

A wide-angle photograph of the Nashville skyline, Tennessee, viewed from a distance. The foreground is filled with a dense, lush green forest. In the middle ground, the city skyline is visible, including several prominent skyscrapers. The sky is overcast with soft, grey clouds.

INVESTING IN ENTREPRENEURS THAT IMPROVE
HEALTHCARE

Investment Area of Interest:
Nutrition Based Startups Impacting Healthcare

December 2018

Nutrition Based Startups Impacting Healthcare

Executive Summary

Obesity is a complicated health issue in that its causes are both behavioral and genetic. Certain individuals may have a genetic predisposition to obesity, while others consume too many calories or exert too little energy, or sometimes a combination of both. Obese individuals may deal with both genetic and behavioral causes as well.¹ Research on genetic factors and their relationships with environmental ones are still premature, though one conclusion that evidence supports is that genetic variation can cause a predisposition to obesity, not a predetermination – individuals who are predisposed to obesity may overcome this genetic variation through healthy lifestyle choices. Though estimates vary widely, heritability estimates can explain between 40% and 70% of body mass index (BMI). However, genetic factors alone do not explain the rise in obesity: because the obesity gene variants take so long to spread throughout a population, environmental factors, like the proliferation of fast-food and increased portion sizes and availability of food.² A number of studies have also shown how physical activity can decrease the risk of genetic predispositions to obesity: in Denmark, a 2008 study found that active individuals with a particular genetic predisposition have BMIs equivalent to those without the gene variant.³ Additional research has found that individuals with this same gene variant who are physically active have a 30% lower chance of becoming obese than their inactive genetic counterparts.⁴ Obesity can be clinically diagnosed by measuring an individual's BMI, which examines the relationship between height and weight; a BMI greater than 30 constitutes obesity. In 2016, the prevalence of obesity was estimated to be 39.8%, which equates to roughly 93.3 million US adults. Prevalence was highest among adults aged 40 to 59, and impacted Hispanics and non-Hispanic blacks the most.⁵ Obesity rates in the Medicare and Medicaid populations are responsible for a significant portion of obesity related treatment costs; in 2013, severe obesity treatment amounted to roughly \$69 billion, about 60% of total obesity related treatment costs, with approximately \$7.6 billion coming from Medicaid and \$20.7 billion coming from Medicare. As efforts to expand weight management treatment options under these programs strengthen, so will the costs of treating obesity in these populations.⁶ Some of the most recent research estimates that in 2006, the prevalence of obesity among Medicare beneficiaries was 29%, though general obesity estimates for individuals 65 and older are closer to 35%. Among the AARP Medicare Supplement insureds population, prevalence between 2009 and 2011 was 22.9%.⁷ There are several comorbidities

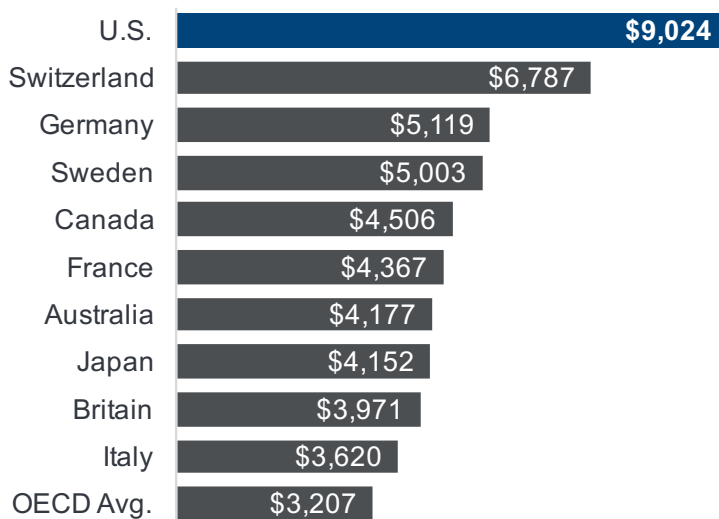
associated with obesity. Obese individuals with healthy metabolic regulation, for example, are four times more at risk for type 2 diabetes than their normal weight and metabolically healthy counterparts. Obesity is also associated with heart and vascular diseases, with heart disease and stroke being the leading causes of death in the United States and in the world.

Dyslipidemia (high cholesterol) and hypertension (high blood pressure) are both risk factors for poor cardiovascular health, in addition to excess body weight. Obesity also contributes to lower backpain and osteoarthritis, two highly common conditions in the United States. The economic cost of obesity is significant, with just over one-fifth of US healthcare expenditures going towards the treatment of obesity (\$190 billion per year).⁸ The comorbidities of obesity drive up healthcare costs as well: a 2014 study found that the average expenditure for in- and outpatient services totaled about \$1,907 per visit. When a single comorbidity was added in to treatment, specifically congestive heart failure, treatment increased to \$5,275 per visit. The most expensive combination of two comorbidities were diabetes and depression, increasing the total to \$15,226. Diabetes, hypertension, and depression comorbidities drove costs per visit to \$15,733.⁹ The Center for Social Dynamics and Policy and the World Food Center at the University of California-Davis estimated lifetime economic and social costs of obesity to be \$92,235 per individual more than individuals who are not obese.¹⁰

Unprecedented Spending

The U.S. healthcare industry on its own would be ranked as the fifth largest economy in the world. In 2015, the U.S. spent \$3.2 trillion—or about 18% of its GDP—on healthcare, only slightly less than Germany’s entire GDP.¹¹ Healthcare spending in other OECD member-nations was, on average, only 9% of their GDPs, yet most other developed countries had significantly lower infant mortality rates and higher life expectancies than the U.S.³

Healthcare Spending Per Capita (2015)⁵⁴

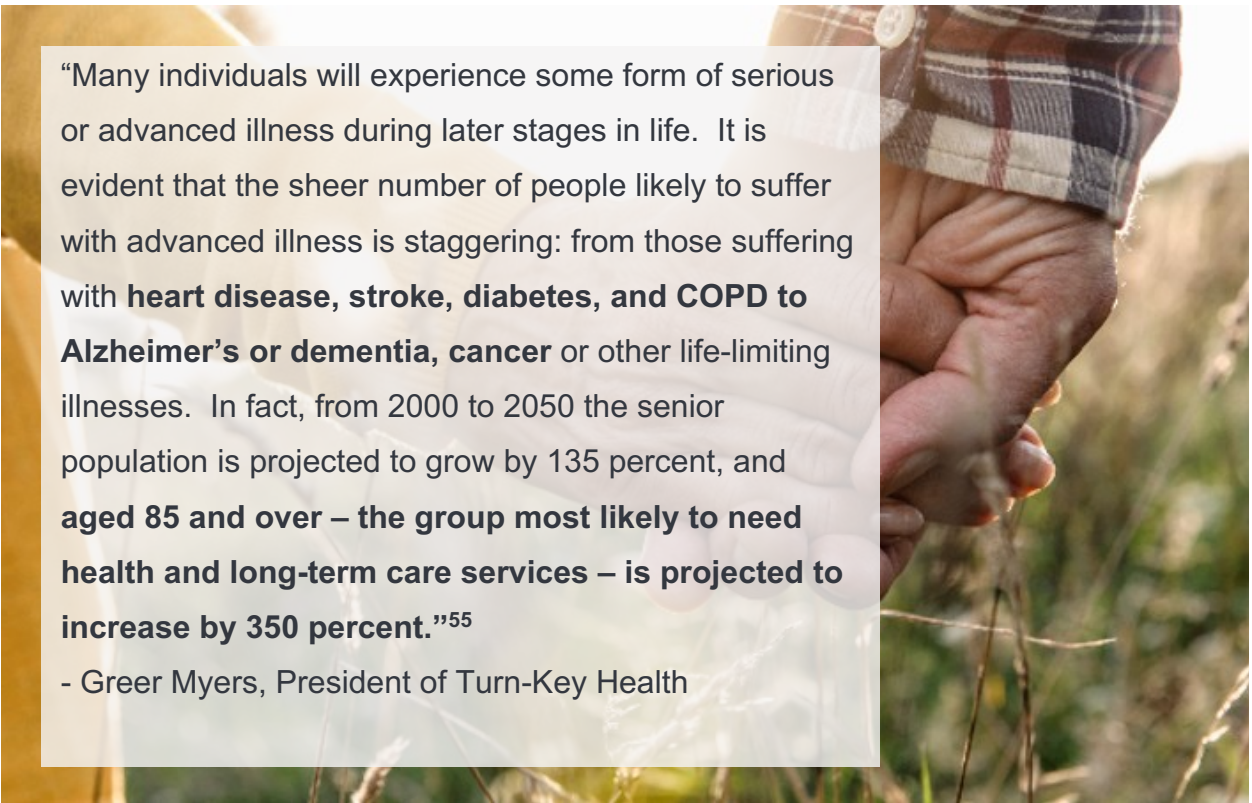


How is it that Americans spend the most on healthcare but have relatively worse health outcomes?

This conundrum is at least partly explained by America’s high prevalence of chronic conditions and relatively unhealthy lifestyle behaviors, both of which contribute heavily to burgeoning healthcare spending and relatively poor health outcomes. In 2016, Medicare and Medicaid combined for 37% of healthcare spending by source of funds.¹² The drivers of high healthcare costs are widespread and complex; however, a 2015 Journal of American Medical Association (“JAMA”) research study reveals that, aggregately, nearly one third of all spending on healthcare is attributed to cardiovascular conditions, diabetes (including urogenital, blood, and endocrine disorders), and mental health and substance abuse.¹³

“Despite investing heavily in healthcare, Americans live shorter lives than people in 30 other countries, data from the World Health Organization showed”⁵⁴

-As reported by the Los Angeles Times



“Many individuals will experience some form of serious or advanced illness during later stages in life. It is evident that the sheer number of people likely to suffer with advanced illness is staggering: from those suffering with **heart disease, stroke, diabetes, and COPD to Alzheimer’s or dementia, cancer** or other life-limiting illnesses. In fact, from 2000 to 2050 the senior population is projected to grow by 135 percent, and **aged 85 and over – the group most likely to need health and long-term care services – is projected to increase by 350 percent.**”⁵⁵

- Greer Myers, President of Turn-Key Health

America’s Weight Problem

[Picture Credit to Getty Images](#)

The rise of chronic illness in America is not only due to its graying but also its alarmingly high obesity rates. According to the National Institute of Diabetes and Digestive and Kidney Diseases, two thirds of American adults are obese or overweight, and one third of children are obese.¹⁴

Aggregately, Americans’ sedentary lifestyle, poor diet, and overconsumption contribute significantly to preventable chronic conditions and their associated costs. According to behavioral health expert Blue Mesa Health, nearly half of Americans have prediabetes or diabetes, both of which are (largely) preventable chronic conditions.¹⁵ While not all diabetics are overweight, the likelihood of developing diabetes throughout an insured population is higher if that population is overweight.

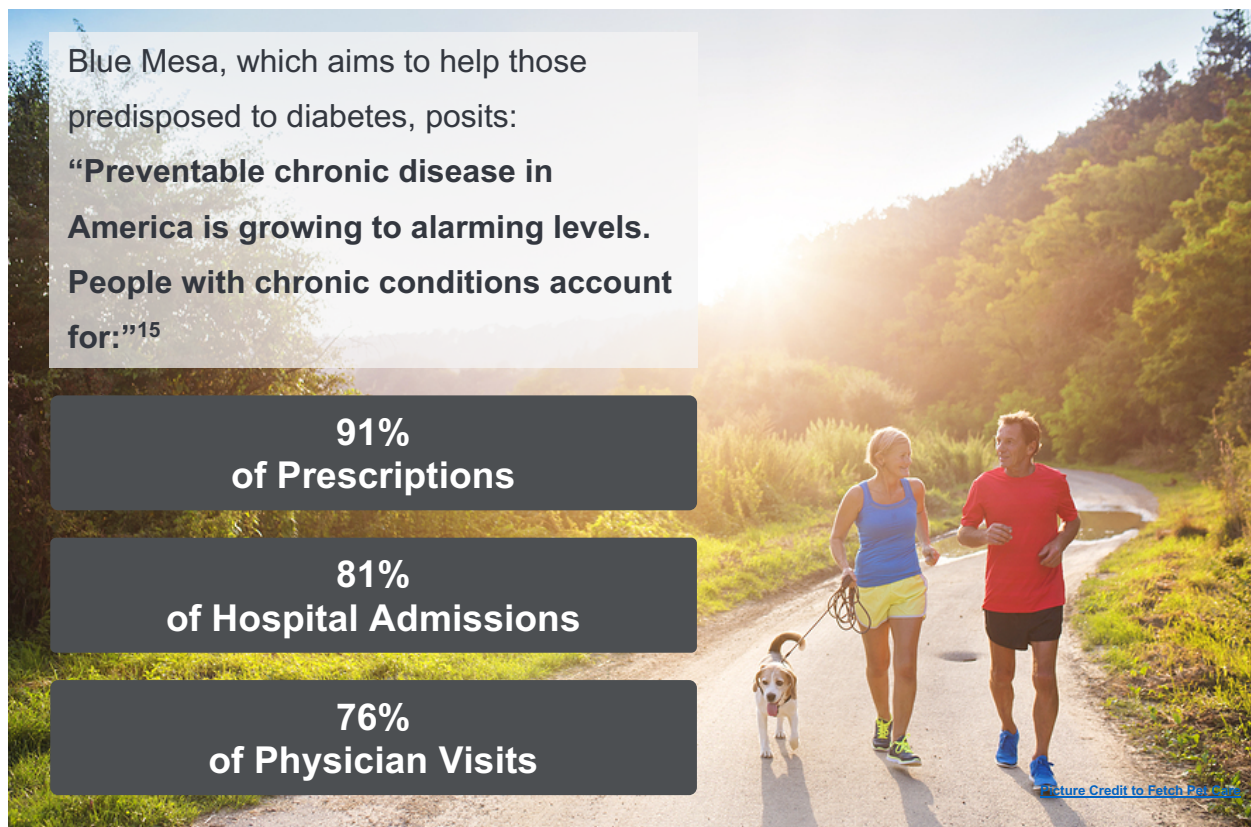
Diabetes is a costly consequence of obesity. In 2017, the total estimated cost of diabetes in America was \$327 billion, with about \$237 billion resulting from medical costs and \$90 billion from loss of productivity. Diabetes and related treatment account for roughly 25% of healthcare expenditures in the

Packing on too many extra pounds greatly increases the risk of developing the following conditions (among others)⁵⁶:

- **Type 2 diabetes**
- **Heart disease and high blood pressure**
- **Stroke**
- **Osteoarthritis**
- **Gallstones**
- **Sleep apnea**

country. On an individual level, annual diabetes expenditures are estimated to be \$16,750, just over two times more than those without diabetes would pay in healthcare costs.¹⁶ Diabetes is a demanding illness, requiring medical attention and lifestyle changes. It can have psychological consequences as well; diabetics have reported hypoglycemia (low blood sugar) as their greatest diabetic fear, causing them to lose sleep, change their work schedule and lifestyle habits. Diabetic parents are even concerned with transmitting the disease to their children. Patients struggle with autonomy as a strict treatment regimen is oftentimes the most effective care plan. For those who use an insulin pump, this is a constant reminder of their condition.¹⁷ Regarding physical symptoms, diabetic retinopathy (DR) is a primary cause of vision impairment throughout the world. Of the global diabetes population of 285 million people, an estimated one third have DR. Studies suggest that up to 40% of type 2 diabetics have DR, further expanding the discussion of potential comorbidities of obesity.¹⁸ Further complicating the quality of life for diabetics is the risk of foot ulcers and foot amputations. High blood glucose levels accelerate damage to nerves and blood vessels through diabetic peripheral arterial disease, increasing the risk of lower-extremity amputations – foot ulcers affect 10% of diabetics. Of the diabetic population with diabetic foot infections who undergo amputations, the mortality rate is about 50% in 5 years, which rivals mortality rates of the deadliest cancers.¹⁹

With type 2 diabetes as a common comorbidity of obesity, obese individuals can find themselves one diagnosis away from a host of new symptoms that weigh heavily on the costs of care and quality of life.



The American Diet in Context

The quality, history, and trajectory of the American Diet can be appropriately discussed in the context of the Healthy Peoples objectives, a set of objectives created by the Department of Health and Human Services designed to encourage healthy eating habits. The Healthy People 2020 (HP2020) objectives were set forth in 2010. Also in 2010, the government established the 2010 Dietary Guidelines for Americans (DGAs), differing in that DGAs discussed elements of a balanced diet in terms of quantity, whereas HP2020 set targets for consumption relative to a healthy, or improving, diet. The Healthy Eating Index-2010 (HEI) helps contextualize HP2020 and DGAs as it is a density-based measure of diet quality across twelve components: adequacy components such as total fruit, whole fruit, total vegetables, greens and beans, whole grains, dairy, total protein foods, seafood and plant proteins, fatty acids, and moderation components that include refined grains, sodium, and empty calories. Higher scores in both adequacy and moderation components indicate healthy consumption of each. A deeper and detailed evaluation of American diet patterns warrants a preliminary discussion of the HEI. The HEI score increased from 49 in 1999/2000 to 59 in 2011/2012. If this trend continues, HEI stands to increase to 65 by 2019/2020, which is 9 points lower than a score that meets the

HP2020 objectives (HEI: 75) and 35 points lower than a score that satisfies the 2010 DGAs (HEI: 100). Broadly, dramatic changes in diet are required to meet these scores. Each of the twelve components are scored individually; please see the table below to understand how each component would need to change as a percent of maximum score per component (only 7 of 12 HP2020 objectives correspond to the HEI index).²⁰

<i>As a Percentage of Maximum Score</i>			
HEI Component	Current 2019/2020 Projection	HP2020 Projection	Change Required
Sodium	22%	100%	78%
Empty Calories	85%	65%	-20%
Total Fruit	65%	100%	35%
Whole Fruit	100%	100%	0%
Total Vegetables	68%	100%	32%
Greens and Beans	68%	100%	32%
Whole Grains	35%	40%	5%

With regards to quantity, the average American consumed 2,481 calories daily in 2010, which is nearly 25% greater than the quantity consumed in 1970. Over this same time period, flours, grains, fats, and oils have grown to represent 46.8% of calories consumed each day, up from a combined 37.3%. Caloric intake with regards to meat, dairy, fruits and vegetables have all decreased. Average chicken consumption has more than doubled since 1970, while beef consumption has fallen by more than a third, as evidenced by changes in average consumption in pounds: chicken consumption has increased from about 23 pounds to 48 pounds, while beef consumption has fallen from roughly 62 pounds to 38 pounds per person per year. This is a step in the right direction, though likely not a sufficient one. Studies have identified processed meats as carcinogens and red meat as a probable carcinogen. The consumption of processed meats contributes to an additional 34,000 deaths globally on a yearly basis, driving up healthcare costs and mortality rates.²¹ In terms of dairy, Americans are drinking 42% less milk in 2014 than they were in 1970, but consuming cheese close to three times the amount consumed in 1970. Yogurt, too, consumed at nearly negligible amounts in 1970, has soared to close to 1.2 gallons per person per year in 2014. Lastly, Americans consume 29% more grains than they did in 1970.²²

The “Standard American Diet” (SAD) is one that has become synonymous with high red meat, high processed grains and sugar contents, and with a lack of fruits, vegetables, whole

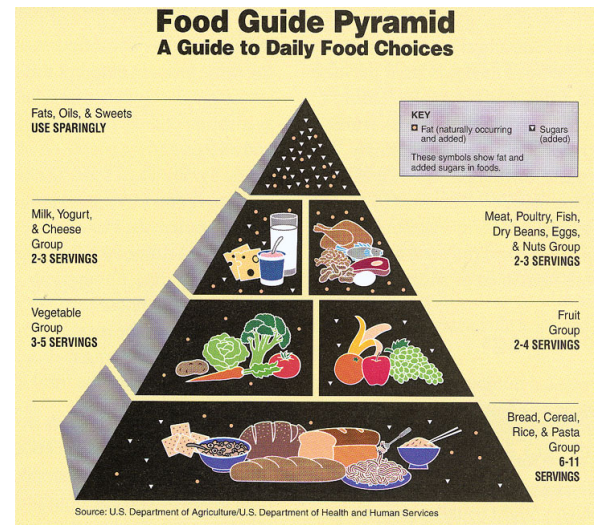
grains, and fiber.²³ On a more technical level, that means a high intake of saturated and omega-6 fats, reduced intake of omega-3 fats, and an overconsumption of salt and refined sugar. While the modern diet may help manage and protect against nutrient deficiencies, caloric abundance and exposure to the elements named above can contribute directly to increased inflammation, risk for allergic and auto-inflammatory disease, increased rates of cancer, and reduced control of infection.²⁴

Globally, the Mediterranean Diet (MD), as opposed to the SAD, is recognized as one of the healthiest diets in the world, if not singularly the healthiest. Benefits of the MD include lower incidence of chronic diseases and improved longevity. Recently, the 2015-2020 DGAs reference the MD as a healthy eating style. The DGAs call for higher consumption of fruits, vegetables, and whole grains, with lower consumption of saturated fat, sodium, refined grains, and added sugar.²⁵ In the MD, most carbohydrates are complex carbs (bread, pasta,

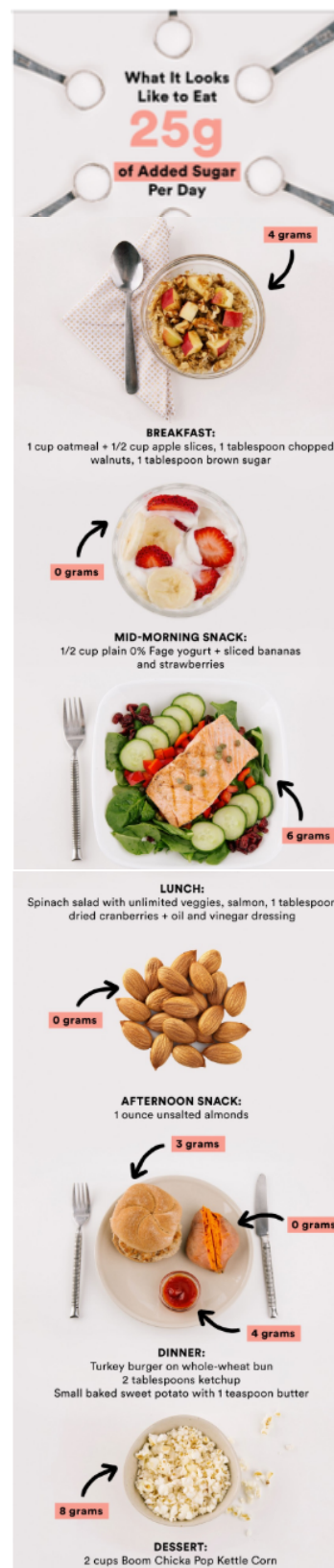
rice), the majority of protein consumption comes from animals, though particularly white meat and fish, and most fat consumption comes from olive oil.²⁶ In terms of particular foods, the MD emphasizes daily consumption of fruits, vegetables, milk and yogurt, and complex carbs, with moderate to low consumption of meat, fish, and eggs throughout the week. However, greater emphasis is placed on lean meats and fish than is on consumption of red meat.

The Rise in Obesity, Processed Foods, and Sugar Levels

A hallmark of processed and ultra-processed foods is the high added sugar content. Added sugar has been shown to increase the risk of type 2 diabetes, obesity, hypertension, heart disease, and a variety of other ailments. Because of these risks, the US Dietary Guidelines Advisory Committee (USDGAC) advises that added sugars comprise of no more than 10% of total calorie consumption. From 2009 to 2010, one study reported that of the average daily caloric intake, 57.9% of calories consumed were from ultra-processed foods.



Surprisingly, the second largest group of foods in terms of calories consumed were unprocessed or minimally processed foods at 29.6%, surpassing processed foods and processed culinary ingredients. In terms of ultra-processed foods highest in calories, breads; cakes, cookies, and pies; and frozen and nonperishable meals, take the prize. Relative to average caloric intake, breads constitute 9.5%, while unprocessed meats (including poultry) constitute the second highest percent of calories consumed at 7.9%. Calorie intake from added sugars comprises just under 15% of average calories consumed, with 89.7% of consumed added sugars coming from ultra-processed foods; the primary culprits are carbonated soft drinks at 17.1%, fruit drinks at 13.9%, and cakes, cookies, and pies at 11.2%. Decreasing added sugars consumed, and consequently reducing consumption of ultra-processed foods, can be an effective way to curb risks of type 2 diabetes and obesity. However, this is as much a reflection of personal choice as it is of the food industry; 2014 data indicates that more than 75% of available sugar and high fructose corn syrup available were used by the food industry.²⁷ Currently, the average American consumes nearly three times the amount of sugar recommended by the American Heart Association. Sugar consumption produces cravings and withdrawals and in addition to these chemical changes, can produce hormonal ones as well. By increasing the glucose in the bloodstream, the pancreas releases more insulin, which causes the body to store more calories in the form of fat. Additionally, increased insulin levels reduce the efficacy of the body's natural appetite suppressant.²⁸ Added sugar is metabolized differently than natural sugars, and consequently, affects the body differently. Added sugar can be directly harmful to the body through its interactions with the liver and the pancreas.²⁹ Further complicating the issue is how widespread added sugar is: a 12 ounce can of soda has 46 grams of sugar, and a household brand of yogurt can have 29 grams of sugar.²⁸



Unhealthy foods (specifically soft drinks, processed and ultra-processed foods) have increased in prevalence for a number of reasons. Producers of unhealthy foods have high margins because these foods are cheap to make, have long shelf-life, and maintain a stable and high retail value. They are also highly accessible to those in low-income groups; previously, malnutrition meant poor access to essential nutrients, now it means poor access to nutrients and obesity, meaning that processed foods facilitate weight gain and lack nutrients. On a demographic level, education, income, age, and race all impact consumption of ultra-processed foods. College educated individuals consume the least amount of ultra-processed foods, while adolescents, blacks, and whites consumed the most. Consumption was inversely related to income and age.³⁰

Companies rely on a number of tactics to help keep consumption of processed foods high and stable. One of the more interesting phenomena of the industry is referred to as vanishing caloric density: when fatty foods melt in the mouth, it distorts the brain's perception of calories consumed in such a way that it thinks there are no calories in the food, allowing consumers to munch endlessly on foods like Doritos and Cheetos. Frito-Lay, at one point, spent \$30 million annually on research to engineer some of food's most gratifying sensations: part of that sum went to a \$40,000 machine that discovered that one characteristic of the perfect chip is that it cracks when chewed with four pounds of pressure per square inch. Companies have spent millions of dollars conducting focus groups to collect data to engineer the best combinations of chemicals and ingredients – Dr. Pepper's 23 flavors are quite literally an algorithmic combination of flavors along with coloring dyes.³¹ The chemical engineering behind these foods is no less marvelous: processed foods aim to deliver half their calories through fat because of the sensation it gives the brain, and Doritos hit this mark squarely. Further, Doritos and its peers are loaded with salt and MSG, sometimes containing up to 50% of the recommended sodium intakes for adults. These ingredients trigger the brain's pleasure center and encourage more consumption.³²

The Politics of Food

The Washington food lobbyists have long since had their clutches in the American dietary and nutrition guidelines. Since 1990, the food and beverage industry has donated \$169 million to parties and candidates, with familiar names like Coca Cola, PepsiCo, and McDonalds leading the way. One of the most commonly cited instances of the food industry attempting to shape federal nutrition recommendations was the U.S. Department of Agriculture's withdrawal of the Eating Right Pyramid in 1991. A pivotal 1993 study highlighted how the withdrawal resulted from an apparent controversy between the government and food lobbyists as dairy

and meat products were placed towards the bottom of the pyramid. The pyramid's subsequent re-release in 1992 was highly political. The pyramid was met with additional dissent: nutritionists and health officials took issue with the Department of Agriculture setting dietary recommendations and felt that the visual representation of the pyramid inappropriately painted less healthy foods in a positive light.³³ In another instance, meat lobbyists pressured federal agents to change recommended meat consumption from "decrease consumption of meat" to "two or three (daily servings)".³⁴

More recently, millennial values have been shaping the politics that are most directly impacting the food industry, with opinions on matters such as GMOs and labeling. The underlying theme connecting these forces is a desire for greater transparency; in the era of the internet, people have access to more information than ever before. The "informed consumer" is more common, and its consequences far reaching. These changing values partially explain the falling popularity of the Grocery Manufacturers Association (GMA), the food and beverage industry's most powerful lobby. Companies like Campbell Soup Co and Nestle both departed from the GMA, allegedly for reasons concerning the lobby's distasteful response to mandatory labeling legislation. These companies are taking the unpopular view that giving consumers the transparency they are asking for and taking the progressive position on such matters may yield success in years to come. This notion is further evidenced by the industry's behemoths acquiring smaller companies with a healthy-living tilt to their products: PepsiCo acquired Naked Juice, Coca Cola acquired Honest Tea, Kellogg's acquired Kashi, to name a few.³⁵

These seemingly benevolent acts do not excuse the current agenda of the food industry and its lobby, though they represent a step in the right direction. The 2015 Dietary Guidelines for Americans, published by the Departments of Agriculture (USDA) and Health and Human Services (HHS), were met with disdain from the nutrition and health community. For instance, it is thought that the absence of an explicit recommendation to eat less red meat, while simultaneously noting how lower consumption of red meat is a characteristic of healthy eating behaviors, is an example of appeasing the meat lobby. Dr. Marion Nestle, former chair of the Department of Nutrition, Food Studies, and Public Health and New York University, who was recruited by the USDA and HHS to help shape the 2015 guidelines, noted: "I was told we could never say 'eat less meat' because USDA would not allow it."³⁶

The government's links to the corn industry are longstanding through its subsidies to farmers and connection with the lobbies that represent the industry. Under the Obama Administration, President Barack Obama issued an executive order that mitigated conflicts of interests by preventing lobbyists from joining federal agencies that they had lobbied in the

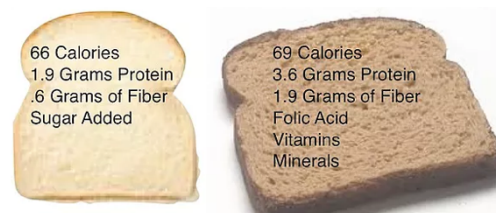
previous two years. President Trump has surpassed this by introducing ethic waivers – in August, 2017, Kailee Tkacz, a former lobbyist in the food and beverage industry and most recently the director of food policy for the Corn Refiners Association (CRA), was cleared by White House administration to work on the 2020 Dietary Guidelines for Americans, published every five years by the USDA. During her time with the CRA, Tkacz lobbied the USDA and the Food and Drug Administration, specifically on matters concerning “education regarding federal food policy,” according to official records. The CRA consists of the top four largest corn syrup producers in the country. The conflict of interest is readily apparent in our nation’s top agencies.³⁷ The subsidies, too, bring into focus their own set of questions. Dietary recommendations today inform Americans that roughly 50% of their diet should be comprised of fruits and vegetables, with reduced consumption of saturated fats, sugars, sodium, and refined grains.³⁸ These subsidy payments amount to nearly \$20 billion annually from the federal government, most of which goes to large farming corporations. Not to mention, these subsidies create a myriad of economic inefficiencies.³⁹ However, one study has found that agricultural subsidies go primarily towards the production of corn, soybeans, wheat, rice, sorghum, dairy, and livestock (dairy and livestock eat the grains listed in the former). These commodities are then produced into fatty meats and dairy products, refined grains, high-calorie juices and soft drinks (sweetened with corn syrup). Given that the domestic agricultural industry produces about 80% of food consumed by Americans, the impact of these subsidies is meaningful. In fact, one study found that from the years 2001-2006, individuals who ranked in the highest quartile of consumers of subsidized foods were associated with a 14% to 41% increased probability of cardiometabolic risk. Accordingly, health officials and professionals alike have criticized such agricultural policy and have recommended either eliminating the subsidies or subsidizing the production of healthier crops.⁴⁰ Also worth noting are how charitable organizations with research as their core mission like the American Heart Association, American Cancer Society, American Diabetes Association and Susan G. Komen accept millions of dollars from pharmaceutical companies each year and are corporate partners with the food manufacturers that contribute to the conditions these organizations seek to prevent and treat.⁴¹ This potentially explains why the American Diabetes Association publishes recipes provided by Kraft Foods, or why their affiliate Diabetes Food Hub publishes recipes that include sodium-rich processed foods like deli-smoked ham (a known carcinogen).^{42,43}

Government Intervention

The government has historically tried to impose measures that, in most cases, were designed to help encourage healthy eating decisions. One of the more notable measures in the

recent past was former New York City Mayor Michael Bloomberg's proposed soda ban in 2013. Under the ban, "sugary beverages", generally defined as a drink with more than 25 calories per eight ounces that has been sweetened by the manufacturer or by additional sweeteners, larger than 16 ounces would be banned from food-service establishments in New York City. The ban, while approved by the city's Department of Health and Mental Hygiene, was struck down in court. State Supreme Court Justice Milton A. Tingling Jr. noted that the several exceptions to the rule were made on "suspect grounds" and would be difficult to enforce evenly. Loopholes like unlimited refills would "defeat and/or serve to gut the purpose of the rule." In addition to calling the ban arbitrary, the judge appealed the ban on constitutional grounds as well, arguing that the ban could give the health department "virtually limitless authority."⁴⁴

Recently, one controversial move has come under the Trump Administration as Agriculture Secretary Sonny Perdue sought to reverse public school lunch improvements that Michelle Obama had introduced during the Obama Administration. In 2017, Perdue reduced regulations on salt and whole grains, making white bread and regular pasta easier to serve in schools instead of their whole-grain counterparts. The move comes from the claim that under the Obama-era regulations, students did not find the healthier alternatives palatable.⁴⁵ It is surrounded by an apparent gap between the intended results of the initiative and the actual results. Patricia Montague, CEO of the School Nutrition Association, remarked that some schools were using food waste as compost because students were not eating the healthier school food options.⁴⁶



Childhood Obesity

Childhood obesity has become one of the largest public health problems in the United States, with one in three children classified as obese or overweight. Prevalence increases with age, as 22.8% of children aged two to five are obese or overweight, scaling up to 34.5% for individuals aged twelve to nineteen. The etiology of childhood obesity is multidimensional, drawing from environmental and genetic factors. Stress can contribute to obesity as children turn to eating as a coping strategy to help manage negative emotions. Also directly related to the prevalence of obesity are consumption of sugary beverages and fast food, time spent watching television and having a television in the child's bedroom, and amount of time spent engaging in physical activity. Reduced levels of physical activity and increased levels of sedentary activity decrease calorie expenditures. Genetic factors can explain between 30% and 50% of the variation in obesity, with polygenetic obesity being the most common genetic

factor. Short stature, dysmorphic features, developmental delay, intellectual disability, retinal changes, or deafness can all contribute to the development of childhood obesity. There are a variety of clinical treatments for childhood obesity. A staged approach to weight management is the primary tactic recommended by the Expert Committee on the Assessment, Prevention and Treatment of Child and Adolescent Overweight and Obesity. Stage 1 (Prevention Plus) recommends dietary and physical activity changes. Stage 2 (Structured Weight Management) involves a balanced diet, structured meals, and supervised physical activity. Stage 3 (Comprehensive Multidisciplinary Intervention) uses more frequent provider-patient interaction and relies on behavioral treatment. Stage 4 (Tertiary Care Intervention) usually requires the patient to receive treatment in a pediatric weight management center where meal replacement, low-energy diets, medication, and surgery are considered as treatment options. Behavioral therapy can be used to encourage healthier dietary decisions and increased physical activity. Pharmaceuticals have been used to help manage childhood obesity though their role in treatment is limited. Bariatric surgery has been used to treat severely obese adolescents though is performed infrequently.⁴⁷ An abundance of research has connected added sugar consumption and weight gain in youths, which is why the American Heart Association released its first ever youth sugar consumption recommendation of 25 grams per day in 2016. This is especially noteworthy as many of the seemingly healthy snacks that children consume regularly are riddled with sugar – foods like peanut butter, yogurt, cereals, and salad dressings all pose risks to heightened sugar consumption.⁴⁸

Better Nutrition Means Better Health Outcomes

Food is the leading cause of healthcare problems in the United States. A better approach to nutrition can have beneficial effects that reach orders of magnitude throughout our country. Solving the American healthcare crisis should be a nonpartisan issue that focuses not only on encouraging healthier individual choice, but reforming the systems that make poor nutrition so regular and accessible for Americans. By focusing on reduced consumption of processed foods, added sugars and sodium, Americans can more effectively manage their health and avoid chronic, sometimes lifelong, conditions like diabetes and obesity. By avoiding these conditions and their comorbidities, the U.S. healthcare system stands to save millions of dollars in health expenditures.

As we start to link the financial costs of a healthcare epidemic in this country to poor nutrition, the choices individuals make and the future of the food industry will be of paramount importance. Consumers are beginning to recognize that traditional, Western medicine – like dependence on prescription medication – may be second to a healthier diet in terms of efficacy

and overall health. More than half of consumers with the available means are seeking diets with fresh and natural foods.⁴⁹ While exercise is important, the lasting effects of healthier diets will send shockwaves through the country's healthcare system: it is estimated that if the government encouraged manufacturers to reduce sodium in packaged foods by just three grams per day, it would prevent thousands of health related deaths and save up to \$24 billion in healthcare costs annually.⁵⁰

How the Healthcare Industry is Responding

Managed care organizations (MCOs) play a vital role in helping patients manage their obesity. While dietary changes may be achievable and sustainable for individuals with healthy BMIs, diet and exercise are not always sufficient solutions to weight management for obese individuals. The tools at the disposal of MCOs are health and wellness programs, prescription drugs, and surgical intervention; however, not all MCOs cover these weight management methods. In 2015, a report revealed that about one third of companies did not include prescription drugs for obesity management in its benefits, one third included drugs but limited their use, and one third included all FDA approved obesity drugs without limitation. The following discussion revealed that insurance coverage of obesity drugs is a question of their efficacy and safety; MCOs cite adherence and the lack of “real-world evidence” as primary reasons for limiting their coverage. MCOs feel similarly about bariatric surgery, as the operation does not always promise probable outcomes and is associated with a number of problems. Further, state and federal governments have made it more difficult for MCOs to cover parts of the procedure. To help increase MCO coverage, there has been strong support to direct research to demonstrate the cost-saving benefits of the weight management tactics discussed above. For example, pharmaceutical companies can direct more resources to long term studies that highlight drug efficacy and cost-effectiveness.⁵¹

One healthcare company has been dominating the “food as medicine” approach by giving away free, nutritious food. Geisinger Health and Geisinger Health Plan have partnered together to create the Fresh Food Farmacy program, a program engineered to help diabetic adults improve their health through access to free, nutritious foods and medical services. The program targeted diabetics who are food insecure, meaning they have inconsistent or unreliable access to nutritious food. On a per patient program cost, providing this initiative costs about \$2,200 per year. Prior to this initiative, the payer cost per patient ranged between \$8,000 and \$12,000 per month: the free food initiative has cost saving potential of great magnitude. On a yearly basis, prior to the initiative, patient payer costs averaged \$120,000. Through this program, payer side costs have dropped by more than two-thirds; relative to the

initial \$2,200 per patient cost of the program, the \$80,000 in savings represents an ROI of ~35x. The clinical outcomes are also laudable, with HbA1c (hemoglobin A1c) levels dropping more than two points per patient on average within 12 months of beginning the program. On medication, HbA1c usually drops between 0.5 and 1.2 points. For context, a one-point drop in HbA1c levels represents a decrease in risk greater than 20% of death or serious diabetes complications.⁵²

Self-insured employers are taking charge by spending more on health benefits than before, as health benefit costs are rising at twice the rate of wage increases. This increase in spending, however, is targeted and aims to keep future costs down through adding select benefits. The National Business Group on Health surveyed employers and found that the top initiative across employers questioned was to add more virtual care solutions – over 50% of respondents identified this as a top priority. Telehealth comes in a variety of different services, and the graphic below depicts the current telehealth landscape among employers and how it is expected to change in the coming year.⁵³ Additionally, several startups aim to leverage corporate benefits programs to help provide on-site nutrition and exercise programs, indicative of potential demand from employers to spend more on corporate wellness and health.

Telehealth Services Expand		
Large employers are providing access to more types of virtual care services:		
	In Place in 2018	Adding in 2019
Minor, nonurgent medical issues	95%	2%
Mental/behavioral health services	65%	13%
Health and lifestyle coaching	58%	7%
Weight management	54%	6%
Diabetes care management	42%	13%
Medical decision support	45%	9%

Source: National Business Group on Health, 2019 Large Employers' Health Care Strategy and Plan Design Survey.

The efforts by employers, MCOs and Geisinger illustrate some of the problems and opportunities that the industry is facing in responding to the obesity crisis. The broader understanding that healthy eating habits can be the primary key to managing obesity and diabetes has created a flourishing landscape for healthcare startups. By engaging and teaching users about these conditions, these startups have made access to weight management tools and healthcare providers easier than ever before. With their efforts, coupled with changing industry, Americans will have the resources needed to lead a healthy lifestyle.

Select Startups Impacting the Industry

The following pages outline some of the companies operating in the outsourced care management space that often partner directly with payers to provide programs designed to improve patient population health and lower the cost of care.

Companies are organized in the following two categories:

- Technology-enabled Care Management
- Technology Solutions

Technology-enabled Care Management



Help those with invisible, neglected, and stigmatized chronic digestive illnesses overcome barriers standing in their way to optimal care and healthier lives

Headquarters:
Houston, TX



A software platform that drives outcomes through real-time technology, tailored health and diet improvement, and a dedicated care team



1 in 5 women have IBS, and 1 in every 3 visits to a doctor are GI related. Annual medical costs for a single person can reach as much as \$90K, with drug costs reaching up to \$140K annually



\$3.7 Seed Round
11 to 50 employees (Crunchbase / LinkedIn)



United States
<https://www.vivantehealth.com>



Omada Health is technology-enabled outsourced care that improves members' health, reduces their risk of chronic disease and reduces economic burden on payers

Headquarters:
San Francisco, CA



A software platform that uses behavioral science to help people change their exercising, eating, and sleeping habits to improve health outcomes



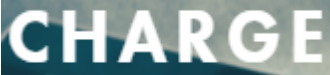
Omada targets individuals "on the brink of tipping over into certain chronic conditions, like Type 2 diabetes and heart disease." Omada results in meaningful, sustained weight loss over time



\$253M Venture Capital since 2011
201 to 500 employees (Crunchbase / LinkedIn)



United States
<https://www.omadahealth.com>



CHARGE provides corporate insurance-funded, customized onsite health and nutrition programs for employer groups

**Headquarters:
Media, PA**



CHARGE enables individuals to work towards personal health goals by offering customized health and nutrition plans that are covered under health benefit programs



CHARGE Nutrition can be used for personal and corporate health services and is an in-network provider for Blue Cross, Aetna, Cigna, and Highmark



11 to 50 employees (LinkedIn)



Eastern PA, NJ, NY, DE
<http://www.thechargegroup.com>



Rise provides affordable personal diet coaching by matching clients to top registered dietitians through their mobile application

**Headquarters:
San Francisco, CA**



Pairs individuals with personal registered dietitians through a questionnaire to engage in a guided 12-week nutrition bootcamp



Distinct from other weight-loss methods in that it provides lasting weight-loss solutions, personalized plans, enforces daily accountability, and promotes a healthy lifestyle



Acquired by One Medical
11 to 50 employees (Crunchbase)



United States
<https://www.rise.us/>



An app that collects blood glucose, blood ketones, weight, and blood pressure to help guide eating habits to reverse type 2 diabetes

**Headquarters:
San Francisco, CA**



Virta seeks to reverse type 2 diabetes through its clinically proven methods by providing a personal health coach, individualized treatment, physician supervision and a comprehensive mobile app



Virta has provided lasting results through reversal of type 2 diabetes, decreasing quantity of medication, and lowering A1c. Weight loss is not a function of low-calorie diets or fasting



\$37M Series A
\$45M Series B
51 to 100 employees (Crunchbase)



United States
<https://www.virtahealth.com>



Improves adherence and health outcomes for diabetes patients through personalized care and coordinated outreach via certified diabetes educators (CDE)

**Headquarters:
New York, NY**



Works with health plans, providers, pharma and device companies to provide scalable and affordable treatment to diabetes patients



Leverages a national network of CDEs to provide personalized support and patient outreach to empower individuals, motivate healthy behavioral changes, and drive results.



\$6.8M Venture Capital – Round Unknown
11 to 50 employees (Crunchbase)



United States
<https://www.fit4d.com>



Savor Health provides personalized, clinically-supported nutrition recommendations to cancer patients and their caregivers

Headquarters:
New York, NY



Leverages a team of oncology-credentialed RDs and RNs and proprietary technology to help guide healthy and effective eating habits during and after cancer treatment



Improves clinical and quality of life outcomes for patients and caregivers and reduces healthcare costs, increases satisfaction and improves clinical outcomes for health enterprises



\$1.5M Seed Round
\$5M Series A in progress
11 to 50 employees (Crunchbase / LinkedIn)



United States
<http://savorhealth.com>



Online community-based diabetes prevention platform that engages those with prediabetes to eat healthier and stay active (English and Spanish)

Headquarters:
New York, NY



Weight and activity monitoring coupled with an online diabetes prevention-certified coach; Wireless scale and activity tracker sync to online account



Individual and payer-based 12-week to 16-week prevention programs (with a year of support); Lowers average diabetes-linked costs by roughly 28%



Blue Mesa Health achieves over a 40% engagement rate with its members;
\$2.3M Seed Round in July 2017;
11 to 50 employees (Crunchbase / LinkedIn)



Canada, United Kingdom, United States
<https://www.blumesahealth.com>



**A technology-enable
behavior change
program for diabetics;
Livongo monitors
users' blood sugar
levels remotely and
encourages users to
improve eating habits**

**Headquarters:
Mountain View, CA**



Members use mobile blood sugar meters that feed into Livongo's artificial intelligence system; if a user's blood sugar is out of range, a Livongo Diabetes Response Specialist contacts the user



Through coaching and monitoring, Livongo, on average, saves the payer \$83 per patient per month



\$143.2M raised since 2013;
\$52.5M Series D led by General Catalyst in 2017;
\$49.5M Series C raised in 2016;
51 to 200 employees (Crunchbase / LinkedIn)



United States
<https://www.livongo.com>



**Ornish is a lifestyle
medicine therapy
program that aims to
reverse the
progression of heart
disease.**

**Headquarters:
Atlanta, GA**



Ornish is reimbursed by Medicare and other commercial payers in more than 14 states. Ornish creates cost-saving value by reducing readmissions and more effectively managing patients



Ornish works with patients to optimize dietary patterns, response to stress, physical activity, and their support network. Patients are grouped into cohorts who meet with me clinicians regularly



Part of the Sharecare platform
1001 to 5000 employees (Crunchbase)



United States
<https://www.sharecare.com>



Mealshare is a marketplace that connects consumers with dietitians for stronger adherence to healthy eating behaviors.

Headquarters:
San Francisco, CA



As a two-sided marketplace, MealShare gives provides clients to better access to dietitians by acting as a full sales and support platform for dietitians



Clients use the app's photo-sharing feature to share pictures of their meals with their dietitian, and can then request reviews of their meals or live consults. The app enables direct payment to the dietitian



Part of the StartUp Health platform
11 to 50 employees (LinkedIn)



United States
mealshare.com



Good Measures pairs users with a Registered Dietitian and leverages their online platform to help promote positive eating and exercise behavior

Headquarters:
Boston, MA



Good Measures' services can help treat a variety of nutrition-sensitive conditions, including obesity and its comorbidities, infertility, celiac disease, osteoporosis, and several others



The Good Measures Index (GMI) is a single number that reflects how well an individual is meeting their personal nutrition needs. The RD generates a personalized plan to help maximize a user's GMI



Primary Investor: Tufts University (amount undisclosed)
11 to 50 employees (LinkedIn)



United States
goodmeasures.com

Technology Solutions



A HIPAA-compliant billing platform for registered dieticians to bill insurance for patient visits. Allows for RDs to file better claims and helps RDs start accepting insurance

Headquarters:
New York, NY +
Winston Salem, NC



Building modern tools for the modern dietician by giving them a platform to help manage insurance claims, accept insurance claims, and ultimately save time and money



Gives dieticians the tools they need to interface with insurance companies and Medicare to manage claims effectively



\$2.0M Seed Round
10 to 50 employees (Crunchbase / LinkedIn)



United States
<https://www.healthybytes.co>



Uses its proprietary platform to cross-reference data from wearable devices and clinical studies to create personal fitness plans for individuals

Headquarters:
Phoenix, AZ



Styr aims to change the way people think about fitness, nutrition, sleep, and stress by leveraging wearable devices, digital intervention, and functional food



Offers customized solutions in the forms of vitamins, proteins, and electrolytes gleaned from biometric data for individuals, employees, and personal trainers



\$5.5M Venture Capital – Round Unknown
11 to 50 employees (Crunchbase)



United States
<https://www.styr.com>



Habit uses a proprietary DNA and nutrition test to evaluate your body's sensitivities to carbs, fats, and proteins, then suggests a nutrition plan accordingly

Headquarters:
San Francisco, CA



Users complete a comprehensive nutrition test that examines DNA and blood work to understand genetic and metabolic markers that impact nutrition



A holistic approach to personalized medicine that targets healthy lifestyles and personal health goals through science-backed nutritional guidance



\$32M Venture Capital – Round Unknown
11 to 50 employees (Crunchbase)



United States
<https://habit.com>

HVMN

Develops nutrition and supplement products for optimal performance, with an emphasis on improving cognitive, physical, and metabolic endpoints.

Headquarters:
San Francisco, CA



HVMN offers a variety of products, ranging from ketone-enhancing beverages to nootropics, to help optimize physical and cognitive performance.



HVMN sells nootropics, which is a classification of drugs or compounds with cognitive enhancing properties, colloquially known as “smart drugs”



\$2.6M Venture Capital – Round Unknown
11 to 50 employees (Crunchbase)



United States
<http://www.hvmn.com>



Lume offers a cost-effective, personalized approach to weight loss by providing metabolic insight via calorie intake through scientifically validated lab-grade measurements

Headquarters:
Minneapolis, MN



Lume posits that FDA food labels and wearable devices provide an inaccurate calorie consumption count – Lume more accurately logs calorie intake through proprietary technology



The Lume Scale, App, and Armband empower users to take control of their weight loss through personalized nutrition guidance and easy calorie counting and weight management tools



\$200K Venture Capital – Round Unknown
1 to 10 employees (Crunchbase / LinkedIn)



United States
<http://www.metalogicscorp.com>



Mom's Meals provides refrigerated, home-delivered meals and nutrition services for recovering patients and individuals who manage chronic disease.

Headquarters:
Ankeny, Iowa



Mom's Meals ships each individually selected meal to individuals throughout the country. Meals last up to 14 days in refrigeration after arrival



Home delivered meals designed by chefs with targeted nutrition goals. Meals can be selected from 9 different health condition menus



11 to 50 employees (LinkedIn)



United States
<https://momsmeals.com>



Blue Zones is a health and wellness company that was founded to help individuals mimic the nutrition and lifestyle patterns of the global communities where people live the longest.

**Headquarters:
Minneapolis, MN**



Based on the diets of the 5 Blue Zone communities, Blue Zones Meal Planner delivers personalized, affordable, nourishing and easy to prepare meals to its users.



Blue Zones Meal Planner coordinates recipes with allergies, personal goals and cooking aptitude, and grocers to help individuals eat healthy. Users also have direct access to a personal Food Coach.



11 to 50 employees (LinkedIn)



United States
<https://meals.bluezones.com/>

Looking Forward: Technology Changing Nutrition

Reducing the prevalence of obesity in America will result in numerous economic and health benefits for individuals and for the country. As is the case with many human behaviors, diet choices are difficult to change and maintain. Obesity is primarily attributable to individual choices, environmental and genetic factors, though the inherent conflict of interest that is created by government farm subsidies can make it difficult for consumers to make the right choice consistently. The companies highlighted in this report offer solutions that vary widely across a spectrum, from pairing consumers with registered dietitians, reversing and managing conditions like type 2 diabetes and heart disease, to more effective means of counting calories. These companies rely primarily on two strategies, used together or independently: empowering and engaging the user through programs that promote stronger adherence to healthier diets, and better coordinating efforts between patients and care providers.

Worth highlighting is how technology is revolutionizing the way we think about weight management. The pace of technological and scientific development has allowed for myriad approaches to the issue. Traditional approaches to weight management, like counting calories and nutrients, have been made more effective through the means of technologies like smart watches and smart scales, and their synchronization to mobile fitness applications. Apps also include photo platforms that allow dietitians to comment and give feedback on a user's meal, modernizing a longstanding relationship between a dietitian and a client that had typically been confined to an office. Of the more modern approaches highlighted in this report, some of the newest research has been commercialized through understanding how an individual's metabolism responds to different food groups – fats, carbohydrates, sugars, and proteins – to help build a customized diet. These efforts help users think about not only eating healthier, but also eating smarter, as the basic premise is that a healthy diet varies from person to person and effective and sustainable weight management is achieved through personalized diet.

Building healthier eating habits is an onerous undertaking, and can oftentimes be discouraging – the American food and beverage industry has certainly not made it any easier, either. At FCA, we are excited about the entrepreneurs who recognize this and seek to find a long-term solution to improving healthcare outcomes through concentrated nutrition guidance.



Founded in 1996, FCA Venture Partners has a long history of investing in successful healthcare entrepreneurs. We are passionate about building sustainable businesses and providing strategic value to our portfolio companies.

FCA invests \$3-6M in fast growing healthcare companies making processes in the industry faster, better, and cheaper while improving the quality of care and the patient experience.

With its location in Nashville, roots with Clayton Associates and the McWhorter Family, and deep involvement in the growth of the U.S. healthcare community, FCA Venture Partners is poised to take advantage of disruptive opportunities that help move healthcare forward.

Investing in Entrepreneurs that Improve Healthcare

110 Winners Circle North | Suite 100

Brentwood, TN | 37027

Phone: 615-326-4848 | www.fcavp.com

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