



April 18, 2022

The Honorable Patty Murray  
Chair  
Health, Education, Labor & Pensions Committee  
U.S. Senate  
Washington, DC 20510

The Honorable Richard Burr  
Ranking Member  
Health, Education, Labor & Pensions Committee  
U.S. Senate  
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

The undersigned members of the Patients & Providers for Medical Nutrition Equity, a national coalition of patient and provider organizations that represent individuals for whom specialized nutrition is medically necessary for treatment of their digestive or inherited metabolic disorder, write to request consideration of **the *Medical Nutrition Equity Act (MNEA)* by the Health, Education, Labor & Pensions Committee, with the goal of final passage before the end of the year.** The bipartisan legislation has been introduced in the last several Congresses and was reintroduced in the 117<sup>th</sup> Congress as S. 2013/H.R. 3783 by Senators Casey and Ernst and Representatives McGovern and Herrera Beutler. The undersigned members of the coalition strongly urge you to act on this legislation so it can be enacted this year.

#### **Policy Issue**

The *MNEA* would ensure Americans with certain inherited metabolic conditions and gastric disorders have access to essential treatments for their diseases. While each of the conditions represented in the bill is considered rare, cumulatively, thousands of children and adults in our country live with digestive or inherited metabolic disorders that inhibit their bodies from digesting or metabolizing the food they need to survive. When these conditions are left untreated, food can become toxic or the body can fail to absorb necessary nutrients. These individuals must turn to medically necessary nutrition, such as highly specialized formulas, both as a treatment for their condition and as sustenance.

While medically necessary nutrition is sometimes the best or only treatment for a digestive or metabolic condition, insurance companies often deny coverage. Insurance companies will typically cover pharmaceuticals or biologics for treatment of these diseases; however, they are often used off-label or may not be recommended by the treating physician as first-line therapy. Further, pharmaceuticals and biologics are often costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer. Under the *MNEA*, physicians and patients would be able to select the best treatment option for that patient.

Even when an insurance company does cover medically necessary nutrition, it often comes with the stipulation the formula be administered through a feeding tube (for example, a nasogastric tube, placed through the nose into the stomach or a gastrostomy tube, surgically placed directly into the stomach). Surgery to place a feeding tube is expensive and these tubes carry additional risks. For example, a gastrostomy tube can leak, cause ulcerations, or cause infection at the insertion site. In severe cases, a patient may experience a perforation in the intestinal tract. Medically necessary nutrition, when administered under a physician's order, constitutes life-saving treatment with lower costs and fewer risks.

These types of coverage policies are irrational and interfere with thoughtful medical decision making. Further, without coverage, medically necessary nutrition is unaffordable for many families. For example, some children with Crohn's disease require a pre-digested formula such as Peptamen 1.5, which, at five cans per day, can cost an average of \$1,500/month. For many patients and their families, the out-of-pocket costs for specialized formulas are prohibitive, particularly when you consider these formulas cost less than biologics that are covered for some of these conditions.

### **Formula Recall Highlights Necessity of Medical Nutrition**

You may have recently heard of families who are frantically searching for specialized formulas for their children as a result of a voluntary formula recall which led the FDA to place a hold on all products from the affected location, which include Abbott's metabolic formulas. Many children with conditions specified in the *MNEA* rely on these same formulas for the treatment or management of their diseases and conditions. Oftentimes, these families are the same ones fighting their insurance companies for coverage of these formulas. A recent [story](#) in the *Washington Post* highlighted the medical necessity of these formulas for many patients by sharing the struggle of a Virginia boy's access to his medically necessary formula as a result of the recall. The boy has several health conditions, including Crohn's disease, eosinophilic esophagitis and gastroenteritis, and formula is his sole source of nutrition as well as the treatment for his conditions. When patients with gastrointestinal diseases and metabolic disorders cannot access their formulas, including when insurance companies deny coverage, it is a medical crisis.

When diseases of the digestive system or inherited metabolic disorders are left unmanaged or untreated, the medical consequences are often significant, permanent, and costly. The implications of denied or delayed access to medical nutrition in pediatric populations are particularly profound — inadequate growth, abnormal development, cognitive impairment, and behavioral disorders. In severe cases, without medical nutrition, the outcome can be unnecessary surgery, repeated hospitalizations, intellectual disability, or even death. Children with an unmanaged disease also suffer emotionally and socially. We encourage you to visit [nutritionequity.org/states](http://nutritionequity.org/states) to read stories about the need for this legislation.

### **Congress has already addressed this issue for TRICARE patients**

**Congress recognized the importance of improving coverage of medically necessary nutrition by including language similar to the *MNEA* in the 2016 *National Defense Authorization Act*.** It is time to extend that coverage to other insured populations and to ensure that there is a federal coverage floor.

Congress has also recognized the importance of identifying some of these conditions early in life and has passed and repeatedly reauthorized legislation requiring testing for inborn errors of metabolism as recommended by the Secretary of HHS 'Recommended Uniform Screening Panel (RUSP). Approximately 2,000 of the babies tested each year are diagnosed with inherited metabolic disorders as a result. For most of these babies, medical nutrition is their only option to survive.

### **It is time to help Americans beyond those covered by TRICARE**

The *Medical Nutrition Equity Act* would ensure coverage parity, providing patients the ability to choose the best treatment option in consultation with their physician. The Patients & Providers for Medical Nutrition Equity Coalition respectfully requests your Committee's consideration of the bill and its passage this year. Please contact Megan Gordon Don at 202.246.8095 or [mgdon@mgdstrategies.com](mailto:mgdon@mgdstrategies.com) if you have any questions or need more information.

Sincerely,

American Academy of Pediatrics  
American College of Gastroenterology  
American College of Medical Genetics and Genomics  
American Gastroenterological Association  
American Partnership for Eosinophilic Disorders  
American Society for Parenteral and Enteral Nutrition  
Asthma and Allergy Foundation of America  
Children's National Hospital  
Color of Crohn's and Chronic Illness  
Council for Pediatric Nutrition Professionals  
Crohn's & Colitis Foundation  
CURED (Campaign Urging Research for Eosinophilic Disease)  
Feeding Matters  
Genetic Metabolic Dietitians International  
Global Liver Institute

HCU Network America  
International Foundation for Gastrointestinal Disorders (IFFGD)  
International FPIES Association  
MSUD Family Support Group  
National Organization for Rare Disorders  
National PKU Alliance  
National PKU News  
National Urea Cycle Disorders Foundation  
Nationwide Children's  
Network of Tyrosinemia Advocates  
North American Society For Pediatric Gastroenterology, Hepatology & Nutrition (NASPGHAN)  
Organic Acidemia Association  
Society for Inherited Metabolic Disorders  
The FPIES Foundation  
United Mitochondrial Disease Foundation (UMDF)