

Chairman Brett Guthrie and Ranking Member Pallone—

Thank you for the opportunity to testify today on a priority of mine before the House Committee on Energy and Commerce.

In September of this year, joined by Congressman John Rutherford (R-FL) and Congresswoman Debbie Dingell (D-MI), I introduced the Medical Foods and Formulas Act, formerly the Medical Nutrition Equity Act, a bill that expands coverage under Medicare, Medicaid, and other specified federal health care programs to include foods and formulas that are medically necessary for the management of certain digestive and metabolic disorders and conditions. In the 118th Congress, I proudly co-led the bill with Congressman Rutherford, garnering 17 bipartisan cosponsors in the House.

The Medical Foods and Formulas Access Act prioritizes two distinct populations: those with digestive disease and those with inherited metabolic disorders (IMDs). It is estimated that roughly 62,000 children in the United States have Crohn's Disease — a life-long condition — and the prevalence is increasing. Improved quality of life is a central outcome in the management of Crohn's Disease, and this is especially true in children. When medical nutrition controls inflammatory disease, quality of life improves. When Crohn's disease is not under control, there is a significant risk of growth failure, pubertal delay, developmental delay, decreased bone age, fatigue, school absenteeism, and nutritional impairment.

Thankfully, medical innovation has led to new biologic and pharmacologic therapies that can be effective in the treatment and management of digestive diseases like Crohn's disease. But there are other treatment options for children, including enteral nutrition with specialized formulas. In fact, guidelines from the leading pediatric society dedicated to the treatment of digestive disease and disorders recommend exclusive enteral nutrition above corticosteroids as first-line induction therapy to reach remission in children with active low- to moderate-risk Crohn's disease. Unlike corticosteroids, there are no negative medical side effects of specialized formulas. Specialized formulas play a critical role in the treatment and management of children with Crohn's and other digestive diseases, and they should be covered by insurance.

Eosinophilic esophagitis (EoE) is another disease within the purview of this bill. This is a chronic, immune-mediated disease affecting an estimated 29.5 to 118 per 100,000 U.S. children. The prevalence of EoE has been steadily rising over the past two decades. Without appropriate nutritional support, children with EoE can face devastating consequences, including failure to thrive, malnutrition, and progressive esophageal complications that can lead to strictures (food impactions requiring emergency intervention) and increased health care costs. Medically necessary formulas provide essential nutritional support for many children with EoE; however, lack of insurance coverage for specialized formulas is a problem. The Medical Foods and Formulas Access Act is directed at achieving better access to evidence-based nutritional support,

preventing devastating complications of untreated disease, and reducing overall health care costs for children with EoE.

Newborns diagnosed with metabolic disorders require medical foods and formulas to prevent cognitive and physical impairment and, in some conditions, death. Glutaric Acidemia Type 1 (GA-1) occurs in approximately 1 in 92,300 live births and, without treatment, causes irreversible brain damage that can impair an individual's ability to walk, talk, or even swallow safely, and can be fatal. Very Long-Chain Acyl-CoA Dehydrogenase (VLCAD) Deficiency has an incidence of about 1 in 63,500, and without treatment can lead to metabolic crises resulting in liver, heart, and kidney failure. Phenylketonuria (PKU) occurs in roughly 1 in 16,500 newborns and requires immediate and lifelong treatment to prevent irreversible cognitive impairment, seizures, physical disabilities, and other severe health consequences.

Women with Phenylketonuria (PKU) must maintain strict metabolic control before and during pregnancy to prevent fetal damage. Children born to untreated mothers with PKU may have a condition known as *maternal phenylketonuria syndrome*, which can cause small brains, intellectual disabilities, birth defects of the heart, and low birth weights.

Life-long metabolic disorders require life-long treatment. This country's newborn screening program began detecting the metabolic disorder PKU in Massachusetts in 1963. This means the first babies diagnosed with PKU through newborn screening will reach Medicare age in 2028; yet there is no coverage of medical foods and formulas under Medicare for those with IMDs. Many people with IMDs will face a coverage cliff if we don't take action.

In December 2016, Congress passed improved coverage for medical nutrition for military families enrolled in TRICARE as a part of the National Defense Authorization Act. Our bill expands coverage to include patients covered under Medicaid, the Children's Health Insurance Program (CHIP), Medicare, and the Federal Employee Health Benefit Program. It is narrowly written to focus on individuals for whom medically necessary nutrition is the treatment for their diseases. I respectfully urge you to include H.R. 5684, the Medical Foods and Formulas Act, in a hearing so that the House may pass this important legislation during the 119th Congress.

Thank you for your consideration of these requests and this opportunity to testify.