

REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

**HOUSE BILL 2337: COVERAGE FOR THE
EXPENSE OF AMINO ACID-BASED
ELEMENTAL FORMULAS**

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2010

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To: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 2337 regarding the proposed mandated coverage for the expense of amino acid-based elemental formulas.

Respectfully submitted,

Timothy D. Hugo
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INTRODUCTION

The House Committee on Commerce and Labor referred House Bill 2337 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2009 Session of the General Assembly. House Bill 2337 was introduced by Delegate Kristen J. Amundson.

Delegate Amundson was also the patron of House Bill 615 that proposed mandated coverage for the expense of amino acid-based elemental formulas in 2008. She requested that the Advisory Commission defer the bill until 2009. Delegate Amundson indicated her intention at the time to introduce legislation in the 2009 Session to address concerns raised during the review of House Bill 615.

The Advisory Commission held a hearing on June 29, 2009 in Richmond to receive public comments on House Bill 2337. Delegate Amundson spoke in favor of the bill. A representative of the Virginia Association of Health Plans (VAHP) spoke in opposition to House Bill 2337. Written comments in support of the bill were provided by Children's MAGIC, seven citizens, and two physicians. The VAHP and Virginia Chamber of Commerce (VCC) provided written comments in opposition to House 2337.

The Joint Legislative Audit and Review Commission (JLARC) prepared an *Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas in accordance with Sections 2.2-2503 and 30-58.1 of the Code of Virginia*. The report is available on the JLARC website at <http://jlarc.state.va.us>.

SUMMARY OF PROPOSED LEGISLATION

House Bill 2337 would amend Section 38.2-4319 and add Section 38.2-3418.15 to the Code of Virginia. The bill requires insurers to provide coverage for the provision of amino acid-based elemental formulas, regardless of the method of intake, for the diagnosis and treatment of Immunoglobulin E and non Immunoglobulin E mediated allergies to multiple food proteins for enrollees under age 10, severe food protein induced enterocolitis syndrome, eosinophilic disorders as evidenced by the results of a biopsy, and impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract. The bill applies to each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis; corporations providing individual or group accident and sickness subscription contracts; and health maintenance organizations (HMOs) providing health care plans for health care services. House Bill 2337 provides that the ordering physician must issue a written order stating that the amino acid-

based elemental formula is medically necessary for the treatment of a disease or disorder noted in the bill. House Bill 2337 also provides that a private review agent, acting on behalf of an insurer, nonprofit health service plan, or HMO, may review the ordering physician's determination of the medical necessity of the amino acid-based elemental formula for the treatment of the disease or disorder.

House Bill 2337 prohibits insurers, corporations or HMOs from imposing any copayment, fee, policy year or calendar year, or durational benefit limitation or maximum for benefits or services that is not equally imposed on all individuals in the same benefit category.

House Bill 2337 applies to policies, contracts and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on or after January 1, 2010, or any time thereafter when any term of the policy, contract, or plan is changed or premium is adjusted. The bill does not apply to short-term travel, accident-only, limited or specified disease policies, or individual conversion policies or contracts, nor to policies designed for issuance to persons eligible for Medicare, or similar coverage under state or federal government plans.

PRIOR REVIEW

Similar bills addressing formulas have been reviewed by the Advisory Commission four times during the past ten years. In the past, the members of the Advisory Commission agreed that mandated coverage for medicated formulas was not necessary and recommended that other action be taken.

During the 1999 Session of the General Assembly, The House Committee on Corporations, Insurance and Banking referred two similar bills to the Advisory Commission. House Bill 2197 and House Bill 2199 were introduced by then Delegate Robert F. McDonnell. House Bill 2197 related to coverage for any low protein foods prescribed for treatment of inborn errors of amino acid metabolism, such as phenylketonuria (PKU), maple syrup urine disease (MSUD), and homocystinuria (HCU). House Bill 2199 related to coverage for any medical formula that eliminates specific amino acids for the treatment of inborn errors of metabolism, such as PKU, MSUD, and HCU. On November 22, 1999, the Advisory Commission voted unanimously to recommend that House Bill 2197 and House Bill 2199 not be enacted. During that time, the Virginia Department of Health (VDH) was charging families no more than 2% of their gross income for medical formulas. The Advisory Commission recommended that a mechanism for payment of the formulas or foods be provided either through expansion of the VDH program to include food or a tax credit. The 2000 report of the study was printed as House Document No. 67.

During the 2002 Session of the General Assembly, the House Committee on Commerce and Labor referred a similar bill to the Advisory Commission. House Bill 84 was introduced by Delegate Robert D. Orrock, Sr. House Bill 84 related to coverage for the expense of polypeptide-based or amino acid-based formulas whose protein source has been extensively or completely hydrolyzed. On January 8, 2003, the Advisory Commission voted (9-1) to recommend that House Bill 84 not be enacted. The Advisory Commission believed that the need for assistance for persons requiring polypeptide-based or amino-acid based formulas was significant, but thought that it should not be a mandated insurance benefit. The Advisory Commission believed that the funding for the then current Virginia Department of Health program for individuals with metabolic disorders should be increased and the program should be expanded to cover persons requiring polypeptide-based or amino-acid based formulas. The Advisory Commission recognized that due to the economic environment at the time, the funding for program expansion might not be available. The Advisory Commission believed, however, that expansion of the program to include the additional disorders was the best alternative and that it should be pursued.

During the 2004 Session of the General Assembly, the House Committee on Commerce and Labor referred House Bill 1216 to the Advisory Commission. House Bill 1216 was introduced by Delegate R. Steven Landes. House Bill 1216 related to coverage for the treatment of inborn errors of metabolism that involve amino acid, carbohydrate, and fat metabolism and for which medically standard methods of diagnosis, treatment, and monitoring existed. On November 16, 2004, the Advisory Commission voted unanimously (9 to 0) to recommend that House Bill 1216 not be enacted. The Advisory Commission recognized the need for assistance for individuals with inborn errors of metabolism and their families. The members acknowledged the relatively small number of individuals affected with these disorders and suggested that increased funding for the conditions be directed to the VDH.

During the 2008 Session of the General Assembly, the House Committee on Commerce and Labor referred House Bill 615 and House Bill 669 to the Advisory Commission. House Bill 615 was introduced by Delegate Kristen J. Amundson and House Bill 669 was introduced by Delegate Robert G. Marshall. Delegate Amundson and Delegate Marshall asked that action on House Bill 615 and House Bill 669 be deferred until 2009. The Advisory Commission agreed to defer the bills until 2009. Delegate Amundson indicated her intention to introduce legislation in the 2009 Session to address concerns raised during the review of House Bill 615 and House Bill 669.

House Bill 2337 is very similar to House Bill 615. House Bill 2337 differs in that it includes an age limit of 10 years old for the diagnosis and treatment of Immunoglobulin E and non Immunoglobulin, adds the modifier, severe, for food protein-induced enterocolitis syndrome, and requires a biopsy for eosinophilic disorders. House Bill 2337 also provides that a private review agent, acting on

behalf of an insurer, nonprofit health service plan, or HMO, may review the ordering physician's determination of the medical necessity of the amino acid-based elemental formula for the treatment of the disease or disorder.

Allergic and Gastrointestinal Disorders

The 2008 Legislative Brief by Children's Milk Allergy and Gastrointestinal Coalition (Children's MAGIC), entitled "The Fight for Coverage: Elemental Formulas" stated:

Amino acid-based elemental formulas are made from individual (single) non-allergenic amino acids unlike regular dairy (milk or soy based) formulas and foods that contain many complete proteins. Amino acid-based elemental formulas are made of proteins broken down to their "elemental level" so that they can be easily absorbed and digested. In many cases, amino acid-based elemental formulas are the only thing an infant or child can properly digest and tolerate due to various allergies or gastrointestinal conditions.¹

The Report of the Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas (The Advisory Commission Report) included information from the 2008 California Health Benefits Review Program (CHBRP) assessment of the medical, financial, and public health impacts of Assembly Bill 2174 regarding coverage for amino acid-based elemental formula. The CHBPR report stated:

Amino acid-based elemental formulas are complete nutrition formulas designed for individuals who have a dysfunctional or shortened gastrointestinal tract and are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, and/or carbohydrates.²

Short bowel syndrome (SBS) is a malabsorption disorder due to congenital defects of the gut or surgery to treat acquired diseases. If malabsorption becomes severe, an individual is unable to maintain hydration or nutrient balance and may require the assistance of supplemental parenteral nutrition (the practice of feeding a person intravenously).³

The Advisory Commission Report noted information from the Department of Agronomy and Horticulture at the University of Nebraska-Lincoln's website. Two authors discussed some of the issues that consumers experience following

exposure to certain foods. Module 5: Allergenicity explained that the immune responses of a true food allergy include two categories, the Immunoglobulin E (IgE) and non-Immunoglobulin E mediated.⁴

Module 5 document stated:

The more common allergic response, IgE-mediated, also referred to as an immediate hypersensitivity reaction, involves the rapid onset of symptoms, and is mediated by IgE antibodies. The non-IgE-cell-mediated response, also referred to as a delayed hypersensitivity reaction, involves the delayed onset of symptoms, usually 24 hours or longer after exposure or ingestion of the food.⁵

The symptoms of IgE may involve various systems of the body including the skin, respiratory tract, and gastrointestinal tract. Symptoms involving the gastrointestinal tract are common with food allergies that include abdominal cramping and pain, diarrhea, vomiting, and nausea. When an allergist uses the proper diagnostic tools and approaches, a correct diagnosis can be made using a skin test that involves pricking or puncturing the skin, and discussing the patient's history.⁶

Food Protein-Induced Enterocolitis Syndrome (FPIES) is a non-IgE mediated immune reaction in the gastrointestinal system to specific foods. The reactions can include continuous vomiting and diarrhea. Some children have severe vomiting and diarrhea, they become seriously dehydrated and go into shock. According to Kids With Food Allergy, a child with FPIES may experience what appears to be a severe stomach bug, but the "bug" only starts a couple hours after the allergic food is consumed. It was explained that poor growth weight may occur along with constant ingestion.⁷

Eosinophilic Disorders occur when there is a high number of eosinophils in the blood that may be triggered by certain allergic foods. Eosinophils, a type of white blood cell, are an important part of the immune system that help fight off certain types of infections in the body. Eosinophilic disorders are further defined by the location of the affected area. For example, eosinophilic esophagitis (EE) is coupled with abnormally high numbers of eosinophils in the esophagus. The American Partnership for Eosinophilic Disorders stated:

Symptoms of EE vary from one individual to the next and may differ depending on age. Vomiting may occur more commonly in young children and difficulty swallowing in older individuals. Common symptoms include reflux that does not respond to usual therapy (which includes proton pump inhibitors, a medicine which stops acid production in the stomach), dysphagia (difficulty swallowing), food impactions (food gets stuck in the throat), nausea and vomiting, failure to thrive (poor growth or weight loss), abdominal or chest

pain, poor appetite, malnutrition, and difficulty sleeping. Individuals that display some of the symptoms of EE should have an upper endoscopy biopsy for diagnosis.⁸

The Advisory Commission Report stated that problems with motility of the gastrointestinal tract occur when the stretching or contractions of the muscles in the esophagus, stomach, small intestine, and large intestine are not functioning properly in a coordinated fashion. Each region of the gastrointestinal tract works with other regions to process the food along the digestive tract absorbing nutrients and eliminating waste products. The International Foundation for Functional Disorders stated that motility problems include heartburn, difficulty swallowing, abdominal distention and pain, nausea, vomiting, constipation, and diarrhea. There are different types of gastrointestinal motility tests that provide information to help with diagnosis and treatment.⁹

SOCIAL IMPACT

According to information provided by Children's MAGIC, the US Census projected that there are 503,491 children under five years old in Virginia. Children's MAGIC estimated that between 327 and 503 of those children rely on amino acid-based elemental formulas.¹⁰

The Centers for Disease Control and Prevention reported that in 2007, 3 million children and teenagers under the age of 18 had a food or digestive allergy during the previous 12 months in the United States. From 2004 to 2006, there were approximately 9,537 hospital discharges per year of children from birth to 17 years old with a diagnosis related to food allergy.¹¹

Children's MAGIC received data from the Virginia's Department of Health, Division of Women's Infants, and Children (WIC) program and Community Nutrition Services that reported in December 2007, 68 infants and children received elemental formulas. As of February 2009, the number has increased to 77 participants.¹²

JLARC's assessment of House Bill 2337 stated:

Current prevalence and utilization rates can be used to provide an estimate of the number of children who need amino acid-based elemental formulas in Virginia; however, the precise number of children who need the formula is not known. National prevalence rates for the GI and hypersensitivity disorders listed in HB 2337 range from 100 per 100,000 individuals for eosinophilic esophagitis to 8,000 per 100,000 children under five years of age for food allergies. However, since elemental formula is used for only the

most severe cases of these disorders, the formula use would be substantially less than the prevalence rate.¹³

FINANCIAL IMPACT

The VDH operates two programs that cover amino acid-based elemental formulas for allergic and gastrointestinal disorders. The Care Connection for Children (CCC) Program provides free amino acid-based formulas for children with a family income at or below 300% of the Federal Poverty Level (FPL).

JLARC assessment noted in part:

The formulas must be medically necessary and have a physician's prescription. Children with GI or hypersensitivity disorders may qualify for the program; however, no amino acid-based elemental formulas are currently distributed through this program. VDH program staff report that they do not know why families have not received coverage for elemental formula through this program. However, Care Connection is a payer of last resort; therefore, if the child is eligible and able to receive coverage through another program or private insurance, they are ineligible for the program.¹⁴

The other program is for children whose family's income is at or below 185% of poverty from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). According to JLARC, as of December 2008, 80 children received amino acid-based elemental formulas through WIC in Virginia. The state Medicaid program also covers amino acid-based elemental formula for infants and children that are suffering from food allergies and disease.¹⁵

Children's MAGIC stated that according to the 2006 National Average, the median family income in the United States was \$58,528 and that the average cost of elemental formulas per year was \$5,075. According to the U.S. Census Bureau, 2006 American Community Survey, the median income in Virginia for 2006 inflation-adjusted dollars was \$56,277. A proponent of House Bill 669 stated that her daughter was diagnosed with eosinophilic esophagitis. The family reported that the formula costs more than \$100 per case, approximately \$500 per month, and their insurance company does not provide coverage for the formula.¹⁶

The JLARC assessment noted that the cost of elemental formulas is considerably more than the cost of traditional baby formulas. The JLARC assessment stated:

According to Children's MAGIC, children who use elemental formulas tend to stay on the formula for two years or less. The monthly cost of elemental formulas is more than double the cost of

traditional baby formulas and may be greater depending on the child's age and medical condition.¹⁷

MEDICAL EFFICACY

According to Children's MAGIC's, 2008 Legislative Brief, *The Fight for Coverage: Elemental Formulas*:

Amino acid-based elemental formulas are complete nutritional formulas designed for individuals that are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, or carbohydrates. Amino acid-based elemental formulas are made from individual (single) non-allergenic amino acids unlike regular dairy (milk or soy based) formulas and foods that contain many complete proteins. Amino acid-based elemental formulas are made of proteins broken down to their elemental level so that they can be easily absorbed and digested. In many cases, amino acid-based elemental formulas are the only thing an infant or child can properly digest and tolerate due to various allergies or gastrointestinal conditions.¹⁸

Children's MAGIC explained that the medical efficacy of amino acid-based elemental formulas has long been proven. Within two weeks of using amino acid-based elemental formulas or medical foods, hives and rashes clear and diarrhea disappears. After a few months, infants and children return to their normal weight and continue on a normal growth pattern. Children's MAGIC explained that the formulas help infants and children get back on track towards a healthy existence.¹⁹

The Director of Cincinnati Children's Hospital Medical Center, Division of Allergy and Immunology, provided information about eosinophilic gastrointestinal disorders and why elemental amino acid-based formulas are medically necessary for the diagnosis and treatment of these disorders. The information included the following:

Eosinophilic gastrointestinal disorders are relatively new and are estimated to afflict 1 in 10,000 children. Eosinophils are white blood cells that are normally associated with fight parasitic infections. Rarely, eosinophils respond to food and food areas of the gastrointestinal tract. They then release toxins that cause tissue damage. Symptoms include difficulty swallowing, abdominal pain, malnutrition, failure to grow, uncontrolled reflux, nausea, vomiting, food impactions where food actually gets stuck in the esophagus, difficulty sleeping, and diarrhea.

There are no medications to cure these disorders, but some medication, such as steroids, can alleviate the symptoms. The best treatment is to remove the triggers, foods, that attract these white blood cells to the GI tract.

About half of the children with these disorders also have food allergies. For some children, an elimination diet is prescribed where they eliminate all positive allergy foods from their diet. In some cases, this involves removing many common foods from the child's diet, without leaving adequate sources for sustainable nutrition. Many of these children require the addition of an amino acid-based formula to their very restricted diet in order to maintain health.

For other children, it is necessary to use an elemental diet in order to sustain life or as a diagnostic measure to determine which foods are causing the disorder. An elemental diet is composed of no proteins, which means no foods since all foods have some protein. Elemental formulas are composed of amino acids. These formulas allow the body to heal and then foods can be sometimes introduced one at a time to determine which ones were causing the disorder. Some children cannot drink enough of the amino acid formulas and require tube insertion. Other children can drink the formula orally.²⁰

The 2009 CHBRP Executive Summary, Analysis of Assembly Bill 163: Amino Acid-Based Elemental Formulas discussed the medical effectiveness of elemental formulas for the treatment of a person diagnosed with eosinophilic gastrointestinal disorders (EGID). The summary focused on two eosinophilic disorders (EE and eosinophilic gastroenteritis (EG)). EG is a rare condition that involves eosinophilic infiltration in one or more areas of the gastrointestinal tract.²¹

The executive summary stated:

- No randomized controlled trials have been conducted to assess the efficacy of elemental formula for the treatment of EGID.
- Four nonrandomized studies on the use of elemental formulas to treat EE have been published. Two of these studies were case series involving small numbers of subjects that did not include a comparison group.
 1. No studies were found that addressed using an elemental diet to treat adults with EE.
 2. The evidence reviewed suggests that elemental formula improves the following clinical symptoms associated with the food allergic response of EE including symptoms

such as diarrhea, vomiting, poor weight gain, food refusal, and abdominal pain.

- The evidence regarding the effectiveness of elemental formula as a treatment for EG is very limited. A case study of one child found that symptoms of EG improved after 9 weeks of dietary therapy with elemental formula. However, findings from this single case may not generalize to other persons with EG.²²

The 2008 CHBRP Assembly Bill 2174 discussed the medical effectiveness of treatments for short bowel syndrome (SBS). CHBRP stated that for children diagnosed with congenital SBS, a major therapeutic goal is to promote normal growth and development. Intravenous feeding is not a desirable method for treating SBS for extended periods as it can result in further complications. Because of the rarity of these disorders, few research studies have addressed the usage of elemental formulas to treat SBS. CHBRP reported that three uncontrolled studies of children suggested that elemental formula is associated with the following outcomes:

1. Decrease in the duration of parenteral nutrition therapy and successful transition to oral intake of food that can be easily absorbed by the intestinal tract.
2. Decrease in co-morbidities associated with SBS.
3. Decrease in hospitalizations.²³

The JLARC assessment noted in part:

Amino acid-based elemental formulas are a standard medical treatment for children with eosinophilic esophagitis and the treatment of last resort for certain severe cases of GI and hypersensitivity conditions. The population that needs elemental formula is relatively small, but the formulas are medically necessary for the treatment of these individuals. HB 2337 includes many conditions for which amino acid-based elemental formulas are recommended as a treatment of last resort, but it also includes conditions for which their use is not recommended by medical practice guidelines or medical experts. The mandate specifies that the use of elemental formulas to treat the listed conditions must be medically necessary. In addition, it could specify that more common formulas be tried and eliminated prior to prescribing elemental formulas, with the exception of eosinophilic esophagitis where it is a standard treatment.²⁴

The American Journal of Gastroenterology 2003 article, entitled *Elemental Diet is an Effective Treatment for Eosinophilic Esophagitis in Children and Adolescents*, reported a study of 346 patients with chronic gastroesophageal reflux disease symptoms and eosinophils on esophageal biopsy. Of that number, 51 patients were eventually diagnosed with EE. The study concluded that elemental diets resulted in significant reduction in vomiting, abdominal pain, and dysphagia for children and adolescents with EE. ²⁵

The Journal of Pediatrics 2002 article, entitled *Allergy to Extensively Hydrolyzed Cow's Milk Proteins in Infants: Safety and Duration of Amino Acid-based Formula*, reported on a study that surveyed infants that were allergic to cow's milk protein and extensively hydrolyzed formulas that received an amino acid-based formula. The results indicated that amino acid-based formulas proved to be safe and infants exhibited an overall gain in length and weight. Children that were restricted extensively to hydrolyzed formulas were diagnosed much earlier than children with multiple food allergies. ²⁶

Kids With Food Allergy, a national nonprofit food allergy organization, stated that treatment for food protein-induced enterocolitis syndrome varies from child to child. Infants that have reacted to both dairy and soy formulas should be placed on hypoallergenic or elemental formulas. Children should be introduced to new foods, one at a time, for an extended period of time. ²⁷

According to information from the University of Virginia Health System, Division of Pediatric Gastroenterology and Nutrition website, a small group of children are unable to tolerate the hydrolyzed protein contained in casein formulas and will only tolerate free amino acids, such as those elements contained in Neocate.

Neocate is a hypoallergenic, nutritionally complete powdered infant formula that is especially designed for infants and young children with milk protein allergy. Neocate allows infants and young children to receive all the necessary nutrients for their growth and development. Neocate relieves the various symptoms of infant food allergy and can be used for a range of allergy induced conditions such as gastroesophageal reflux disease (GERD) and eosinophilic esophagitis. The product is labeled as hypoallergenic, elemental, amino acid-based, and nutritionally complete. ²⁸

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission in 2009. Thirty-nine companies responded by June 16, 2009. Three indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could

not provide the information requested. Of the 36 respondents that completed the survey, nine reported that they currently provide the coverage required by House Bill 2337.

Five insurers reported cost figures that ranged from \$.03 to \$ 1.00 per month per individual policy to provide coverage required by House Bill 2337. Six insurers provided cost figures that ranged from \$.03 to \$1.00 per month per standard group certificate to provide the coverage required by House Bill 2337. Two insurers provided cost figures of \$.21 and \$5.00 per month per individual policyholder for coverage required by House Bill 2337 on an optional basis. Three insurers provided cost figures from \$.11 to \$3.00 per month per group certificateholder for coverage required by the bill on an optional basis.

Five insurers reported cost figures that ranged from \$.01 to \$.13 per member per month for an individual policy to provide coverage required by House Bill 2337. Thirteen insurers provided cost figures that ranged from \$.01 to \$.45 per member per month for a standard group certificate to provide the coverage required by House Bill 2337. Seven insurers provided cost figures from \$.13 to \$1.12 per member per month for group certificateholder for coverage required by the bill on an optional basis.

One respondent reported \$606.59 for the monthly cost of its total policy premium and did not supply an estimate or cost for the coverage required by House Bill 2337.

Four insurers reported the following medical conditions covered by elemental formulas when the formulas provide at least 50% of the individual's nutritional intake:

Conditions associated with an inborn error of metabolism such as PKU or methylmalonic acidemia. Conditions that interfere with nutrient absorption and assimilation, including allergy to cow or soy milk, anaphylaxis to food, allergic or eosinophilic enteritis, cystic fibrosis, diarrhea or vomiting resulting in clinically significant dehydration requiring treatment by a medical provider, malabsorption when associated with failure to gain weight, and failure to thrive, unresponsive to standard age appropriate interventions.²⁹

Three insurers noted that coverage is provided for the treatment of malabsorption disorders and based on medical necessity. The insurers' medical policy includes the following:

Amino acid-based elemental formulas are a class of nutritional formulas designed for use in the treatment of patients with

conditions of the bowel which cause maldigestion or malabsorption. Amino acid-based elemental formulas contain free amino acids as the only protein source and are highly osmotic. They can be administered orally (by mouth) or enterally (through nasogastric, gastrostomy or jejunostomy tubes). The nutritional requirements for patients requiring these formulas are established by medical evaluation and strict medical supervision is required for their usage.³⁰

Another insurer provided the following list of conditions that they cover only if the formula represents 50% or more of the individual's nutritional intake.³¹

- Inherited diseases, amino-acid organic, or organic acid metabolism
- Crohn's disease
- Gastroesophageal reflux with failure to thrive
- Disorders of gastrointestinal motility
- Multiple, severe food allergies which left untreated will cause malnourishment, chronic physical disability, mental retardation, or death
- Glutaric academia
- Histidinemia
- Hyperlysinemia
- Homocystinuria
- Maple syrup urine disease/syndrome
- Maternal phenylketonuria (PKU)
- Methylmalonic academia
- PKU
- Propionic academia
- Tyrosinemia
- Urea cycle disorders

SIMILAR LEGISLATION IN OTHER STATES

Children's MAGIC stated that eleven states (Arizona, Connecticut, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, and New York, Rhode Island) have legislative mandates for coverage of amino acid-based elemental formulas.

REVIEW CRITERIA

SOCIAL IMPACT

- a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

Children's MAGIC received data from the Virginia's Department of Health, Division of Women's Infants, and Children (WIC) program and Community Nutrition Services that reported in December 2007, 68 infants and children received elemental formulas. As of February 2009, the number has increased to 77 participants.³²

The Centers for Disease Control and Prevention reported that in 2007, 3 million children and teenagers under the age of 18 had a food or digestive allergy during the previous 12 months in the United States. From 2004 to 2006, there were approximately 9,537 hospital discharges per year of children from birth to 17 years old with a diagnosis related to food allergy.³³

- b. *The extent to which insurance coverage for the treatment or service is already available.*

In a 2009 State Corporation Commission Bureau of Insurance survey of the 50 top writers of accident and sickness insurance in Virginia, 39 companies currently writing applicable business in Virginia responded. Of the 36 respondents that completed the survey, nine (25%) reported that they currently provide the coverage as required by House Bill 2337.

The VAHP provided written comments on House Bill 2337. The VAHP stated:

Many health plans offer coverage for amino acid based elemental formulas under certain circumstances. In fact, most of the fully insured population in Virginia, receive their coverage from plans that offer coverage of amino acid based elemental formulas. The benefit may be limited to certain diagnoses, conditions, methods of administration, or inpatient settings. The variance among plans is in keeping with the larger debate amongst the medical community as to the categorization of formulas as food when delivered orally.³⁴

- c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

The VDH operates two programs that cover amino acid-based elemental formulas for allergic and gastrointestinal disorders. The Care Connection for Children (CCC) Program provides free amino acid-based formulas for children with a family income at or below 300% of the Federal Poverty Level (FPL). The other program, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), is for children whose family has income at or below 185% of FPL.

Families shared the personal experiences of their children. One family stated that their child experienced the failure to grow, constipation, eczema, fussiness, vomiting, bloody and watery stools. After an examination, the doctor diagnosed him with allergic colitis and prescribed amino acid-based elemental formula. After a week, the family saw major improvements in their child's condition. There was a reduction in skin rashes, and digestion difficulties.

Another family stated that the benefits of House Bill 2337 are vitally important. The family stated:

The absence of this medical food will result in weight loss, lack of healthy development, and related failure to thrive issues. Ironically, failure to thrive issues are likely to ultimately lead to a necessary tube feeding situation.³⁵

- d. *If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

One parent reported that they were paying \$800 per month for their child's formula, \$400 a month for insurance, plus a \$5,000 deductible. They stated that providing coverage for elemental formula saves on visits to specialists, emergency care costs, and other medical treatments.

One family provided written testimony of the financial hardship they faced because one parent had to take an extended leave from work to care for their child. Daycare was not an option because of the severity of their child's reaction to food. The child received amino acid-based formula for two years, and they used their savings to pay for the formula that cost approximately \$35 a day. The parent stated that if they had continued to feed their daughter regular formula or foods, there would have been more emergency room visits and more overall health problems because there was no other form of protein that their child could tolerate.

e. *The level of public demand for the treatment or service.*

Children's MAGIC stated that the level of public demand for House Bill 615 and House Bill 669 was low because very few individuals utilize amino acid-based elemental formulas. The bills will affect a tiny segment of the population and the level of demand will be miniscule. The majority of children will use these formulas for a short period of time, two years or less on average.

Written comments in support of House Bill 2337 were provided by Children's MAGIC, seven citizens, and doctors from Cincinnati Children's Hospital Medical Center and Johns Hopkins University. Parents stated that amino acid-based elemental formulas are essential and the source of nutrition to sustain life. Parents stated that the only way for their children to reach a healthy calorie intake, maintain weight, and continue to develop is through the use of an elemental formula. Without the formula, they will become malnourished and die.

Five families testified in favor of House Bill 615 and House Bill 669 at the public hearing on September 29, 2008. They testified that the formulas are medically necessary and needed for the rest of their children's lives.

f. *The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.*

A member of the staff of Cincinnati Children's Hospital Medical Center stated:

When an amino-acid formula is prescribed, it is because there are no other options for that patient. These formulas are necessary and coverage for them shouldn't be dependent on diagnosis or delivery method. As a medical professional I see no reason why insurance companies will cover the tube feeding method only and not the oral method – oral is inherently much cheaper as it requires no surgery or maintenance and it's significantly less invasive on the patient.

Many insurance companies will only provide coverage for these expensive formulas if the patient is diagnosed with a metabolic disorder, or if the formula is fed only through an enteral tube.

Children who need these amino acid-based elemental formulas tend to heal quickly and become healthier in not just the short term but the long term. Amino acid-based elemental formulas are medical treatments and should be treated as such. ³⁶

A member of the staff of Johns Hopkins University stated:

For the children who do suffer from severe allergies, eosinophilic disorders, and the other gastrointestinal diseases, amino acid-based elemental formulas are an important tool and provide the life sustaining nutrition these children are unable to get from other formulas or foods.³⁷

Seven families strongly recommended that insurance companies be required to cover amino acid-based elemental formulas because their children would not live a normal life without the formulas.

- g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contract is unknown.

- h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

Similar, but not identical, bills addressing formulas including House Bill 615 and House Bill 669, House Bill 2197, House Bill 2199, House Bill 84, and House Bill 1216 have been reviewed by the Advisory Commission four times during the past ten years. The members of the Advisory Commission agreed that mandated coverage for medicated formulas was not necessary and recommended that other action be taken.

JLARC assessment on House Bill 2337 stated:

The population that needs elemental formulas is relatively small, but the formulas are medically necessary for the treatment of these individuals. HB 2337 includes many conditions for which amino acid-based elemental formulas are recommended as a treatment of last resort, but it also includes conditions for which their use is not recommended by medical practice guidelines or medical experts.³⁸

FINANCIAL IMPACT

- a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

It is not anticipated that House Bill 2337 would increase the cost of treatment over the next five years. However, Children's MAGIC reported that the cost of formulas could decrease, if insurers choose to enter into agreements with pharmacies, manufacturers, and distributors of these formulas.³⁹

- b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

It is unlikely that the proposed mandate would significantly increase the inappropriate use of treatment because House Bill 2337 requires coverage for amino acid-based elemental formulas when the ordering physician has issued a written order stating that the formula is medically necessary for the treatment. House Bill 2337 also provides that a private review agent, acting on behalf of an insurer, nonprofit health service plan, or HMO, may review the ordering physician's determination of the medical necessity of the amino acid-based elemental formula for the treatment of the disease or disorder.

- c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

Children's MAGIC stated that House Bill 2337 provides coverage of specialized elemental formulas for a very small number of sick children. They noted:

- Insurers deny the easiest, cheapest and medically preferable method and that House Bill 2337 would fix this problem.
- The benefits of this proposal strongly outweigh its minimal costs.
- Long-term healthcare costs projected to decrease as a result.

Providing the correct treatment of amino acid-based elemental formulas, at the right time when needed, will reduce, if not entirely eliminate the need for expensive and unnecessary enteral feeding and other related costs.⁴⁰

- d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

It is unlikely that the proposed mandate would significantly affect the number and types of providers in the next five years because the number of insureds needing elemental formulas is relatively small.

- e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

Five insurers reported cost figures that ranged from \$.03 to \$ 1.00 per month per individual policy to provide coverage required by House Bill 2337. Six insurers provided cost figures that ranged from \$.03 to \$1.00 per month per standard group certificate to provide the coverage required by House Bill 2337. Two insurers provided cost figures of \$.21 and \$5.00 per month per individual policyholder for coverage required by House Bill 2337 on an optional basis. Three insurers provided cost figures from \$.11 to \$3.00 per month per group certificateholder for coverage required by the bill on an optional basis.

Five insurers reported cost figures that ranged from \$.01 to \$.13 per member per month for an individual policy to provide coverage required by House Bill 2337. Thirteen insurers provided cost figures that ranged from \$.01 to \$.45 per member per month for a standard group certificate to provide the coverage required by House Bill 2337. Seven insurers provided cost figures from \$.13 to \$1.12 per month per group certificateholder for coverage required by the bill on an optional basis.

- f. *The impact of coverage on the total cost of health care.*

Children's MAGIC stated that coverage for amino acid-based elemental formula would save money by preventing medical costs of surgeries, physical visits, and emergency room visits. They believe that by providing the formula to children when needed not only reduces immediate medical costs but also future costs as they become teenagers and young adults.⁴¹

MEDICAL EFFICACY

- a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

A member of the staff of Cincinnati Children's Hospital Medical Center provided written comments in support of House Bill 2337 that stated:

Elemental formulas are composed of amino acids. These formulas allow the body to heal and then foods can be sometimes introduced one at a time to determine which foods are causing the disorder. Some children cannot drink enough of the amino acid formulas and require tube insertion. Other children can drink the formula orally. When an amino-acid formula is prescribed, it is because there are no options for that patient. Children who need these amino acid-based elemental formulas tend to heal quickly and become healthier in not just the short term but the long term. Amino acid-based elemental formulas are medical treatments and should be treated as such.⁴²

The 2008 CHBRP Assembly Bill 2174 discussed the medical effectiveness of treatment for short bowel syndrome (SBS). CHBRP stated that for children diagnosed with congenital SBS, a major therapeutic goal is to promote normal growth and development. Intravenous feeding is not a desirable method for treating SBS for extended periods as it can result in further complications. Because of the rarity of these disorders, few research studies have addressed the usage of elemental formulas to treat SBS. CHBRP reported that three uncontrolled studies of children suggested that elemental formula is associated with the following outcomes:

1. Decrease in the duration of parenteral nutrition therapy and successful transition to oral intake of food that can be easily absorbed by the intestinal tract.
2. Decrease in co-morbidities associated with SBS.
3. Decrease in hospitalizations.⁴³

The JLARC assessment stated:

The medical efficacy and effectiveness of amino acid-based elemental formulas are well established as a treatment of last resort for certain conditions listed in HB 2337 and a standard treatment for eosinophilic esophagitis (Table 2); however, the bill also would cover conditions for which the use of formula is not standard medical practice.⁴⁴

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

- 1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

- 2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

- a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

Proponents believe that House Bill 2337 addresses both the medical and social needs of treating individuals diagnosed with allergic and gastrointestinal disorders. The benefit is consistent with the role of health insurance.

The JLARC assessment noted:

Amino acid-based elemental formulas are a standard medical treatment for children with eosinophilic esophagitis and the treatment of last resort for certain severe cases of GI and hypersensitivity conditions. The population that needs elemental formula is relatively small, but the formulas are medically necessary for the treatment of these individuals. HB 2337 includes many conditions for which amino acid-based elemental formulas are recommended as a treatment of last resort, but it also includes conditions for which their use is not recommended by medical practice guidelines or medical experts. The mandate specifies that the use of elemental formulas to treat the listed conditions must be medically necessary. In addition, it could specify that more common formulas be tried and eliminated prior to prescribing elemental formulas, with the exception of eosinophilic esophagitis where it is a standard treatment. ⁴⁵

JLARC assessment on House Bill 615 and House Bill 669 stated:

Further evidence that the mandates, particularly coverage of amino acid-based formulas for IEM disorders, are consistent with insurance is that Medicaid and the State employee health plan cover formulas for this purpose. ⁴⁶

- b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

The VAHP does not believe it is appropriate to mandate benefits that will only affect a small portion of the residents in the Commonwealth of Virginia, during a time when employers, especially small and medium sized businesses, are struggling to provide basic health coverage during a recession. They stated that the proposed mandated bill will only apply to the fully insured policies offered by employers with more than 50 employees. House Bill 2337 does not apply to self-insured plans that are offered by large employers. ⁴⁷

The Virginia Chamber of Commerce (VCC) presented written comments in opposition to House Bill 2337. The VCC provided information from the Council for Affordable Health Insurance (Council)'s national report dated May 2009 regarding the impacts mandates have on the affordability of health insurance. The Council states:

1. While mandated health benefits make health insurance more comprehensive – for some, the also make it more expensive.
2. While one mandate by itself may not generate a large increase in premium, it is the culmination of many mandates that increase the cost of coverage.
3. Mandates can boost the cost of a policy between 20 to 45 percent, depending on which state you are looking at.
4. Experience demonstrates that when health insurance costs go up, more people drop or decline coverage - swelling the ranks of the uninsured.
5. The introduction of state-mandated benefits legislation is slowing down. That reduction implies that policymakers are finally getting the message. These things cost money. ⁴⁸

The JLARC assessment stated:

A more limited version of the mandate would more directly meet patient's needs and would reduce the impact on insurance premiums. Mandated coverage of the formulas would help to relieve financial hardship of those self-paying because the financial hardship may be significant, from five percent to almost ten percent of median household income. In comparison, mandating coverage

is estimated to have a modest impact on premiums. The impact could be lessened further, however, by (1) limiting the bill to those conditions for which elemental formulas are recommended as a standard or last resort treatment according to medical practice guidelines and medical experts, (2) eliminating coverage for adults, and (3) requiring other potential treatments to be attempted first, with the exception of eosinophilic esophagitis.⁴⁹

- c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insured.

RECOMMENDATION

The Advisory Commission voted unanimously (10 to 0) on November 17, 2009 to recommend against the enactment of House Bill 2337.

CONCLUSION

The Advisory Commission members believed that based upon the information presented and reviewed, a mandate for the coverage of amino acid-based elemental formulas is not necessary at this time.

ENDNOTES

¹ Children’s MAGIC, Children’s Milk Allergy and GastroIntestinal Coalition, The Fight for Coverage: Elemental Formulas, 2008 Legislative Brief.

² Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

³ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁴ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁵ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁶ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁷ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁸ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

⁹ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

¹⁰ Children’s MAGIC (Milk Allergy and GastroIntestinal Coalition) Assessment of House Bill 2337 – June 2009.

¹¹ Centers for Disease Control and Prevention (CDC), Press Release October 22, 2008.

¹² Children’s MAGIC (Milk Allergy and GastroIntestinal Coalition) Assessment of House Bill 2337 – June 2009.

¹³ Joint Legislative Audit and Review Commission of the Virginia General Assembly, “Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas,” June 2009.

¹⁴ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

¹⁵ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

¹⁶ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

¹⁷ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

¹⁸ Children's MAGIC, Children's Milk Allergy and GastroIntestinal Coalition, The Fight for Coverage: Elemental Formulas, 2008 Legislative Brief.

¹⁹ Children's MAGIC, Children's Milk Allergy and GastroIntestinal Coalition, The Fight for Coverage: Elemental Formulas, 2008 Legislative Brief.

²⁰ Cincinnati Children's Hospital Medical Center. June 29, 2009.

²¹ 2009 California Health Benefits Review Program. Executive Summary, Analysis of Assembly Bill 163: Analysis of Assembly Bill 163: Amino Acid-Based Elemental Formula. March 30, 2009.

²² 2009 California Health Benefits Review Program. Executive Summary, Analysis of Assembly Bill 163: Analysis of Assembly Bill 163: Amino Acid-Based Elemental Formula. March 30, 2009.

²³ 2008 California Health Benefits Review Program. Executive summary, Analysis of Assembly Bill 2174: Coverage for Amino Acid-Based Elemental Formula. April 8, 2008.

²⁴ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

²⁵ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

²⁶ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

²⁷ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

²⁸ Report of The Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 615: Coverage for the Expense of Amino Acid-Based Elemental Formulas and House Bill 669: Coverage for the Expense of Amino Acid-Based Formulas.

²⁹ State Corporation Commission, Bureau of Insurance Survey, June 16, 2009.

³⁰ State Corporation Commission, Bureau of Insurance Survey, June 16, 2009.

³¹ State Corporation Commission, Bureau of Insurance Survey, June 16, 2009.

³² Children's MAGIC (Milk Allergy and GastroIntestinal Coalition) Assessment of House Bill 2337 – June 2009.

³³ Centers for Disease Control and Prevention (CDC), Press Release October 22, 2008.

³⁴ Virginia Association of Health Plans. June 18, 2009.

³⁵ Interested parties public comments, June 29, 2009.

³⁶ Cincinnati Children's Hospital Medical Center, Director of Allergy & Immunology Division. June 29, 2009.

³⁷ Johns Hopkins University, Department of Pediatrics, June 29, 2009.

³⁸ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

³⁹ Children's MAGIC. The Fight for Coverage: Elemental Formulas, 2008 Legislative Brief. www.childrensmagic.org.

⁴⁰ Children's MAGIC (Milk Allergy and GastroIntestinal Coalition) Assessment of House Bill 2337 – June 2009.

⁴¹ Children's MAGIC, Children's Milk Allergy and GastroIntestinal Coalition, The Fight for Coverage: Elemental Formulas, 2008 Legislative Brief.

⁴² Cincinnati Children's Hospital Medical Center, Director of Allergy & Immunology Division. June 29, 2009.

⁴³ 2008 California Health Benefits Review Program. Executive Summary, Analysis of Assembly Bill 2174: Coverage for Amino Acid-Based Elemental Formula. April 8, 2008.

⁴⁴ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

⁴⁵ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.

⁴⁶ Joint Legislative Audit and Review Commission of the Virginia General Assembly, Evaluation of Proposed Mandated Health Insurance Benefits, "Evaluation of House Bill 615 and House Bill 669: Mandated Offer of Amino Acid-Based Formulas," September 2008.

⁴⁷ Virginia Association of Health Plans. June 18, 2009.

⁴⁸ Virginia Chamber of Commerce, public meeting June 23, 2009.

⁴⁹ Joint Legislative Audit and Review Commission of the Virginia General Assembly, "Evaluation of House Bill 2337: Addendum to 2008 Evaluation of House Bill 615 and House Bill 669, Mandated Coverage of Amino Acid-Based Formulas," June 2009.