



**May 25, 2022**

**Patients & Providers for Medical Nutrition Equity Coalition**

Statement for the Hearing Record

**The Infant Formula Crisis**

**House Committee on Appropriations**

The Patients & Providers for Medical Nutrition Equity Coalition (PPMNE) commends Chairwoman DeLauro, Chairman Bishop, Ranking Member Granger, Ranking Member Harris and members of the Agriculture Subcommittee for their leadership to address the current formula shortage crisis and would like to offer the following statement for the hearing record.

The PPMNE Coalition is a national coalition of more than 40 patient and provider organizations that represent individuals for whom specialized nutrition, including the formulas that are the subject of this hearing, is medically necessary for treatment of their digestive or inherited metabolic disorder.

### **This Crisis is Jeopardizing the Health of Children and Adults with Certain Inherited Metabolic Diseases or Gastrointestinal Conditions**

There have been many news reports showing the plight of families who are frantically searching for specialized formulas for their children. This situation is clearly a crisis that must be addressed, and we applaud this Committee for holding bi-partisan hearings on this issue. This formula shortage affects healthy infants, but, more significantly, infants, children of all ages and adults who rely on specialty formulas to treat certain inherited metabolic diseases or gastrointestinal conditions that prevent their bodies from digesting or metabolizing regular foods. The formula crisis is terrifying for patients with these conditions – many of whom cannot find suitable or tolerable substitutes for their current formula.

When these conditions are left untreated, food can become toxic or the body can fail to absorb necessary nutrients. 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 Americans of all ages who rely on these specialized formulas.

Ensuring that there is adequate supply of the specialty formulas is an essential first step in securing the health of the individuals who rely upon them, but more needs to be done to fully resolve the crisis.

### **Solving this Crisis Requires Addressing the Supply Shortage AND ACCESS**

Tragically, the ordeal these individuals and families are currently facing will not magically end when specialty formulas are no longer in shortage because of coverage and cost barriers to accessing these same formulas. These barriers existed long before the current shortage and will continue long after, unless Congress acts.

The formula shortage crisis has shown us that medically necessary nutrition is a critical medical treatment for these individuals. While medically necessary nutrition is sometimes the best or only treatment for a digestive or metabolic condition, insurance companies often deny or restrict 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 can be costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer. The *Medical Nutrition Equity Act (H.R. 3783)* would ensure Americans with certain inherited metabolic conditions and gastroenterological disorders have access to these formulas and other medical necessary nutrition to treat their diseases.

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 per 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.

There is congressional precedent for the *Medical Nutrition Equity Act*. 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 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). Diseases were added to the RUSP because they can be treated when diagnosed early. Approximately 2,000 of the babies tested each year are diagnosed with inherited metabolic disorders. For most of these babies, medical nutrition is their only option to survive.

In addition, nearly 40 states require some level coverage of medically necessary nutrition, but coverage is highly variable from state to state and does not reach patients enrolled in health plans covered by the Employee Retirement Income Security Act (ERISA).

The *Medical Nutrition Equity Act* has strong bi-partisan support, including 92 Representatives and approximately half of the members of this Subcommittee, including Chairman Bishop. The Senate bill (S. 2013) has 22 bi-partisan co-sponsors. We strongly urge Congress to include passage of the *Medical Nutrition Equity Act* as part of the legislative package to address this crisis by the end of the year.

## CONCLUSION

PPMNE appreciates this opportunity to share its perspectives on the formula shortage crisis and suggestions on steps Congress can take to ensure that Americans with certain gastrointestinal and inherited metabolic diseases and disorders are never without access to these critical formulas and other medically necessary nutrition. For more information or questions, please contact PPMNE Executive Director, Megan Gordon Don, at [mgdon@mgdstrategies.com](mailto:mgdon@mgdstrategies.com) or 202.246.8095.