BACKGROUND

Approximately 75% of total U.S. health care expenditures are spent on preventable diseases but only 3% of total health care expenditures are invested in disease prevention programs.

Problem Statement

A common question among policymakers, public health experts, and consumers that is, in many ways, still unaddressed is whether health care costs can be avoided if more preventive measures are adopted. On the surface, it seems that the answer would be a logical yes, in that preventing diseases is a better option than having to pay for costly treatments. According to the Centers for Disease Control and Prevention (CDC), approximately three quarters of total U.S. health care expenditures are spent on preventable diseases, including such conditions as coronary heart disease, diabetes, age-related eye disease, and osteoporosis (Centers for Disease Control and Prevention), but only 3% of health care expenditures are invested in disease prevention programs (American Public Health Association - Center for Public Health Policy, 2012).

Although the U.S. health care system today does not have as strong an emphasis on preventive medicine as other Western countries, many observers predict that the United States is in the midst of a slow revolution of its health care model—transitioning to a model that is more focused on maintaining individual and overall health and wellness as opposed to a continued reactive approach focused on single-event interventions. However, a deeper look into the cost-effectiveness of prevention reveals many variables that must be accounted for—including which diseases are preventable, the efficacy of the proposed preventive measures, and, ultimately, the relative cost—before an informed decision on the optimal distribution of health resources by policymakers, public health experts, and consumers can be made.

Some observers question investing more money and effort into preventive health and wellness programs, citing two key issues that may make prevention less cost-effective than one would expect (Cohen, Neumann, & Weinstein, 2008) (Russell, 2007). The first issue is that the most well-known prevention practices, such as regular physician checkups or healthy people participating in more laboratory-based procedures (including cancer screenings and blood work), do not actually improve one's health. However, this is also not prevention in the true sense of the word; rather, it is a form of health diagnostics, and diagnostics do not prevent illness. Instead, they identify illnesses for possible utilization of costly acute treatment services. The second issue is that prevention realizes relatively little net cost savings because of the large number of people who would need to adopt preventive measures to avoid just one costly disease-attributed event. However, this argument ignores the core definition of prevention, which is a set of activities that an individual adopts to help minimize his or her chance of experiencing an undesired disease-attributed event.

The adoption of a prevention regimen can help mitigate possible damage to an individual's health and wellness, as well as possible financial impacts that could occur if the individual develops a preventable disease.

Proponents state that true prevention implies a lifelong habit of adopting lifestyle practices that are known to favor better health. These include paying attention to diet and weight, adopting an active lifestyle, and avoiding risky behaviors such as smoking and drinking alcohol. The use of certain dietary supplements may also help delay or prevent certain diseases. The objective of prevention is to improve health throughout life—in the growing years, during reproduction, and while aging. Improved health can also be expected to result in lower health care costs, especially in those life stages (such as older adults and seniors) when costs are most likely to occur. Specifically, the adoption of a prevention regimen helps to mitigate potential damage to an individual's health and wellness, as well as financial effects that could occur, if the individual develops a disease.

Despite the uncertainty surrounding the cost-effectiveness of prevention, its role as a component in overall health and wellness is gaining traction. Most Americans are aware of the challenges facing the country's health care system: escalating costs, denied tests and treatments, fragmented care, less time available for a patient-physician relationship, medical errors and inefficiencies, and other problems. However, important cultural, technological, and demographic trends are increasingly putting more control into the hands of patients to directly manage their health. This transformation has enormous potential to change how medicine is practiced and how the health care system, as a whole, operates.

This shift is directly driven by the need to look for smarter ways to control the escalating costs associated with rising disease-incidence rates for preventable diseases—or, at a minimum, to identify high-risk populations and minimize their chances of experiencing costly events. There are many ways to address rising costs, including the use of new technologies that identify high-risk populations before they experience costly acute treatment events; the adoption of a new health care model that incentivizes consumers, health care professionals, and other key stakeholders to address the antecedents of disease as opposed to the utilization of acute treatment services; and increased education. A low-technology, yet smart, approach that could be more extensively used by consumers and physicians might feature certain dietary supplements that have been scientifically shown to help reduce the risk of experiencing a costly disease event among high-risk population groups.

In the United States, dietary supplements are defined by the Dietary Supplement Health and Education Act (DSHEA) of 1994 as products that are orally ingested and contain nutrients or other dietary components meant to supplement the diet (U.S. Food and Drug Administration, 2013). Dietary supplements come in many forms, including tablets, capsules, liquids, powders, and more. Nutritional components of dietary supplements include vitamins, minerals, fatty acids, proteins, and amino acids (U.S. Food and Drug Administration, 2013). A significant amount of scientific research has been conducted involving dietary supplements, and many studies demonstrate that these supplements have a positive effect on reducing the risk of a disease event. Disease events require costly treatments, but there have been few efforts to calculate the cost-effectiveness of such dietary supplement use.

There is a need for an objective and systematic assessment of the current state of scientific findings regarding the link between the use of dietary supplements and the reduction in the risk of a disease that requires costly treatment services. Understanding this link will help key stakeholders—including patients, physicians, governments, and private insurance companies and employers—make recommendations on the best course of action to help minimize current and future costs and maximize benefits. This report examines the potential health care cost savings if people over the age of 55 use certain dietary supplements that have been shown to lower disease risks. Specifically, this report will examine evidence that demonstrates that the use of key dietary supplement ingredients can reduce illness-related hospital utilization costs associated with heart disease, age-related eye disease, diabetes, and bone disease in the United States.

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If an event risk reduction can be determined and applied into a cost-benefit model, then this will help patients, health care professionals, governments, insurance companies, and employers determine whether a given treatment regimen is cost-effective.

Research Methodology

This report presents a cost-benefit analysis (CBA) comparing the effect on overall disease management costs if a high-risk population were identified and if that population were to increase its use of dietary supplements and incur the cost of such supplementation, with the expectation that supplement use would decrease each person's odds of experiencing a costly treatment event. CBA can be used to assess various cost scenarios and to identify the potential savings or loss that can be realized if one scenario occurred versus another.

This analysis is centered on a series of hypothetical scenarios for a set of common dietary supplements to determine whether a net savings can be realized in the costs of disease management services if costly medical events are avoided through the use of a specific dietary supplement compared with scenarios of no supplement usage. Net savings will suggest a strong economic argument for each person in a given high-risk population to use the given dietary supplement to reduce lifetime disease management costs.

This issue is similar to many that pharmacoeconomic/clinical studies aim to address, which is the determination of an overall treatment's effect on the outcome of a given event when a treatment regimen is applied to one group versus a control group. From these types of analyses, risk—and subsequently risk reduction of an event occurring—can be calculated and applied into a cost-benefit model that helps key decision makers (including patients, health care professionals, governments, insurance companies, and employers) determine whether a treatment is cost-effective.

To deduce the true effect of treatment with a given dietary supplement on the occurrence of a specific disease event, a rigorous search was conducted focusing on published studies that quantified the effect of dietary supplementation on the incidence of disease events that required direct medical treatment. The goal was to collect a set of studies that represented the overall state of understanding and general acceptance on the level of efficacy a given dietary supplement has on affecting the relative risk of a disease event occurrence.

Basically, a thorough review of scientific evidence that shows a likely effect of the intake of each key dietary supplement on the occurrence of chronic, disease-related events was undertaken. This intervention effect can be quantified into a risk reduction metric, which can be included in a cost-benefit model for scenario assessment. The process of deriving the risk reduction metric for each key dietary supplement followed the same overarching, rigorous process of identifying the relevant and representative scientific studies that show an effect on disease event occurrence through a rigorous search exercise and deducing an overarching measure of relative risk between dietary supplement users versus nonusers. Specifically, Frost & Sullivan took the following steps to derive the expected risk reduction metrics for use in the cost savings model:

Review of the scientific literature related to the given chronic disease and the dietary supplement

Frost & Sullivan first instigated a rigorous scientific literature search and built a database of key studies that investigated a causal relationship between supplement intake and the incidence of specific health conditions of interest. Studies were included in the database. Scientific studies included in the database include case studies, observational epidemiologic studies, and clinical trials adhering to best practice scientific methodologies and inclusion was independent of whether the findings were positive, negative, or null. The search exercise used the U.S. National Library of Medicine's PubMed database. All studies reviewed were retrieved between February 1 and May 31, 2013. More than 400 studies were identified based on the use of a strict set of keyword combinations including the dietary supplement of interest, the disease of interest, and the words "risk reduction" or similar phrasing.

Identification of a representative set of qualified studies that investigated a causal relationship between supplement intake and the incidence of specific health conditions of interest

Once the database of possible studies was created, each study was thoroughly reviewed and assessed to determine whether there was a quantifiable relationship between supplement intake and the incidence of a specific chronic disease event, either directly or indirectly through a specified biomarker. Specifically, a study was considered qualified for inclusion in the analysis if it tested for a relationship between the intake of a given dietary supplement at a specific dosage level range and the reduction in the odds of a disease event occurring, independent of the direction of the relationship.[1] Typically, observational epidemiologic studies and randomized clinical trials fit this criterion. If such studies were not found, then studies were reviewed that tested for causal relationship between supplement intake and the level of a biomarker that is correlated to the relative risk of a disease event. Frost & Sullivan strove to include studies that were similar in study protocol in an attempt to control for observable variance. In addition, the research team strove for the ideal of exhaustive inclusion of all studies, but that cannot be guaranteed because of time and resource constraints. Frost & Sullivan makes no claims of endorsing the specific findings of any scientific study reviewed.

1 The selection of studies included in this analysis was not based on the direction, the magnitude, or statistical significance of the reported findings.

Weighting and aggregation of the qualified study findings in order to determine an overall expected impact of dietary supplement intervention on disease event occurrence

In any cost-benefit analysis, there is a need to identify a variable that reflects the effect that the activity will have on overall costs and benefits. Only then can one undertake a comparative analysis between two scenarios. Economists refer to this as output elasticity, which is a ratio that shows a change in a specified output given a change in a specified input. Frost & Sullivan searched for scientific studies that showed a direct relationship between the usage of a specific dietary supplement and the risk of experiencing a defined disease-attributed hospitalization event or a biological marker, such as LDL cholesterol levels and hemoglobin A1c (HbA1c) levels, which can be linked to the chance of a disease-attributed event.

To deduce an estimate on these output elasticities, each qualified study result was weighted by the precision of its findings to derive an overall expected risk reduction (RR) metric. For this study, two approaches were used to derive the expected effect of dietary supplement intervention on disease event occurrence. The specific approach adopted per dietary supplement type was dependent on the quantity of the qualified studies that explore the relationship between intake and disease event risk and the nature of the collective literature.

The DerSimonian and Laird random-effects literature review approach (D-L approach) was used in cases where a dietary supplement had a significant number of scientific/clinical studies that directly explored the specific question that this study aims to address (DerSimonian & Laird, Literature Review in clinical trials, 1986). The D-L approach allows one to properly assess the results of a set of studies that address the same research question, even though each study varies in terms of sample size, study protocol, research team, and a host of other study qualities. This variance is addressed by controlling for inter-study and intra-study variance, and provides a more probable and exact estimate of the overall effect of intervention (see Appendix for details on the D-L approach methodology and details on the calculation of relative risk (RR) and relative risk reduction (RRR) metrics.

In cases where the D-L random-effects literature review approach is not appropriate, such as the case when the number of qualified studies is small or when the relationship between the supplement intervention's impact and the utilization of costly treatment services is indirect, the Center for Evidence-Based Medicine (CEBM) approach was adopted to calculate the number of people needed to treat in order to avoid one major disease event (Center for Evidence Based Medicine, 2012). In these cases, all that is needed for the calculation is an estimate of the relative risk reduction and the observed event rate (ER) or the observed disease prevalence in the target population. It should be noted that the estimated number needed to treat is less accurate compared to the D-L approach and consequently the calculated estimate tends to be inflated. Thus, the determined cost saving estimates will be less precise compared to the cost savings calculated using the D-L approach but still provide invaluable insight of the given supplement's potential cost savings and health care cost effectiveness (see Appendix for details on the CEBM methodology and details on the calculation of relative risk reduction (RRR)).

Health care cost savings scenario analysis

Independent of which literature review approach was used, the key metric needed for inclusion in the cost models is the number needed to treat (NNT), which can easily be calculated using the deduced RRR metrics from the literature review. The NNT is the total number of people who would have to undergo a preventive or treatment intervention to realize one avoided undesired event. This metric was selected as the variable of focus in this study because it is easy to associate an expected health care cost per person experiencing an event. For example, if it was found that a given dietary supplement had an NNT of 100, this would mean that 100 people would need to be supplemented to avoid one major disease event in the target population.

Once the NNT for a given dietary supplement regimen is known, the number of possible avoided events that could be realized if everybody in a given population were to use the supplement at an adequate or protective daily intake level can be calculated; knowing the cost per event, the total avoided costs can be estimated. For example, consider the case of omega-3. It is known that 17.0 million adults over the age of 55 have documented CHD and that 4.8 million people in this group will experience a new CHD event in 2012. Thus, if the total population had used omega-3 at preventive daily intake levels, 127,601 CHD hospital utilization events would have been avoided based on the deduction from current scientific literature that the expected relative risk reduction in experiencing a costly CHD event is 6.9%. This implies an NNT metric of 133 people who needed to be treated to avoid one event (refer to Figure 3.5 for the detailed description of the derived relative risk metric for omega-3 intake). Given that the cost of each CHD event averaged $13,317 in 2012, the potential avoided hospital utilization costs would have been approximately $1.7 billion in 2012.

In order to have realized this total cost savings potential, then all 16.6 million adults over the age of 55 with CHD would have had to take omega-3 at preventive daily levels at a total subpopulation supplement utilization cost of $1.57 billion. Thus, the net benefit that could have been gained would have been more than $131.0 million in avoided CHD-related hospitalization costs in 2012.

Figure 2.1—Summary of Cost Calculations Assuming Omega-3 and Coronary Heart Disease Cost Hypothetical Case, 2012

Reference column	Metric	Measure	Note
A	Target population with CHD, 2012*	17,016,536	Source: CDC and Frost & Sullivan
B	Expected number of people within the target population who will experience a CHD hospitalization event, 2012	4,831,679	Source: MEPS and Frost & Sullivan
C	NNT (from literature review)	133	Source: Frost & Sullivan
D	Expected annual cost of CHD hospital utilization per person, 2012	$13,316.66	Source: MEPS
E	Annual cost of omega-3 dietary supplementation per person, 2012	$92.15	Source: Frost & Sullivan
F	Number of events avoided if everybody in the target population took a supplement, 2012	127,601	A/C = F
G	Avoided hospital utilization costs, 2012	$1,699,224,829	D*F = G
H	Costs of omega-3 supplementation, 2012	$1,568,065,776	A*E = H
I	Net cost savings, 2012	$131,159,053	G - H = I

* Among all U.S. adults over the age of 55 with CHD
Source: Frost & Sullivan

Thus, once the expected risk reduction factor is derived from the literature review, the potential cost savings derived from dietary supplement usage among a given high-risk population at preventive daily intake levels can be calculated and compared with the extreme scenario of zero usage. The calculation of total cost savings is straightforward:

- Total expenditure on chronic disease events at zero usage
- **MINUS** total expenditure on chronic disease events given the use of dietary supplements at protective levels and the expected reduction in chronic disease events because of reduced risk
- **PLUS** the dietary supplement utilization costs
- **EQUALS** potential net cost savings derived from the lower occurrence of disease events because of increased dietary supplement usage

Thus, if the possible net cost savings is positive, then the dietary supplement regimen in question should be considered an effective means to help reduce overall disease-related individual lifetime costs and total social health care costs. Of course, the prior cost-benefit analysis approach makes the assumption that in the supplementation scenario, the entire population of the target high-risk population must fully utilize the given dietary supplements at protective intake levels from a base of zero use among this same population segment. In other words, the calculated net savings is actually the total potential net savings that are realizable. However, because it is known that it is likely that a percentage of the target high-risk population is already regularly using the dietary supplement in question, this share of the target population has already reduced its risk of experiencing a costly disease event and is already realizing its risk-reducing benefits.

If the possible net cost savings is significantly positive, then the dietary supplement regimen in question should be considered as an effective means to reduce overall disease-related individual lifetime costs and total social costs as a whole.

Logically, this also implies that the remainder of the potential regular users has yet to realize the potential preventive benefits from regular use of the given dietary supplements. Because avoided expenditures and net cost savings are a direct function of the total number of people in the target population using the dietary supplements, the calculation of avoided health care expenditures and net cost savings yet to be realized is simply a proportional adjustment of the total potential avoided expenditures and net cost savings. These yet-to-be-realized adjustments are also calculated in each of the scenario analyses conducted in this study and are reflected in their respective chapters.

Research Limitations and Assumptions

It should be noted that each dietary supplement explored in this study was analyzed independently, and cross-comparisons should be avoided. This is basically because the state of the science today does not support this approach; event risk for each supplement was examined in a controlled setting, independent of the use of other supplements. The definition of disease-attributed events and the associated per-person costs of treatment vary by disease condition; thus, derived benefits and costs are not comparable across disease conditions. Also, benefits of different supplements (such as omega-3 fatty acids and B vitamins) in reducing the risk of a single disease (such as CHD) cannot be considered to be additive. In addition, variance because of study sample size, research methodologies and study protocols, and patient population characteristics within each study and among all studies is high, making cross-comparison of dietary supplements unadvisable.

However, there is enough evidence from this report's findings that suggest that the net cost savings realizable were people to take a set or a combination of dietary supplements is highly likely to be greater than just using one of the dietary supplements. Certainly, more research would be required to substantiate this statement and determine if cost savings is accumulative (the sum of the savings), synergistic (the sum of the savings is higher than the net savings from using a combination of supplements due to offsetting effects/redundancies in the mechanism of action), or antagonistic (the sum of the savings is lower than the net savings from using a combination of supplements). Frost & Sullivan makes no claims of endorsing the specific findings of any scientific study reviewed.

Regarding cost estimate forecasts, expected compound annual growth rates were derived from a historic assessment of population growth rates, costs, and prices. Specifically, health care costs per person are expected to grow at an average annual growth rate of 5% from 2013 to 2020 based on the historical growth rate over the last 10 years. This growth rate was applied for all procedures for all conditions assessed in this study. Growth in the targeted population is expected to occur at an average annual growth rate of 1.7% during the forecast period, and it was assumed that growth in disease incidence is equal to population growth based on a review of population growth and disease incidence trends. Dietary supplement retail prices are expected to grow at a compound annual growth rate of 1% per year. All future expenditures on health care costs and dietary supplements were at a 3% discount rate, which is in line with health economic methods promoted by the World Health Organization to reflect the present value of estimated future expenditures and net savings and control for inflationary effects (World Health Organization, 2008).