



Medical Foods Equity Act Information

S.2766 and HR.4926

The United States has tested newborns for PKU since 1966. Although the law requires that every single state screen newborns for PKU, there is not adequate coverage for the required treatment. The Medical Foods Equity Act would ensure that children and adults with PKU and other inborn errors of metabolism get the coverage they need for the medical foods required to treat these conditions so they can become healthy and productive citizens.

The Medical Foods Equity Act would:

- Require all insurance companies to cover the cost of medical foods for all inborn errors of metabolism, including federal programs, such as Children's Health Insurance Program, Tricare, Medicaid and Medicare.
- Health insurance plans governed by ERISA would not be exempt.
- This bill is based on the recommendations of the Secretary's Advisory Council on Heritable Disorders in Newborns and Children.
- The Secretary of HHS would determine the yearly coverage for all health insurance plans.

The recently passed Affordable Health Care Act does not address the coverage of medical foods for inborn errors of metabolism.

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)
- 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. (2)
- Living with PKU is difficult. The specially manufactured low-protein 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. (3 & 4)

- 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. (5)

What is the impact of PKU?

- An estimated 15,000 in the United States have PKU, while another 5,000 have another type of inborn error of metabolism.
- 5,000 adults with PKU are currently off the recommended treatment. (6)
- 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. (7 & 8)
- The annual cost of diagnosing and treating PKU and other IEM's is approximately \$342 million per year. (9) The annual cost of nursing assisted care in a residential facility for the same population is approximately \$2 billion per year (10). Thus, by spending \$342 million for diagnosis and treatment, we can save over \$1.7 billion.

1 http://www.knowledgene.com/public/glossary_content.php3

2 <http://www.pku.com/AboutPKU/TheScienceOfPKU.aspx>

3 <http://www.mayoclinic.com/health/phenylketonuria/DS00514>

4 <http://www.matt denn.com/category/news/>

5 http://depts.washington.edupku/pro_info/mgmtGuide.html

6 BioMarin

7 Koch et al. "Phenylketonuria in adulthood: A collaborative study," Journal of Inherited Metabolic Diseases 25 (2002): 338.

8 <http://www.pkunews.org/adults/livesin.htm>

9 *Top Clin Nutr* 24 (4):289-306, 2009

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The Medical Foods Equity Act would save and improve lives.

For each \$1 we spend on treating PKU, we save \$5.