You can save American healthcare dollars and improve lives by sponsoring legislation that provides the medical foods (formula and modified low protein foods) needed to treat patients with PKU and other inborn errors of metabolism.

The 2008 Newborn Screening Saves Lives Act guarantees that every newborn in America is screened for PKU, but there are no federal mandates to provide treatment.

- A treated person with PKU lives a normal productive life. They work and pay taxes.
- Without treatment they are severely brain damaged, can’t work, and require costly care.
- The treatment is simple: specially modified food and formula for the rest of their lives.
- The treatment is preventative care and cost effective chronic disease management.

It costs $10,000 or less per year to provide the medical food and formula for a PKU patient.

It costs $200,000 or more per year to care for a brain damaged person with PKU.

It is a 95% savings in medical expenses to treat a PKU patient with food and formula.

There are ~20,000 Americans with inborn errors of metabolism who need this treatment.

38 states have mandates to provide the food and formula for PKU, but many patients are denied access to health insurance and treatment. Most state mandates expire, at age 6 or 18, even though the diet is required for life. As a result, patients can suffer brain damage and cost the health care system and tax payers an additional 1-2 Billion dollars per year.

In states with treatment provisions, many self-insured plans deny treatment under ERISA.
The costs of treating an individual with untreated PKU can be up to 13 times the cost of providing proper treatment. Therefore, screening for PKU and maintaining lifelong care for affected individuals will result in a net gain to taxpayers and a cost-savings to the government.

What Is Phenylketonuria (PKU)?

- PKU is a metabolic disease in which the body cannot process a part of protein called phenylalanine. (1)
- If left untreated, PKU can lead to severe, progressive mental retardation. (1)
- The reported incidence of PKU in the United States ranges from 1 per 13,500 to 1 per 19,000 newborns. (2)
- In order to remain healthy, individuals with PKU are limited to a highly restrictive low-protein diet and must consume a liquid medical formula every day for the rest of their lives. (3)
- Living with PKU is difficult. The specially manufactured low-protein medical foods and medical formula are extremely expensive. The average family cannot afford them without assistance. The medically necessary formula and foods are often not paid for by the state or insurance companies. (4 & 5)
- The highly restrictive diet proves challenging for many teens and adults. There are many social difficulties that come with managing PKU. (4 & 5)
- Women with PKU face a special dilemma in planning a pregnancy. Infants of mothers with high phenylalanine levels exhibit mental retardation, heart defects, and growth retardation. (6)

What is the impact of PKU?

- An estimated 20,000 people in the United States have an inborn error of metabolism, such as PKU. (7)
- 5,000 of these individuals are not currently on a low-protein diet. (8)
- Studies show that individuals who discontinue diet before age 10 will experience an average 12 point drop in their IQ by adulthood. Children and adults who are off-diet also experience many other medical issues, including depression, impulse control disorder, phobias, epilepsy, tremors, and pareses. (9 &10)
- On average, it costs $15,000 per person per year for treatment of PKU, including $5,000 for medical visits and $10,000 for medical food and formula.
- Cost of care for an untreated PKU patient is approximately $200,000 per year for care in an inpatient mental health facility (or at least $60,000/yr for residential treatment). (11)

4 http://www.mayoclinic.com/health/phenylketonuria/D500514
5 http://www.matdenn.com/category/news/
6 http://depts.washington.edu/pku/pro_info/mgmtGuide.html
7 http://www2.uthscsa.edu/nsis
8 BioMarin
10 http://www.pkunews.org/adult/livesin.html
11 Richard Koch, MD