



# Helping Americans Regain Their Nutritional Balance

## IT'S A MATTER OF NATIONAL SECURITY

*In April 2010, the U.S. military released the surprising statistics that an estimated 27 percent of our youth, ages 17 to 24, are too overweight to serve in the military.<sup>1</sup>*

*In 2013, 840 million people, or 11.5% of the world population, were over age 60. By 2050, this is expected to reach 21%.<sup>2</sup> One in three seniors dies of Alzheimer's or some form of dementia. It is estimated that the incidence of these diseases will triple by 2050.<sup>3</sup>*

*The estimated annual costs of obesity-related illnesses are a staggering **\$190.2 billion** for health care<sup>4</sup> and **\$153 billion** in lost productivity<sup>5</sup>—a total of over **\$340 billion annually**.*

*It is estimated that 29.1 million Americans, or 9.3% of the population, have diabetes. Approximately 1.25 million Americans have type 1 diabetes and 27.9 million Americans have Type 2 diabetes. Of that total, it is estimated that 8.1 million are undiagnosed.<sup>6</sup> The national annual cost of diabetes in the U.S. in 2012 was more **than \$245 billion**, up from \$174 billion in 2007, and **\$69 billion** in lost productivity.<sup>7</sup>*

*More than 5 million Americans are living with Alzheimer's.<sup>8</sup> It is the seventh leading cause of death in the United States.<sup>9</sup> **Alzheimer's disease is the most expensive condition in the nation.** In 2014, the direct costs of Alzheimer's totaled an estimated **\$214 billion**, excluding home care where 15.5 million family and friends provided 17.7 billion hours of unpaid care to those with Alzheimer's and other dementias—care valued at **\$220.2 billion**.<sup>10</sup>*

*These are just some of the statistics documenting the drain on the U.S. economy caused by failed nutrition and aging baby boomers.*

Although some people are predisposed genetically to some of these diseases, many of these so-called “Western diseases” are either caused by or exacerbated by metabolic dysregulations caused by poor nutrition. Nutritional scientists have identified that the manifestation of many of these diseases is tied to the body’s inability to properly generate or regulate cellular energy.

All humans are equipped with a dual-energy system comprising both a glucose engine<sup>11</sup> (glycolysis – capable of burning glucose) and a ketone engine<sup>12</sup> (ketosis – capable of burning ketones) for energy production. In times of plenty, consumed carbohydrates and sugar are metabolized to glucose and burned through glycolysis. In times of famine, the body burns its fat stores to create and burn ketone bodies. Thus, depending on the prevalence of food, the human body can intermittently change energy systems to most effectively adapt to the environment and achieve a nutritional balance.

However, over the past 200 years, as the commercialization of processed food (and our addiction to sugar) made low-cost carbs so abundantly available, we have fallen into an artificial nutritional condition of always using our glucose engine—leaving our ketone engine dormant and denying us the benefits of nutritional energy balance. This singular and artificial use of the “sugar/glucose” engine and constant consumption of nutritionally deficient, high-carb diets has caused a number of metabolic dysregulations and contributed to the escalation of a number of epidemic issues like obesity, type 2 diabetes, Alzheimer’s and other neurodegenerative diseases, and cancer. ***America must return to a balanced nutritional energy system.*** Our lives, economic well-being, and national security depend on correcting this nutritional imbalance.

### **Why do we need ketones?**

Ketones help solve cellular energy dysregulation by improving “mitochondrial function,” reducing premature cell death and protecting and energizing neurological tissues. Research into the benefits of ketones has established that ketones:

- Improve Brain and Cognitive Function – Ketones are an effective treatment for epilepsy and are now being tested on other brain disorders such as Alzheimer’s, Parkinson’s, and ALS.

- Provide Neuroprotection for the Brain – Ketones protect this vital organ from trauma, concussions, aging, and reduced capacity.
- Optimize Energy – Using ketones and glucose together allows optimal use of the body’s two energy engines to boost performance.
- Control Glucose – Ketones put less pressure on the body to produce insulin, thereby decreasing the risk and impact of type 2 diabetes.
- Provide Anti-aging Effects – Ketones cleanse and “de-junk” cells by producing 10 times fewer free radicals that cause cell damage and premature cell death.
- Facilitate Fat Loss – Ketones support low-carb diets by minimizing the “keto flu” and keeping metabolism high during a calorie-reduced diet that consumes fat stores.
- Inhibit Cancer Growth – Many types of cancer cells have difficulty utilizing ketones as a fuel source, thereby retarding their abnormal growth rates.

## GETTING KETONES INTO OUR NUTRITION

The average American will never see starvation or famine, the conditions that historically triggered the endogenous production of ketones. Indeed, more people will die worldwide this year of obesity-related diseases than from hunger.<sup>13</sup> Virtually no U.S. citizen will experience the consecutive days of starvation or undergo the multi-day fast required to trigger their ketone engine.

Until recently, short of starvation, the only other recognized way of including ketones in the diet was to induce the body to make them endogenously through a low-carbohydrate, “ketogenic-type” diet that forces glucose and insulin levels down, thereby inducing the body to burn fatty acids to make ketones for energy. This approach requires strict dietary compliance, making its widespread adoption impossible given the present American diet.

Recent research in this field, however, has established an alternative method for including ketones in the average person’s nutritional profile. By adding ketones to the diet (consuming *exogenous* ketones), many of the advantages of ketosis can be obtained. Utilization of ketones will help return us to our *natural state* of nutritional energy balance.

## **WHAT ARE WE ASKING CONGRESS TO DO?**

Recognize ketones as a formal 4th macronutrient on food labeling

Fund education to recognize the importance of ketones in achieving the proper nutritional balance

Direct the FDA to establish a recommended daily allowance of ketones as part of a balanced diet

Support agriculture in providing an energy-balanced food supply

Provide incentives to produce ketone rich foods to benefit school lunch programs

Fund the inclusion of exogenous ketones in standard military rations

Fund military research into optimal energy-balanced nutrition

Fund research for continued ketone testing for improving nutrition in the general population

Fund research of the use of ketones for minimizing the effects of diseases such as obesity, diabetes, Alzheimer's, cancer, Parkinson's, ALS, epilepsy, etc.

## **THE SCIENCE BEHIND KETONES**

The attached Appendix lists an exemplary collection of studies demonstrating the wide application of ketones in addressing the issues discussed above.

# Science Appendix

## Alzheimer's, Epilepsy, Other Neurodegenerative Disease

- Winkler EA, et al., "[GLUT1 reductions exacerbate Alzheimer's disease vasculo-neuronal dysfunction and degeneration.](#)" Nature Neuroscience (2015).
- Newport MT, et al., "[A new way to produce hyperketonemia: Use of ketone ester in a case of Alzheimer's disease.](#)" Alzheimers Dement. (2015)11, 99-103. (Demonstrate the efficacy of KE in an AD patient)
- Kashiwaya Y, et al., "[A ketone ester diet exhibits anxiolytic and cognition-sparing properties, and lessens amyloid and tau pathologies in a mouse model of Alzheimer's disease.](#)" Neurobiol Aging. (2013) 34, 1530-9. (Demonstrate KE improves the cognitive function and reduces  $\beta$ -amyloid and tau in AD mice)
- Kashiwaya Y, et al., "[D-beta-hydroxybutyrate protects neurons in models of Alzheimer's and Parkinson's disease.](#)" Proc Natl Acad Sci U S A. (2000) 97, 5440-4. (demonstrated the neuroprotective effect of beta-hydroxybutyrate in neurons)
- Zhu DN, et al., "[Therapeutic effect of ketogenic diet for refractory epilepsy in children: a prospective observational study.](#)" Zhongguo Dang Dai Er Ke Za Zhi. (2014) 16, 513-7. (30% of patients became seizure free, 65% of patients had reduction in seizure frequency with ketogenic diet)
- Pires ME, et al., "[Ketogenic diet for infantile spasms refractory to first-line treatments: an open prospective study.](#)" Epilepsy Res (2013) 105, 189-94. (35% of patients became seizure free after 1 month with KD, 65% of patients became seizure free after three months with KD)
- Caraballo R, et al., "[Long-term follow-up of the ketogenic diet for refractory epilepsy: multicenter Argentinean experience in 216 pediatric patients.](#)" Seizure (2011) 20, 640-5. (20.5% became seizure free, 36% had 75-99% reduction in seizures)

## Traumatic Brain Injury, Cognition and Neuroprotection

- Lui HD, et al., "[Expression of the NLRP3 inflammasome in cerebral cortex after traumatic brain injury in a rat model.](#)" Neurochem Res. 2013 Oct;38(10):2072-83.
- Youm YH, et al., "[The ketone metabolite  \$\beta\$ -hydroxybutyrate blocks NLRP3 inflammasome-mediated inflammatory disease.](#)" Nat Med. 2015 Feb 16.
- Prins ML & Matsumoto JH, "[The collective therapeutic potential of cerebral ketone metabolism in traumatic brain injury.](#)" J Lipid Res (2014) 55, 2450-7. (summary of preclinical studies on cerebral ketone and TBI and spinal cord injury, see references therein)
- Veech RL, et al., "[The mitochondrial permeability transition pore provides a key to the diagnosis and treatment of TBI.](#)" IUBMB Life (2012) 64, 203-7. (theoretic paper on the therapeutic potential of ketone bodies on TBI)
- Gasior M, et al., "[Neuroprotective and disease-modifying effects of ketogenic diet.](#)" Behav Pharmacol. (2006) 17, 431-9. (review article, see references therein)
- Prins ML, "[Cerebral metabolic adaptation and ketone metabolism after brain injury.](#)" J Cereb. Blood Flow Metab.(2008), 28: 1-16.
- Hu ZG, "[Ketogenic diet reduces cytochrome C release and cellular apoptosis following traumatic brain injury in juvenile rats.](#)" Ann. Lab. Clin. Sci. (2009) 39: 76-83.

## Optimized Energy/Energy Dysregulation

- Clarke K, *et al.* (unpublished data, enhanced physical performance in UK Olympic athletes).
- Clarke K, *et al.*, "[Kinetics, safety and tolerability of \(R\)-3-hydroxybutyl \(R\)-3-hydroxybutyrate in healthy adult subjects.](#)" Regul Toxicol Pharmacol. (2012) 63, 401-8 (Safety study of KE in healthy adult human).
- Sato K, *et al.* "[Insulin, ketone bodies and mitochondrial energy transduction.](#)" FASEB J (1995) 9: 651-8.
- Kashiwaya Y, *et al.*, "[Substrate signaling by insulin: a ketone bodies ratio mimic insulin action in heart.](#)" Am J Cardiol. (1997) 80: 50A-64A.

## Glucose Control/Type 2 Diabetes

- Kashiwaya Y, *et al.*, "[Substrate signaling by insulin: a ketone bodies ratio mimic insulin action in heart.](#)" Am J Cardiol. (1997) 80: 50A-64A.
- Sato K, *et al.*, "[Insulin, ketone bodies and mitochondrial energy transduction.](#)" FASEB J (1995) 9: 651-8.

## Anti-aging

- Veech RL, *et al.* (unpublished data)

## Obesity and Metabolic Syndrome

- Srivastava S, *et al.*, "[Mitochondrial biogenesis and increased uncoupling protein 1 in brown adipose tissue of mice fed a ketone ester diet.](#)" FASEB J. (2012) 64, 203-7.
- Kashiwaya Y, *et al.*, "[A ketone ester diet increases brain malonyl-CoA and Uncoupling proteins 4 and 5 while decreasing food intake in the normal Wistar Rat.](#)" J Biol Chem. (2010) 285, 25950-6.

## Cancer

- Poff AM, *et al.*, "[Ketone supplementation decreases tumor cell viability and prolongs survival of mice with metastatic cancer.](#)" Int J Cancer (2014) 135, 1711-20 (see references therein).

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<sup>1</sup> "[Too Fat to Fight](#)," Mission: Readiness (2010).

<sup>2</sup> "[World Population Ageing 2013](#)," United Nations (2013), p. 11.

<sup>3</sup> "[2014 Alzheimer's Disease Facts and Figures](#)," Alzheimer's Association (2014).

<sup>4</sup> Cawley J, Meyerhoefer C., "[The Medical Care Costs of Obesity: An Instrumental Variables Approach](#)," Journal of Health Economics (2012).

<sup>5</sup> "[Unhealthy US Workers Absenteeism Costs \\$153 Billion](#)," Gallup (2011).

<sup>6</sup> [National Diabetes Statistics Report, 2014](#).

<sup>7</sup> "[The Cost of Diabetes](#)," American Diabetes Association.

<sup>8</sup> "[2014 Alzheimer's Disease, Facts and Figures](#)," Alzheimer's Association.

<sup>9</sup> "[Leading Causes of Death](#)," Centers for Disease Control and Prevention.

<sup>10</sup> "[Alzheimer's Facts and Figures](#)," Alzheimer's Association.

<sup>11</sup> [Wikipedia](#), Glycolysis.

<sup>12</sup> [Wikipedia](#), Ketosis.

<sup>13</sup> "[Global Burden of Disease Study 2010](#)," The Lancet (2012).