**Financial Impact Study**

**Summary**

The financial impact of mandating health insurance coverage of the vitamins and co-factors prescribed to treat mitochondrial disease (hereafter referred to as the mito cocktail) in the state of California is described below. We conducted a calculation in which a variety of factors were considered, and find that a premium increase of $0.07 - 0.22 per insured individual per month will cover the cost of the mito cocktail, in full, for all affected Californians.

**Cost of coverage**

Estimates of the occurrence of primary mitochondrial disease in the general population can be as high as 1 in 5,000 [1] or 7,850 individuals in California. The cost of the mito cocktail can range from $500-1,000 per month, or $7.9 million per month statewide. In 2016, 92% of Californians or 36.1 million individuals had some form of health insurance, including 25% and 11% covered by Medicaid and Medicare, respectively. [2] Were the burden for the cost of covering the mito cocktail shared evenly, monthly premiums would rise $0.22.

This is a conservative figure, as it does not account for the lower use of supplementation in patients with more mild forms of mitochondrial disease or the lowered cost of the cocktail the insurance companies will be able to negotiate once it's covered. In Massachusetts, where a bill was recently proposed to cover the mito cocktail, compounding pharmacists estimated that the cost to insurers could be as low as $300/month. [1] At this rate, the per capita monthly premium increase is reduced to $0.07.

**Benefits of coverage**

In 2012, nationwide hospitalization rates for patients with a mitochondrial disease were 1.9 pediatric and 0.8 adults per 100,000 for a total cost of $113 million, or $21,730 per hospitalization. [3] Mapped to California, this translates to 1,060 admissions for a total cost of $23 million. This is likely an underestimate as it includes only those admissions that were tagged with the mitochondrial disease diagnostic code, a code that is omitted up to 50% of the time. [3] Also not included in this cost estimate is the yearly outpatient follow-ups required after a hospitalization.

While the aggregate financial impact of decreased hospitalization rates from increased access to the mito cocktail is difficult to calculate, the mito cocktail is currently the only treatment available for mitochondrial disease, and it has been shown to stabilize symptoms, slow disease progression, and prevent the metabolic crises that lead to hospitalization, [4,5,6]. And it is clear from the above analysis that the monthly per patient cost of the cocktail ($300) is much smaller than the cost of hospitalization ($20,000+), making coverage of the mito cocktail a sound investment.

**References**

[1] Mandated Benefit Review of House Bill 977: An Act Relative to Providing for Care of Patients with Mitochondrial Disease. Center for Health Information and Analysis, September 2013.

[2] The Henry J. Kaiser Family Foundation. https://www.kff.org/other/state- indicator/total-population

[3] McCormack, S., et. al. *Hospitalizations for mitochondrial disease across the*

*lifespan in the U.S.* Molecular Genetics and Metabolism 121 (2017) 119**–**126

[4] Scholte, H.R., et. al. *Riboflavin-responsive complex I deficiency*. Biochimica et Biophysica Acta 1271 (1995) 75-83 .

[5] Bugiani, M. *Effects of riboflavin in children with complex II deficiency*. Brain & Development 28 (2006) 576-581.

[6] Haas, R. *The evidence basis for coenzyme Q therapy in oxidative phosphorylation disease*. Mitochondrion 7S (2007) S136-S145.