her crib, she was covered in hives. Her face looked like she had second degree burns on it and she looked swollen. She had never looked so bad in all of her life. The color picture on the title page of this document is a picture taken 16 hours after Anne had eaten the buckwheat and after receiving Benadryl.

After I got her dressed, I loaded the three kids in the car, grabbed the snack bag and drove off to our pediatrician's office so that the pediatrician could document her visible reactions. The pediatrician was not yet in the office, but the nurse said that she would note it in the chart. I had the nurse call the pediatrician by telephone who told me that he did not know what to do with us, that I knew more about food than he did, and that we should go and see the AAEM physician about this problem. After we left our pediatrician's office I drove the three kids to our HMO office and requested a medical doctor from the benefit interpretation

department come out to see Anne and make a medical note in her HMO chart about her hives, edema, and raw eczema on her face.

I did this because it has become crystal clear to me over the past 4-½ years that there is next to zero knowledge about food allergies. I wanted to demonstrate to both the Pediatrician and to our HMO what a delayed food reaction could look like. A Dr. Sheryl came out to see Anne and she indicated that she was surprised at how Anne looked.

Anne was 20 months old when she first saw the AAEM physician for allergy testing and treatment through an approved HMO referral. Through intradermal neutralization testing the AAEM doctor was able to pinpoint Anne's allergies and provide the exact neutralizing dose that offset the allergies, and as a result Anne was able to eat corn, rice, and potatoes. Anne, at age 20 months did not know, nor would she know today what she was being tested for. Anne is a healthy, normal child in every way. She is not autistic, delayed, or otherwise impaired in any way. There is no physical way that she could force herself to have eczema, diarrhea, hives or an upset stomach.

Anne's propensity to have allergies is supported by the study published in the August 2003 Journal of Allergy and Clinical Immunology which firmly establishes that infants born by C-Section to mothers allergic to fish, nuts or eggs have a seven-fold risk of being food allergy babies.²⁸ I am severely allergic to nuts, and Anne was not only born by C-Section, but was also nearly 7 weeks premature that one could speculate may have exacerbated the already existing allergy preponderance. Any physician with a background in basic food allergies could have suggested that we give newborn Anne a small dose of probiotics mixed in with water which could have reduced her allergy problems by up to 50%.^{29, 30} Had we known this information at the time, we certainly would have followed this course of action.

Daily Life with our "Food Allergy Princess"

Feeding Anne on a daily basis is a huge struggle, which is directly related to the fact that she was deprived of the allergy testing and treatments at one year of age. Because Anne was limited to such bland, flavorless foods for the bulk of her first two years of life, Anne does not have a taste for some of the foods that she can now eat due to the allergy treatments. I remember well, how Anne gobbled up raisin pieces, craisins, cookies, crackers and other foods at 12 months of age. These same foods, having been deprived of them for a significant time are not foods that she will eat today.

At present Anne is on a three-day rotation diet. While we have been instructed that she should be on a four-day rotation diet, we have not managed to figure out enough foods that she (a) can eat, and (b) will eat to have a fourth day. Anne's rotation diet days are comprised of potato & beef, corn & pork, and rice & turkey in those combinations. What that means is that on a "potato & beef" day, Anne should only consume foods containing potato and/or

²⁸ Is Delivery by Cesarean Section a Risk Factor for Food Allergy? The Journal of Allergy and Clinical Immunology, August 2003, pp420-426. Eggesbo, Merete MD et al.

²⁹ Dr. Jon Vanderhoof, Other Manifestations of GI Allergy, p.9. CSA/USA, Inc. Lifeline Publication Winter 2003.

³⁰ The Neonatal Immune System and Risk of Allergy A Delicate Balancing Act, Positively Influenced by Probiotics and Fatty Acids; Nigel Plummer, PhD, Cathryn Woods, BA, Townsend Letter for Doctors and Patients, Feb/Mar. 2002.

beef. It means that on a "potato & beef" day, Anne should not have rice crackers or corn chips. What it means for our family is a lot of time baking and cooking in the kitchen.

Anne is also able to have a few fruits and a few vegetables however while she can eat them, she typically will not eat them. That means getting her daily caloric requirement into her takes all the more effort and planning. So every day of every week we offer her new foods that she can now eat in the hopes that she will start eating any of them. And this plan has been working although not as quickly as we would like. The first eight to ten times Anne was offered orange juice and bananas, she refused them saying "Yucky." We did not make a big deal of this, and just drank the juice and ate the banana ourselves saying "Yummy!" Eventually Anne tried orange juice and bananas and said "yummy!"

Now she had never eaten more than a few bites of a banana or had more than a few ounces of orange juice, but Rome wasn't built in a day and so it will take time and creative approaches to get Anne eating foods that she has been deprived of for so long. Even with the allergy treatments, most foods are still off limits for Anne. She cannot eat any type of egg or any foods with egg in them. She cannot drink milk nor have any foods made with milk. And she cannot have many foods that comprise the bulk of the typical American diet like wheat, oats, barley, rye, celery, cheese, nuts, peanuts, zucchini, asparagus, beets, cauliflower, cantaloupe, pineapple, plums and a host of other foods.

What this means is that most of the foods that a normal, typical family purchases at the grocery store we have to make from scratch because of the foods that Anne cannot eat. When Anne eats a food that she has not been tested and treated for she gets diarrhea, an upset stomach, patches of eczema, hives, and usually wakes up crying at night. The combination of these symptoms result in a weight loss of typically 3-4 ounces per day.

Because of Anne's allergy history we weigh her every morning upon waking and every night before bedtime and record her weight on her daily food log. Every day we record every food that she eats and the quantity and calories of each food as well as any physical symptoms that we observe. At the present time we are aware that some thing is causing a problem as Anne has had patches of eczema on the inside of her left arm and on her left hand. In addition, she has had redness under her nose and a corresponding although intermittent runny nose with no symptoms of a cold or other illness. Thus it is the daily food log that we will use in consultation with the Medical Specialist to try to determine the source of the offending food.

The other difficulty that arises in having a child with so many food allergies when just feeding her and maintaining her weight is such a difficult struggle is the issue of colds and infection. Most people with cancer or who have an autoimmune deficiency are instructed to take extra precautions and avoid people with colds and places where germs are present. The last thing in the world that we need as parents struggling on a daily basis to simply feed Anne is to let her get sick. That has already happened despite our extra precautions, and Anne lost over a pound in two days. Because nearly all of her calories at the present time come from solid foods and not liquids, it was impossible to get the necessary calories into her when she caught a cold in October 2003.

It took over four weeks of extraordinary efforts on the part of my Husband, Randy, and I to get the extra calories into Anne to get her weight back to where it had been prior to the cold. For that reason, we are forced to take extreme caution to avoid being around other children or adults who may either be sick or who may be coming down with a cold. Our life with Anne is in no way, shape or form what you could call normal. It is excruciatingly difficult.

The only thing that makes it bearable is that we are surrounded by parents whose children have bigger medical problems like autism and seizures. We get through each day knowing while our life is not great, and most people would be appalled to see what we do to keep Anne thriving, our lives could be infinitely worse. Little Anne has no idea that she has a medical problem and is a happy, articulate, sweet little girl with no other medical issues, delays or problems having been released from the Erie County Early Intervention program earlier in 2004.

3. Effectiveness of Allergy Testing and Treatments

Anne began intradermal neutralization testing by a Medical Doctor specializing in the treatment of food allergies and non-IgE mediated food and environmental allergies at 20-months of age. A twenty-month old child does not have the distinction of light-headedness, dizziness, shortness of breath, or any other physical symptom. Anne is a typical and normal child in every way except for her food allergies. Anne does not suffer from some psychosomatic illness. She does not even know (at her present age of 25-months) that she even *has* food allergies.

The selection of the neutralizing dose for 's allergy treatments have all come from the wheal on her arm, her heart rate, and from the extraordinary expertise of the medical specialist. Anne is not able to report "symptoms" during testing because she lacks the distinction of a "symptom." Additionally, the intradermal neutralization testing has never at this point provoked a symptom in Anne that we are aware of from a visual observation standpoint, which is the only method that we have to assess any provocation of a response.

There is no medical question that the allergy testing and treatments of intradermal neutralization treatment is 100% effective. We have unintentionally or inadvertently tested this allergy treatment and it is working 100% of the time. Two examples illustrate this fact. We inadvertently ran out of Anne's sunflower extract in December 2003, only realizing this after Anne had eaten white rice to which sunflower oil had been added for fat and extra calories. Anne presented with visible symptoms that included red eyes, runny nose, and several hours later, an upset stomach.

More recently in January 2004, we suspected that Anne's endpoints or neutralizing dose had either changed or she was ingesting a food she was allergic to that she was not being treated for at present. We suspected this because at the end of December 2003, Anne had eczema on her back, which she had scratched until it was bleeding. We then had Anne retested for a select group of foods, using our daily food diary as a tool, and found that Anne's endpoints or her neutralizing dose had changed for beef and corn.

Anne's previous beef and corn extracts were in two separate vials that contained several other foods. Therefore, so that we did not have to throw away 2 vials containing

approximately 12 foods when only two food doses had changed, the treating M.D. made up separate extracts to correct the old dose which we were to give to approximately 20 minutes after she got the first (now incorrect dose). While this may all seem quite simple, it took us over a week to come up with a “system” to remember to give Anne the corrected beef and corn neutralizing doses all the while she was scratching her back until it bled.

Within 12 hours of receiving the new, correct doses for beef and corn Anne’s eczema began clearing and the scabs were healing. Within 24 hours, the scabs were gone leaving only discolored but healing spots. Anne does not have any psychological abilities to force herself to have diarrhea, eczema, a stuffy or runny nose, or to wake up crying with hives. She is just not capable of such behaviors.

We keep a daily food log of every food and liquid that goes into her mouth with the corresponding calories. We weigh her each and every day, once in the morning and once in the evening. This is all done so that we can gauge reactions from untested/untreated food items, and for gauging any need for retesting in the future. In less than 3 weeks time, Anne had nothing less than a remarkable and astounding improvement under the care of the medical specialist treating Anne. Anne’s chronic diarrhea cleared up, her eczema cleared up, and she was able to eat several foods without a problem. In addition, for the first time Anne began gaining weight, which is critical in a child of her age.

During the first 6 weeks of allergy testing and treatment by the medical doctor, Anne demonstrated an extraordinary surge and improvement in her speech abilities which was recorded and documented by Anne’s speech therapist from the Erie County Early Intervention Program. It was the unbelievable improvement that we saw in our child that sent me off to the medical library at the University at Buffalo to do research this field of allergy. **Anne is the acid test for intradermal neutralization testing and treatment, and it is extremely effective.**

4. Dispelling the Myth that there is any real controversy in this allergy field

Until some time around or about 1988, Medicare covered provocation-neutralization testing and treatment.³¹ Medicare is seen by the insurance and HMO organizations as the “leader”, and often follow suit in coverage relative to Medicare policies and practices. Medicare’s decision to stop covering provocation-neutralization had nothing to do with efficacy and positive health outcomes, and everything to do with a medical community’s intent on keeping this science and technology from the very people that require it. This section of the paper will be devoted to addressing the so-called “negative” papers used to disparage intradermal neutralization testing and treatment, the very science that has saved the life of our daughter. We will begin with the most widely used yet very flawed “Jewett Study”.

The Jewett Study³²

One of the first glaring issues with the “Jewett Study”, as it is most frequently referred to, is the lapse of time from the completion of the study to the time of publication, which was seven

³¹ Joseph B. Miller, Letters to the Editor. *Clinical Ecology*. Vol. VI, Number 1 pp 30-37

³² Jewett, DL., Fein, G, Greenberg MH. A double-blind study of symptom provocation to determine food sensitivity. *New England Journal of Medicine*.1990:323:429-33.

years. Jewett's study was presented in October 1983 to a meeting of the Society for Clinical Ecology. When the Jewett study was finally published seven years later, it was presented as a "current" study with no mention of the fact that it had been presented seven years prior.³³ In the medical community, completion of medical studies and publication go hand in hand, and the seven-year lapse calls into question the integrity and validity of the study.

Further casting doubt on the Jewett Study's validity is the fact that the Jewett study failed to cite any of the 7 conflicting articles. This glaring omission was either ignored or not recognized by the New England Journal of Medicine who published the study. In the issue of the NEJM in which the Jewett study was published was an editorial reviewer, a person normally quite familiar with the field being discussed, who coincidentally omitted or failed to cite any of the 7 conflicting articles. This casts an extremely questionable light on the Jewett Study and the "peer-reviewed" handling of said study.

An additional problem with the Jewett study is that the originators of the study had no direct clinical experience with Provocation-Neutralization testing. This is no small factor. Experience in any field allows an individual to make better decisions and better assumptions regarding a future event. Probably the biggest draw back of the fact that the originators of the study had no direct clinical experience with provocation neutralization testing was in the area of underlying or unstated assumptions for the study.³⁴ Their lack of clinical experience would have had a direct and negative impact in this area. It is clinical experience that provides the wisdom and expertise to properly evaluate underlying assumptions and alternative explanations for non-significant results. While the Jewett study raises some questions, it in no way proves that provocation-neutralization testing or treatment is not valuable.

Caplin Study

While this study was well designed, there exist major problems with the Caplin Study.³⁵ One major issue is that data from each participating physician's office was not presented. Presentation of data allows for interpretation and assessment of study conclusions, which can not be done if the data is omitted. Additionally, the text cites 48 patients directly tested for reaction to food challenge, 48 are compared to SC tests and yet only 40 are noted positive in comparing atopics and non-atopics.³⁶ It is significant to note that one member of the committee contested interpretation of the data and presented an independent statistical interpretation to support his position³⁷, which further underscores that positive data, can be presented in a negative light and vice versa.

The Draper Paper³⁸

The Draper paper or study attempted to correlate deliberate feeding tests with intradermal provocative tests in 121 subjects without attempting neutralization treatment in any way. The

³³ Gerdes, K., Letters to the Editor. *Environmental Medicine*. Volume 9, Number 1.

³⁴ Gerdes, K., Provocation/Neutralization: State of the Art for 1993. *Environmental Medicine*. Volume 9, Number 1, pp 34-40.

³⁵ Caplin I, Bronsky EA, Crozier W, et al Report on the Committee on Provocative Food Testing. *Annals of Allergy* 1973: 31;375-81.

³⁶ Gerdes, K. Provocation/Neutralization Testing: A Look At The Controversy. 1989. *Clinical Ecology* Volume VI, Number 1, p27.

³⁷ Willoughby and Sharp; Caplin, *Ann Allergy* 32:47-55. 1974.

³⁸ Draper WL. Food Testing in Allergy. *Arch Otolaryngology* 1972;95:169-71.

Draper study was actually a positive study, which the American Academy of Allergy and Immunology turned into a negative in their Position Statement.³⁹ Dr. Draper's study actually proved that there was a 62% correlation between intradermal provocation and deliberate feeding. Dr. Draper actually used and supported provocative neutralization testing, and stated that his work supported provocative testing.⁴⁰

The Lehman Study⁴¹

This study is important because it was used in the Position Paper by the American Academy of Allergy and Immunology to disparage provocation neutralization or intradermal neutralization. The Lehman study has quite simply, many large and glaring errors. Dr. Lehman knew in advance of conducting his study that none of the patients in the study were allergic to corn or yeast, only one had a sensitivity to egg, and only seven were allergic to milk, all of which were the foods he was allegedly testing.⁴² What that means is that only eight positives could have been expected out of a total of sixty tests. Three of Dr. Lehman's patients had no clinical food allergies, which again calls into question the intention and objectivity of the study.

Also at issue in the Lehman Study was Dr. Lehman's selection of his endpoint for sensitivity. Dr. Lehman chose to rely primarily on observed changes in the degree of swelling and edema of the nasal mucosa rather than symptom provocation. In pointing out all of the flaws of the Lehman study, Dr. Joseph B. Miller wrote it best in his Letter to the Editor for Clinical Ecology:

Yet Dr. Lehman admits: "Nasal mucosal edema is constantly changing from one ten minute interval to another, independently of placing food antigens versus placebo under the tongue."⁴³

This study was not a study on the efficacy of intradermal neutralization testing in any way, shape or form. More accurately, the Lehman study was at best to again quote Dr. Miller:

This was a study of food allergy diagnosis in patient's predominately not sensitive to the foods being tested, using a non-endpoint, and no controls.

Dr. Lehman contradicts his own position however, because when Dr. Lehman actually tested a food allergic patient with a food that the patient was allergic to, the testing was reliable.⁴⁴

The Crawford Abstract

The American Academy of Allergy and Immunology Position Statement also relied on the Crawford Abstract, which was an abstract only and never published as an article in a peer-reviewed medical journal. Because it was published only as an abstract, the data was not available for review, which is critical for a "study" to be considered valid. Nonetheless, it is important to address the serious issues with the Crawford abstract since it was used to cast a negative light on intradermal neutralization testing. One issue is the fact that this study only

³⁹ Miller Joseph B. Letters to the Editor. *Clinical Ecology* Volume VI, Number 1 p. 33.

⁴⁰ Gerdes, Kendall A., Provocation/Neutralization Testing: A Look At The Controversy. 1989. *Clinical Ecology* Volume VI, Number 1, p.21.

⁴¹ Lehman CW. A Double-Blind Study of Sublingual Provocative Food Testing. *Annals of Allergy* 1980;45:144-49.

⁴² Miller, Joseph B. Letters to the Editor, *Clinical Ecology* Volume VI, Number 1, p34.

⁴³ Text quoted from Miller, Joseph B. Letters to the Editor, *Clinical Ecology* Volume VI, Number 1 p. 34.

⁴⁴ Miller, Joseph B. Letters to the Editor, *Clinical Ecology* Volume VI, Number 1, p35.

looked at provoking symptoms with subcutaneous injections, *not* intradermal injections which are not one and the same. Secondly, physicians who had no experience with the technique and little opportunity to obtain experience in the methodology conducted this “study”.⁴⁵

A third issue with the Crawford abstract was the fact that the Crawford Committee was advised by Dr. Joseph B. Miller, who attended all of the Crawford Committee meetings, that the study as it was set up could not possibly work. This study was not at all about intradermal neutralization testing or testing and treatment.⁴⁶

Breneman et al^{47, 48}

There are two studies by Breneman, et al, which contain serious enough flaws to call them completely into question. In the first study, the statistician is quoted as saying, “because of the design,...one must be careful about drawing any conclusions.”⁴⁹ That statement says it all. In both studies major parts of the data were removed with an unsatisfactory explanation, which again makes both of these studies insufficient, to be used to negate all of the positive, double blind studies published in medical journals on intradermal neutralization treatment.

The Kailin-Collier Letter

The Kailin-Collier “study” was never published as a study, but rather was reported in a letter published in *JAMA*. There are several major flaws with this study sufficient enough that it could not be used in a serious way to refute the contributions of intradermal neutralization testing or treatment. One of the first problems was Dr. Kailin’s complete lack of knowledge and experience with neutralization in any form. Dr. Joseph B. Miller was invited to join this study but declined because the protocol of the study guaranteed that it would not work.⁵⁰

Another serious issue with this study is the fact that the physicians were not allowed to see the wheals. The viewing of the wheals of the skin is a key component of the intradermal neutralization method, just as much as a gas gauge is to knowing how much gas you have in your gas tank. It is ludicrous to even consider such a “study”. Further damaging any value of the Kailin-Collier “study” was the omission of the information on the techniques and responses used in the “study”.

The Bronsky Abstract

The Bronsky abstract was also used by the American Academy of Allergy and Immunology in their Position Statement to disparage intradermal neutralization. The Bronsky abstract has several glaring issues, the first of which is that this “study” was never published as an article in a peer-reviewed medical journal for all to evaluate. Rather it was published in abstract form with information critical to its evaluation, omitted. A second very large issue is the fact that neither Dr. Bronsky nor Dr. Berkely, two physicians in training, had any experience with

⁴⁵ Miller, Joseph B. Letters to the Editor. *Clinical Ecology*. Volume VI, Number 1, p32.

⁴⁶ Miller, Joseph B. Letters to the Editor. *Clinical Ecology*. Volume VI, Number 1, p.32.

⁴⁷ Breneman JC, Crook WC, Deamer W, et al. Report of the Food Allergy Committee on the Sublingual Method of Provocative Testing for Food Allergy. *Annals of Allergy* 1973;31:382-5.

⁴⁸ Breneman JC, Hurst A, Heiner D, et al. Final Report of the Food Allergy Committee on the sublingual Method of Provocative Testing for Food Allergy. *Annals of Allergy* 1974;33:164.

⁴⁹ Gerdes, Kendall A. Provocation/Neutralization Testing: A Look At The Controversy. *Clinical Ecology*. Volume VI, Number 1, p.21.

⁵⁰ Miller, Joseph B. Letters to The Editor. *Clinical Ecology* Volume VI, Number 1, p.32.

intra-dermal neutralization.⁵¹ Drs. Bronsky and Berkely visited Dr. E. L. Binkley, Jr. and observed Dr. Binkley for three hours and then went off and concocted a so-called “study”.

Drs. Bronsky and Berkely also refused to allow Dr. Binkley to have any input into the study even though Dr. Binkley had been kind enough to allow these two physicians to come into his office and watch him at work doing provocation neutralization testing. This study is not at all a study on intra-dermal neutralization testing or treatment. It is simply difficult to believe that an organization like the American Academy of Allergy and Immunology (which you would think would pride itself on medical protocols for studies) would even acknowledge such a “study” as the Bronsky abstract.

The Terr Study⁵²

This study by Dr. Terr was retrospective in nature dealing only with the global outcome of 50 patients that he saw in referral. A major issue with the Terr Study is that 46 of the 50 patients were in litigation and may have seen Dr. Terr when he represented their legal adversary.⁵³ Dr. Terr failed to state who referred the patient in 46 of 50 cases which presents an issue of possible bias. The medical history of the patients in the study could have been influenced by a perceived adversarial relationship if they (the patients) had been sent to Dr. Terr by the Workman’s Compensation Board for example.

Additionally, Dr. Terr indicates that 31 of the 50 patients had symptoms that were most likely of psychological origin, but makes no reference to having done a psychological evaluation or referred for one.⁵⁴ Dr. Terr also fails to consider the continuing stress of litigation as a possible factor contributing to the patients’ conditions. With all of these issues, this study has little relative value.

The Miller Paper⁵⁵

This paper was actually in favor of intra-dermal neutralization treatment but was used as a reference against intra-dermal neutralization by the American Academy of Allergy and Immunology in their Position Statement.⁵⁶ Dr. Joseph B. Miller, who conducted the study, used intra-dermal neutralization in a double blind crossover basis. The American Academy of Allergy and Immunology however referred to Dr. Miller’s study as “subcutaneous” which is distinctly different and separate from intra-dermal techniques which should raise some questions in and of itself. Dr. Miller’s study clearly demonstrated the value of neutralization to foods.

American College of Allergists 1973 Final Food Allergy Committee Report

Having already addressed the American Academy of Allergy and Immunology, we will now turn to the 1973 Final Food Allergy Committee Report of the American College of Allergists, which also contains several major issues. The first problem with this report is that it included

⁵¹ Miller, Joseph B. Letters To The Editor. *Clinical Ecology*. Volume VI, Number 1, p.33.

⁵² Terr AI. Environmental Illness, A Clinical Review of 50 Cases. *Arch Intern Med* 1986;146-145-49.

⁵³ Gerdes, Kendall A. Provocation/Neutralization Testing: A Look At The Controversy. *Clinical Ecology* Volume VI, Number 1, p.21-22.

⁵⁴ Gerdes, Kendall A. Provocation/Neutralization Testing: A Lookk At The Controversy. *Clinical Ecology* Volume VI, Number 1, p.29.

⁵⁵ Miller J: A Double-Blind Study of Food Extract Injection Therapy: A Preliminary Report. *Annals of Allergy* 1977;38:185-191.

⁵⁶ Miller J. Letters to the Editor. *Clinical Ecology*. Volume VI, Number 1, p.32.

two experienced and seven “purposely” inexperienced investigators.⁵⁷ That corresponds to about 77.7% of the investigators as lacking experience. If experience and expertise were not critical to studies, then the medical community could just let the lay people do medical studies, which would certainly save money.

Another critical factor, which damages the Final report, is the fact that “fifty percent of the data from the 1973 study was discarded because the design of the study was faulty and gave an inordinate number of positive responses.”⁵⁸ These two factors together cast a black mark on the American College of Allergists and their 1973 Final report.

The 1974 Food Allergy Committee Report failed to correct the known problems of the 1973 Report, which in and of itself calls the 1974 Report into question.⁵⁹ When you know there is a problem with a study or protocol, it would be typical to make the necessary changes to correct future studies. The fact that this was not done, in light of the importance of the American College of Allergists position statement, makes an outsider wonder if something more insidious was really at play.

According to Dr. Doris Rapp:

“Part of the conclusions of the 1974 study, however, were based on the admittedly flawed 1973 report. In both studies there were flagrant inconsistencies in data found in the tables versus that in the text of the article, confounding variable, and obvious errors in design and execution.”⁶⁰

All of which makes the American College of Allergists position statement quite suspect.

5. The Issue of Medical Necessity

There is no question that it is a medical necessity for parents to be able to feed a child. There is no question that it is a medical necessity for a child to be able to eat food and take in enough calories to sustain their body weight, grow, and develop normally. Currently, Garrett is on an extremely limited diet due to her food allergies. With allergy treatment, Garrett can eat some very basic foods like corn, rice, potatoes, beef, pork, chicken, and turkey. Even with the allergy treatments, it is extremely difficult to maintain her body weight. Because Garrett was deprived of this allergy testing and treatment she does not eat foods that she is allowed to eat. That is to say, while can drink fruit juice with the allergy extracts, was never afforded the luxury of eating fruits or drinking fruit juices until she was 21 months old. Therefore, must acquire the “tastes” for the new foods that she was deprived of for most of her life.

Removal of the allergy treatments causes the immediate return of diarrhea, eczema, upset stomach and weight loss. This is a known fact since the parents have inadvertently run out of

⁵⁷ Breneman JC, Crook WC, Deamer W, Exline L, Gerrard JW, Heiner D, Hurst A, Leney FL. Report of the Food Allergy Committee on the sublingual method of provocative testing for food allergy. *Annals of Allergy* 31:382. 1973.

⁵⁸ Breneman JC, Crook WC, Deamer W, Exline L, Gerrard JW, Heiner D, Hurst A, Leney FL. Report of the Food Allergy Committee on the sublingual method of provocative testing for food allergy. *Annals of Allergy* 31:383. 1973.

⁵⁹ Breneman JC, et al. Final Report of the Food Allergy Committee of ACA on Clinical evaluation of sublingual provocative testing method for diagnosis of food allergy. *Annals of Allergy* 33:164. 1974.

⁶⁰ Randolph, Theron G. Environmental Medicine-Beginnings & Bibliographies of Clinical Ecology. 1987. Clinical Ecology Publications, Inc. Fort Collins, CO. p.302.

allergy extracts and had unknowingly given foods for which they did not have extracts. This is also a known fact because all untested and untreated foods that the parents have tried resulted in an upset stomach which presented in a refusal to eat for many hours, as well as diarrhea, eczema, hives, and a runny or stuffy nose.

The parents had exhausted the food supply prior to finding Dr. Patel and nothing worked. There is no other alternative for Garrett. Without allergy treatments from Dr. Patel, Garrett will starve to death over time. In most States in the U.S. the determination of "medical necessity" is determined by the physician providing the treatments, and *not* by the insurance company or HMO. It is a medical necessity that Garrett be able to eat food. It is a proven fact that Garrett has been allergic to all foods tested for except one food item (turmeric). It is a medical fact that the allergy treatments and testing and consultation services rendered by Dr. Patel for Garrett have been extremely effective.

6. The Issue of Experimental or Investigational Services

Univera Healthcare's Medical Protocol number 11.01.03 section addresses Experimental or Investigational services. The following is offered as proof positive that the allergy testing, treatments and services offered by Dr. Patel for Garrett could not be considered as experimental or Investigational by virtue of having met the conditions set forth in the Protocol Guidelines of section 11.01.03 of said document. The italicized text is directly from Protocol Guidelines section 11.01.03 **our response to each point follows in boldface print:**

- II. *In determining whether there is rigorous scientific evidence to determine if a service is experimental or investigational we require that any or all of the following five criteria be met:*
- A. *A service that is a medical device, drug, or biological product must have received **final** approval from the appropriate government regulatory bodies; such as the United States Food and Drug Administration (FDA).*

The allergy extracts used in Garrett's allergy treatments are FDA approved, and have been for many, many years. Additionally, this treatment has proven to be extremely effective for Garrett.

- B. *Published, peer-reviewed, medical literature must provide conclusive evidence that the service has a definite, positive effect on health outcomes. The evidence must include reports of well-designed investigations that have been reproduced by nonaffiliated, authoritative sources with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.*

The number of published, peer-reviewed, medical studies providing conclusive evidence that intradermal neutralization testing which is also referred to as intracutaneous provocative-neutralization food testing (IPFT), and originally was called provocation-neutralization, has a definite, positive effect on health outcomes is substantial.^{61 62 63 64 65 66 67 68 69 70 71 72}

⁶¹ Investigation of the clinical usefulness of the intracutaneous provocative-neutralization food test (IPFT); King, WP, Rubin, WA, Fadel RG, et al: Otolaryngology/Head & Neck Surgery, 99: 263-271, 1988.

The American Medical Association (AMA) provides Continuing Medical Education Credits to physicians taking courses in intradermal neutralization testing offered by the American Academy of Environmental Medicine. Intradermal neutralization testing is also covered in medical textbooks recognized throughout the world.⁷³ The positive health outcomes can not be denied.^{74, 75} The initial works providing the medical basis for intradermal neutralization testing began nearly 100 years ago⁷⁶, and has been duplicate over and over again^{77, 78} and is based in solid research and science. Garrett is the acid test for this service proving that it is indeed very effective.

C. *Published, peer-reviewed, medical literature must provide demonstrated evidence that, over time, the service leads to improvement in health outcomes (e.g. the beneficial effects of the service outweigh any harmful effects).*

There is no question from the published, peer-reviewed, medical literature that intradermal neutralization testing and treatment leads to improvement in health outcomes. () This question begs the question of safety (e.g. the beneficial effects of the service outweigh any harmful effects) and efficacy (improvement in health outcomes). Intradermal neutralization testing is like any other medical testing, treatment or procedure in that the safety of said service rests partly with the knowledge and expertise of the physician administering the said service or treatment. Given a choice most mature adults would pick a surgeon who had done 5,000 surgeries over a surgeon new to the medical field who had only done 1,000 or less. There is always something to be gained from experience.

⁶² A triple-blind crossover study that investigates the efficacy of subcutaneous neutralization food hypersensitivity therapy. King, WP, Fadal RG, Ward WA, et al. *Otolaryngology/Head & Neck Surgery*, 99: 272-277, 1988.

⁶³ Rea, WJ, et al. Elimination of Oral Food Challenge by Injection of Food Extracts. *Arch Otolaryngology* 110:248-52, 4/1984.

⁶⁴ Miller J: A double-blind study of food extract injection therapy: A preliminary report. *Annals of Allergy* 1977:38: 185-191.

⁶⁵ O'Shea J, Porter S: Double-blind study of children with hyperkinetic syndrome treated by multi-allergen extract sublingually. *Journal of Learning Disabilities*, 1981:14:189-190.

⁶⁶ Rapp, D: Double-blind confirmation and treatment of milk sensitivity. *Med J. Aust* 1978:1:571-572.

⁶⁷ Rapp, D: Food allergy treatment for hyperkinesis. *J Learning Disabilities* 1979:12:42-50.

⁶⁸ Rapp, D: Weeping eyes in wheat allergy. *Trans Am Soc Ophthalmol Otol Allergy* 1978:18:149-150.

⁶⁹ Boris M., Schiff M., Weidorfs, et al: Bronchoprovocation blocked by neutralizing therapy, abstracted. *J Allergy Clin Immunology* 1983:71:92.

⁷⁰ Boris, M, Weindorf, Corriel, et al: Antigen induced asthma attenuated by neutralization therapy. *Clinical Ecology*: 1985: 3:59-62.

⁷¹ Boris M, Schiff M, Weindorf S. Injection of low-dose antigen attenuates the response to subsequent bronchoprovocative challenge. *Otolaryngology Head Neck Surgery*, 1988:98: 539-545.

⁷² Brostoff J, Scadding G: Low dose sublingual therapy in patients with allergic rhinitis due to house dust mite. *Clinical Allergy*, 1986:16:483-491.

⁷³ Jonathan Brostoff and J.J. Challacombe, *Food Allergy Intolerance* (London: Bailliere Tindall, 1987.)

⁷⁴ David L..J.Freed, "Part I: The Provocation-Neutralization Technique. Part II: Can We Diagnose Allergies, Do We Know What We Are Doing, Does It Matter?" in *Food Intolerance*, ed. John Dobbing (London: Bailliere Tindall, 1987), pp151-84.

⁷⁵ Joseph B. Miller, *Relief At Last* (Springfield, IL: Charles C. Thomas, 1987).

⁷⁶ Schofield, Alfred T. *A Case of Egg Poisoning*. London: *Lancet*, 1908, p. 716.

⁷⁷ Vaughn WT. Some observations on food allergy. *Am J Digest Dis & Nutrition* 1:384: 1934.

⁷⁸ Hansel, French K. *Allergy of the nose and Paranasal sinuses*. St. Louis: C.V. Mosby Co. 1936.

With that said, intradermal neutralization testing is as safe, if not safer than traditional allergy testing given a standard and reasonable medical background of the provider doing the testing. A summary of 46,672 provocative food tests done by seven experienced physicians, yielded no violent reactions and only 12 reactions that required medication. Therefore since 99.995% of the provocative food tests required no medication like epinephrine to correct induced symptoms, and there were no violent reaction to the testing this is an exceptionally safe testing and treatment modality.⁷⁹

Traditional allergy injection therapy however has been associated with over thirty deaths in the past thirty years in the United States alone. Foreign literature mentions other deaths.⁸⁰ Additionally, it has been recorded that in the British Isles, the routine use of traditional allergy injection therapy is not allowed unless cardio-resuscitation equipment is available and each patient must wait one or two hours after the injection.⁸¹

Physicians using intradermal neutralization testing and treatment do so because it is safe and very effective. They use it because it leads to definite, positive health outcomes. One study on the efficacy of the neutralizing dose provides that it accurately took care of the symptoms 93.68% of the time used.⁸² Our personal experience is that intradermal neutralization testing and treatment is right on track and effective 100% of the time.

The efficacy rates of studies vary. One study done by an experienced physician quite familiar with intradermal neutralization testing provides a 99.8% level of efficacy and confidence.⁸³ In the summary of the article published in a peer-reviewed medical journal, Dr. Miller writes:

“In many cases the response of lifelong, severe, intractable syndromes was rapid and dramatic, often beginning within three to four days and symptoms often returned within three to four days after beginning a course of placebo therapy. In clinical practice this should prove to be a very useful practical tool for demonstrating the etiologic role of foods and providing substantial relief in several serious syndromes for which no other satisfactory method of etiologic diagnosis or effective therapy is available.”⁸⁴

⁷⁹ Rinkel, HJ, Lee, CH, Brown, DW, Willoughby, JW, Williams, JM. The diagnosis of food allergy. *Archives of Otolaryngology*, 1964:79:71-79.

⁸⁰ Weber, R.W., Vaughn, T.R., Dolen, W.K. A Ten-Year Review of Adverse Reactions to Immunotherapy. *Journal of Allergy and Clinical Immunology*. abs. no 510 (Jan. 1988), p. 295.

⁸¹ Rapp, D. *Is This Your Child's World?* 1996. A Bantam Book., p. 486.

⁸² Rinkel, HJ, Lee, CH, Brown, DW, Willoughby, JW, Williams, JM. The diagnosis of food allergy. *Archives of Otolaryngology*, 1964:79:71-79.

⁸³ Miller J.B., A Double-Blind Study of Food Extract Injection Therapy: A Preliminary Report. *Annals of Allergy* 1977: Vol 38: p.186.

⁸⁴ Miller J.B., A Double-Blind Study of Food Extract Injection Therapy: A Preliminary Report. *Annals of Allergy* 1977: Vol 38: p.186.

According to a multi-center, double-blind comparison study of the IPFT, “Overall, neutralization subcutaneous treatment should be beneficial approximately 75% of the time, and further enhanced by supplemental diet manipulation.”⁸⁵ One other study indicated that with experienced personnel intradermal neutralization would be effective in about 80% of the patients.⁸⁶

The American Medical Association would certainly not endorse a science or service that did not lead to an improvement in health outcomes or one where the harmful effects were greater than the health benefits. As previously stated, the AMA endorses this service as evidenced by AMA continuing medical education credits. Garrett is proof that the health benefits are positive and quite substantial.

D. *Published, peer-reviewed medical literature must provide proof that the service is at least as effective in improving health outcomes as established services or technologies, or is usable in appropriate clinical contexts in which established service or technology is not employable.*

Typical allergy services only address IgE mediated allergies which account for only about 5-10% of food allergies.^{87, 88, 89, 90, 91} Typical allergy “prick & scratch” testing is known to be very unreliable and inaccurate.^{92, 93} In addition, the “prick & scratch” standard allergy tests provide no treatment options for the patient, thus they are substantially inferior to the intradermal neutralization testing technique.

The double blind, placebo-controlled food challenge (DBPCFC) is an accepted method for testing for food allergies according to the present medical establishment. Comparing the results of intradermal neutralization testing to the deliberate feeding challenge demonstrates that the intradermal neutralization testing provides the same results as the DBPCFC with some added benefits not available in the DBPCFC.⁹⁴ The double-blind, placebo-controlled food challenge (DBPCFC) is not practical for infants and young

⁸⁵ King WP, Fadal RG, Ward WA, et al: Part II: Subcutaneous neutralization therapy: A multi-center study. *Otolaryngology Head & Neck Surgery*, 1988;99:272-277.

⁸⁶ Willoughby, J.W. Subcutaneous provocative food challenge test. *Clinical Ecology* Vol II, No. 2, Winter 1983-84. p.103.

⁸⁷ Brenemen JC. Basics of food allergy. Springfield, Ill: Charles C. Thomas. 1978:8,9,14-6,156-63.

⁸⁸ Rinkel JH, Randolph TG, Zeller M. Food allergy. Springfield, IL: Charles C. Thomas. 1951:5-147.

⁸⁹ Rinkel JH. The management of clinical allergy. Part IV. Food and mold allergy. *Arch Otolaryngology Head & Neck Surgery*. 1963;77:302-26.

⁹⁰ Rinkel RJ, Lee CH, Brown DW, Willoughby JW, Williams JM,. The diagnosis of food allergy. *Arch Otolaryngology Head & Neck Surgery*. 1964: 79:71-9.

⁹¹ Trevino RJ. Immunology of foods. *Otolaryngology Head & Neck Surgery*. 1986:95:171-176.

⁹² Rinkel, HJ, Lee, CH, Brown, DW, Willoughby, JW, Williams, JM. The diagnosis of food allergy. *Archives of Otolaryngology*, 1964:79:71-79.

⁹³ Vanderhoof, Jon. Other Manifestations of GI Allergy. *Lifeline Celiac Sprue Association, USA, Inc.* Winter 2003 Vol.23, No. 1 p.5-6.

⁹⁴ Rinkel RJ, Lee CH, Brown DW, Willoughby JW, Williams JM,. The diagnosis of food allergy. *Arch Otolaryngology Head & Neck Surgery*. 1964: 79:71-9.

children who are not capable of swallowing a gelatin capsule which is the preferred vehicle for this testing methodology.⁹⁵

Another issue with the DBPCFC is the amount of time that the testing takes between the ingestion of capsules, which is targeted to be 40 minutes after each negative challenge.⁹⁶ Infants and young children can not endure prolonged periods of fasting for such testing. Yet another issue with the DBPCFC is the fact that the gelatin capsules are typically made from pork or beef which basically poses a problem in the testing validity for individuals with a pork or beef allergy.

Therefore, the intradermal neutralization testing or IPFT is more effective than no testing at all, as offered by typical allergists who offer only IgE mediated testing. Intradermal neutralization testing or IPFT is more effective than the DBPCFC method, which would not work for infants and the very young children. Since Garrett is not able to swallow capsules, and has such delayed food allergies, other technologies would not work for testing, and they offer no treatment modalities. Therefore, intradermal neutralization testing and treatment is more effective than established services. Garrett provides definitive proof that intradermal neutralization testing and treatment is more effective than other allergy services.

E. Published, peer-reviewed medical literature must provide proof that improvement in health outcomes is possible in standard conditions of medical practice, outside of clinical investigatory settings.

From very early on, the published, peer-reviewed medical literature provides more than a preponderance of evidence that improvement in health outcomes is possible in standard conditions of medical practice, outside of clinical investigatory settings. Desensitization to foods by treatment with the foods was first described in 1908 by Dr. Alfred Schofield who treated a young boy with an egg allergy.⁹⁷ In 1936, in his *Allergy of the Nose and Paranasal Sinuses*,⁹⁸ Dr. Hansel described superior symptom relief achieved from up to 100 times weaker immunotherapy dilutions than the standard dilutions used at the time. After hearing a presentation at the 1965 meeting of the American College of Allergists in Chicago, Dr. Joseph B. Miller, who is a traditional allergist certified by the American Board of Allergy and Immunology, went back to his practice and tried the testing methods he had just learned about. Dr. Miller writes:

“I was naturally skeptical, but tried his suggestions when I returned to my office. The results can only be described as astounding. Many patients with unresolved allergic problems responded markedly and rapidly. Many with

⁹⁵ Food Allergy Adverse Reactions to Foods and Food Additives. Blackwell Scientific Publications, 1991. pp 86 section by S. Allan Bock. Book edited by D. Metcalf, H. Sampson, R. Simon.

⁹⁶ Food Allergy Adverse Reactions to Foods and Food Additives. Blackwell Scientific Publications, 1991. pp 90 section by S. Allan Bock. Book edited by D. Metcalf, H. Sampson, R. Simon.

⁹⁷ Schofield, Alfred T. *A Case of Egg Poisoning*. London: *Lancet*, 1908, p. 716.

⁹⁸ King, WP, King HC. The Evolution of Otolaryngic Allergy Practices. *Ear, Nose and Throat Journal* Vol 69; Jan 1990. p11.

*resistant asthma or perennial allergic rhinitis improved greatly or cleared completely when food injection therapy was added to their inhalant injection therapy. Some patients whose asthma or rhinitis was well controlled by inhalant therapy obtained remarkable relief of other types of symptoms, such as headache, vertigo, laryngeal edema, spastic colon, chronic urticaria, learning problems, and extrasystoles when food injection therapy was added. I gradually found myself successfully treating and relieving not just the half-dozen clinical entities normally seen in allergy practice, but fifty or more formerly refractory symptoms and syndromes.*⁹⁹

It is the very success and proof of positive health outcomes outside the clinical study environment that has kept intradermal neutralization testing or IPFT alive and well despite efforts to the contrary.^{100, 101, 102, 103} Garrett is the acid test for allergy, and proves conclusively that intradermal neutralization testing and treatment is extremely effective.

III. This exclusion shall not limit in any way benefits available for prescription drugs otherwise covered under the subscriber's/member's contract which have been approved by the FDA for the treatment of certain types of cancers, when those drugs are prescribed for the treatment of a type of cancer for which they have not been approved by the FDA, so long as the drugs prescribed meet the requirements of Section 4303(q) of the New York Insurance Law.

Statute 4303 (q) provides that as long as a cancer drug is “recommended by review article or editorial comment in a major peer reviewed professional journal” it will be covered even though it has not received FDA approval for that cancer indication. This policy, in stark contrast to the multitude of published studies on intradermal neutralization testing (or IPFT), could only be viewed as discriminatory reimbursement policies and practices. It would be most beneficial for Univera Healthcare and Excellus Health Plan, Inc. to consider the legal ramifications of having such a policy. In addition, this paper shall serve as “DIRECT AND CONSTRUCTIVE NOTICE – WITH WARNING” in regards to your discriminatory policies, which means that you will be liable for failure to correct such policies as such notice removes your legal protection of being ignorant of the law and provides intent of said actions.

IV. Under the Federal Employees Health Benefit Program (FEHBP/FEP), services and procedures that are regulated and approved by the FDA may not be denied as investigational/experimental.

⁹⁹ Joseph B. Miller. Food Allergy Provocative Testing and Injection Therapy. 1972 Charles C. Thomas Publisher. Springfield, IL. pp.9-10.

¹⁰⁰ Hansel, F.K., Sublingual Testing and Therapy. *Trans Am. Soc. Opth & Otolaryngology Allergy*. 1970:11:93-103.

¹⁰¹ Willoughby JW. Presentation> Update provocative food test technique. 31st Congress American College of Allergists. March 1975.

¹⁰² Lee, CH. A new test for detection of food allergies, pollen and mold incompatibilities. *Buchanan County Med. Bull* 1961:26:9.

¹⁰³ Morris, DL. Use of Sublingual Antigen in Diagnosis and Treatment of Food Allergy. *Annals of Allergy*. 1969:27:289-94.

The fact that any Federal Employee covered by the FEHBP/FEP would be covered by intradermal neutralization testing or IPFT is further evidence of discriminatory reimbursement policies and practices. Covering a select service for one class of customers is discriminatory without question. It would again behoove Univera and Excellus Health Plan, Inc. to review their position regarding intradermal neutralization testing, IPFT, or provocative-neutralization testing.

Allergy Testing Policy Number 2.01.10

POLICY:

Based upon our criteria and review of the peer-reviewed literature the following tests are medically appropriate in the diagnosis of the allergic patient:

<u>CODE</u>	<u>DESCRIPTION</u>
95015	<i>Intracutaneous (intradermal) tests, sequential and incremental, with drugs, biologicals, or venoms, immediate type of reaction</i>
95024	<i>Intracutaneous (intradermal) tests with allergenic extracts, immediate type of reaction</i>
95028	<i>Intracutaneous (intradermal) tests with allergenic extracts, delayed type of reaction, including reading</i>

Based on the above information, it would appear that Univera is violating their own Allergy Testing Policy by failing to approve Anne for services for allergy testing from the treating specialist because codes 95024 and 95028 provide for immediate and delayed reaction testing by intradermal testing which is the testing that Anne receives. It therefore would seem to most individuals reviewing this case that there are some discriminatory reimbursement policies and practices being utilized within Univera Healthcare, and Excellus Health Plan, Inc.

8. Summary

This External Review is for continued healthcare services for Anne and as such expedited handling of this matter is requested. As with some of our previous documents we are serving this appeal with “DIRECT AND CONSTRUCTIVE NOTICE – WITH WARNING”.

The history and significance of food allergies has been well documented by medical physicians for over two thousand years beginning with Hippocrates, the Greek Physician who is considered to be the Father of Medicine. Each Century moving forward to the present medical physicians have duplicated Hippocrates findings although independently of each other which strengthens the body of evidence available even more. In the past, medical doctors who were judged to be the best were those physicians capable of manipulating the patient’s diet in order to make them well.

In 1905, Dr. Francis Hare of Australia wrote a two-volume, 1,000 page book titled *The Food Factor in Disease*¹⁰⁴ which described how headache, eczema, epilepsy, mania, asthma, hypertension, gout, nervousness, biliousness, bronchitis, gastrointestinal disturbances, and other degenerative diseases were caused by food allergies. Years later in 1941, Dr. Warrant T. Vaughan in his book *Strange Malady*¹⁰⁵ would make similar observations regarding food allergies and health all borne out of an observation that he made in his medical practice that then to a theory which culminated in the testing of this theory or hypothesis.

There is no study, no documentation, and no peer-reviewed published literature that can wipe away over two thousand years of medical literature, studies, and reports that establish that food allergies can affect physical health, mental health, wellness and well-being. Food allergies can cause physical illness, diseases, neurological and mental illness. The treatment of food allergies has existed for nearly 100 years with volumes of studies supporting the positive health outcomes and safety of intradermal neutralization, provocation neutralization, IFPT, or any other name that could be used.

While there are so-called “studies” that make an attempt to disparage intradermal neutralization, there are no negative double blind, placebo controlled studies that meet medical protocols and guidelines. The earlier mentioned two groups of allergists who have participated in the process of trying to kill a medical treatment and tool for diagnosis of food allergies will ultimately be shown for what they are. The truth always prevails in the end. There is no medical basis for denying intradermal neutralization testing and treatment for any patient. In fact just the opposite is true.

The primary issues of External Review are the issue of medical necessity and whether or not a medical service is considered experimental or investigational. Anne can not survive without the allergy treatments and periodic testing from the Environmental Medicine Physician. Children must eat foods and take in sufficient calories to grow and thrive. Additionally, nutritional requirements at the young age of 2 years have been proven to be critical to proper growth and development and optimal brain growth. About 90% of brain growth occurs in the first two to three years of life which makes proper nutrition as important as the food and calories itself.

Depriving our child of such necessary and critical brain growth requirements by way of proper nutrition is unforgivable, and certainly unacceptable policy for a company who is in the healthcare business. Our public health policies do not support depriving the youngest children in America from good nutrition. This is a serious violation of the very intent of an insurance company or HMO.

With as much expertise as I have with allergy-free food preparations, there is no way that I can keep her alive without some foods to feed her. Having exhausted both the normal food supply of beef, pork, turkey, rice, corn, and potatoes, and having exhausted the exotic food supply of rutabaga, malanga, ostrich, venison, lotus root, and bison, I have no where to turn. I simply can not sustain my sweet daughter without medical help from the treating

¹⁰⁴ Hare, Francis. *The Food Factor in Disease*. London: Longmans, Vol. I, II, 1905.

¹⁰⁵ Vaughan, Warren T. *Strange Malady*. New York: Doubleday, 1941.

Environmental Medicine Physician. Thus, the services are indeed of a serious medical necessity.

On the issue of experimental or investigational, Univera Healthcare's Medical Protocol and Guidelines section 11.01.03 states that:

*"In determining whether there is rigorous scientific evidence to determine if a service is experimental or investigational we require that **any** or all of the following five criteria be met:"*

Without question this paper demonstrates that intradermal neutralization meets **all five criteria** with ease. The first issue raised (A) is whether the drug, device, or medical service has received "final FDA approval." The allergy extracts used are indeed FDA approved and have been for decades.

The second issue (B) is that "published, peer-reviewed medical literature must provide conclusive evidence that the service has a definite, positive effect on health outcomes, and this evidence must include reports of well-designed investigations that have been reproduced by nonaffiliated, authoritative sources with measurable results backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale." This issue has been met completely and without question as discussed earlier in this paper. The American Academy of Environmental Medicine is a national medical body that supports the efficacy and rationale. Additionally, support for intradermal neutralization testing and treatment in terms of a national body providing endorsements, the American Academy of Otolaryngic Allergy has sponsored a two-part study on this subject^{106, 107} which in effect endorses the advancement and recognition of this science.

While the second issue (B) has been met, let me raise the concern that there is not in any way, shape or form, a definitive body of evidence that includes reports of well-designed investigations that have been reproduced by nonaffiliated, authoritative sources with measurable results that proves that intradermal neutralization testing does not have a definite, positive effect on health outcomes. In the face of no negative studies that meet the above listed criteria, it is only a discriminatory application of insurance reimbursement practices and policies that would continue to deny intradermal neutralization testing and treatment for any patient, not just our daughter Anne.

The third issue (C) is that "published, peer-reviewed, medical literature must provide demonstrated evidence that over time, the service leads to improvement in health outcomes (e.g. the beneficial effects of the service outweigh any harmful effects)" has also been met in spades. Intradermal neutralization testing and treatment is both safe and effective. It is certainly **safer and more effective** than regular or traditional allergy testing and treatments. In an extremely large study of 46,672 provocative food tests which were done by experienced physicians, 99.995% of the time no epinephrine or symptom relieving medication was required. That safety rate is much better than many medical processes and procedures that

¹⁰⁶ King, WP, Fadal, RG, Ward, WA, Trevino, RJ, Pierce, WB, Steward, JA, Boyles, JH. Provocation-neutralization: A two-part study Part I. The intracutaneous provocative food test: A multi-center comparison study. *Otolaryngology-Head and Neck Surgery* 1988. Vol 99:, No. 3, p.263-271.

¹⁰⁷ King, WP, Fadal, RG, Ward, WA, Trevino, RJ, Pierce, WB, Steward, JA, Boyles, JH. Provocation-neutralization: A two-part study Part II. Subcutaneous neutralization therapy: A multi-center comparison study. *Otolaryngology-Head and Neck Surgery* 1988. Vol 99:, NO.3, p272-277.

are routinely done in our current medical climate and that are routinely covered by Univera Healthcare and other insurance companies.

Efficacy rates for intradermal neutralization testing and treatment vary in direct correlation to the expertise and experience of the physician doing the testing and providing the treatment which should come as no surprise to anyone. The medical experience and expertise of a physician can never be fully removed from the formula of success versus procedure or process. Efficacy rates vary from a published high of 93.68% to a lower rate of 75% and yet another study indicating an 80% efficacy which far outstrips the efficacy of traditional allergy treatments.

The fourth issue (D) states that “published, peer-reviewed medical literature must provide proof that the service is at least as effective in improving health outcomes as established services or technologies, or is usable in appropriate clinical contexts in which established service or technology is not employable”. This questions the issue of efficacy, which was addressed in issue (C) above, as well as whether said service would work in a clinical setting. The efficacy of intradermal neutralization testing is superior to the “prick and scratch” testing typically done by traditional allergists as “prick and scratch” testing is known to be very unreliable and inaccurate.

Typical allergists in the United States presently do not test for IgG or delayed food allergies for whatever reason. The lion’s share of food allergies are the IgG or delayed food allergies with 90-95% of the allergy population falling into this category. Typical allergists do not provide any type of food allergy treatment so intradermal neutralization testing and treatment is obviously much superior to no treatment at all. Additionally, the double blind, placebo-controlled food challenge (DBPCFC), the *established technology* used by traditional allergists, is completely inappropriate for our daughter since she can not swallow capsules at the age of two, and she can not sustain all day fasting periods.

The last issue (E) is that of “proof that improvement in health outcomes is possible in standard conditions of medical practice, outside of clinical investigatory settings” substantiated by published, peer-reviewed medical literature. This item is also met conclusively. From as early as 1908, when Dr. Schofield desensitized a child with an egg allergy, to 1965 when Dr. Joseph B. Miller tried the technique in his office after hearing about it at the American College of Allergists, intradermal neutralization has always led to the improvement in health outcomes. It of course would work in conditions of medical practice because that is where the entire concept originated.

There is no way that intradermal neutralization testing and treatment can be considered experimental or investigational based on the above reviewed five criteria. Intradermal neutralization has a long-standing track record of safety and efficacy in private practice.

Section III of Univera Healthcare’s Medical Protocol number 11.01.03, deals with cancer drugs. Basically an FDA cancer drug can be used and will be covered in an “off-label” manner so long as it is just even mentioned even in an “editorial comment” in a major peer reviewed professional journal. No studies are required. No safety data is required. No requirement of reports of well-designed investigations that have been reproduced by nonaffiliated, authoritative sources with measurable results backed up by the positive

endorsements of national medical bodies or panels regarding scientific efficacy and rationale. This screams discrimination. It is so discriminatory that it is repugnant and vile. And given the nearly 100 years of positive proof that intradermal neutralization testing and treatment is safe and effective, this discriminatory reimbursement policy and practice can and will not be tolerated.

According to section IV. of the same protocol and policy: “Under the Federal Employees Health Benefit Program (FEHBP/FEP), services and procedures that are regulated and approved by the FDA may not be denied as investigational or experimental.” To provide services to one class of customers and deny another class the same services is also discriminatory without question and grounds for legal action.

Univera Healthcare’s Allergy Testing Policy Number 2.01.10 provides additional documentation that Univera Healthcare should approve the medical services for our daughter because codes 95024 and 95028 provide for intradermal tests for allergic reactions. It would appear that Univera is in violation of their own allergy policy, which again calls into question the issue of discriminatory reimbursement policies and practices.

I did not set out to have children plagued by food allergies. Clearly I did not sign up for this ordeal when I had my three children. I am known for my expertise in gluten free, milk and casein free cooking and allergy-free cooking and baking in the Western New York Area. But even with my expertise, I am not a magician nor can I pull foods out of a hat. I must have some basic ingredients to make foods and baked goods for my daughter. And Anne has been allergic and reactive to every food tested for except for turmeric. Therefore, while our family history has dictated that I learn how to cook “allergy free”, I cannot keep our daughter alive without the testing, treatment and medical support of the Board Certified Environmental Medicine Physician. For that reason and all of the proof sources provided herein, services for treatment by a Board Certified Environmental Medicine Physician must be provided for our daughter, Anne.