



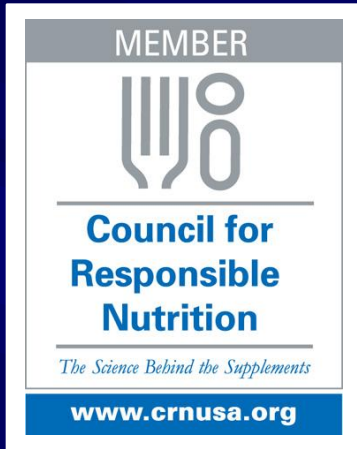
# U.S. DIETARY SUPPLEMENT LABEL CLAIMS – *WHAT CAN YOU SAY ?*

**Steve Mister**

President & CEO

Council for Responsible Nutrition

# Who is CRN?



- National trade association for manufacturers and marketers of dietary supplements and functional foods in the United States.
- Foster a climate for responsible industry members to develop, manufacture and market their products.

- Our global affiliate, CRN-International (CRN-I), promotes science-based policy-making around the world.



# Association Facts

One Association—The Council for Responsible Nutrition (CRN)

## Amount with CRN

Voting Members.....	96
Finished Products.....	52
Ingredient Suppliers .....	44
Associate members.....	46
Staff .....	15
Annual budget .....	\$5.2 million
Years in existence.....	41

*Also contains: scientific, regulatory, international, media relations and government relations expertise not found anywhere else.*





## **ARE DIETARY SUPPLEMENTS REGULATED IN THE UNITED STATES?**

# What the media says . . .

“These views are often fueled by product health claims, consumer testimonials, and an industry that is **largely unregulated** owing to the 1994 Dietary Supplement and Health Education Act.”

*Archives of Internal Medicine,*

“The sentencing ends an unusual criminal case that explored both illegal online pharmacies and the legal but **barely regulated U.S. dietary supplements industry.**” MSNBC

“So why aren't these products regulated? Congress **virtually exempted them from oversight** under a 1994 law...” *Concord Monitor*

“...**supplements are not regulated**...”  
*Nutrition-wise Blog, MayoClinic.com*

“Dietary supplements **are not strongly regulated or evaluated** for claims by the FDA ...”

*NewsStar.com*

“Fifteen years after Congress and the Clinton administration put the dietary-supplement industry **on a loose leash**, the \$25-billion-a-year business still sometimes bites its customers.”

“The dietary-supplement industry is **essentially unregulated,**”

*“How supplements can bite their buyers,”  
Philly.com*

“The consumer should understand that the dietary supplement market is **mostly unsupervised and unregulated. . . .**” *The Legal Examiner*

“**An unregulated industry**” *Consumer Reports*

“. . . these products are both **widely used and largely unregulated** by the U.S. Food and Drug Administration.” *NewsDay*

**They are wrong!  
Dietary supplements ARE  
regulated.**

# Dietary supplements ARE regulated.

- Differently than pharmaceutical drugs, but regulated.
- Treated as a category of food, except where they are singled out for additional requirements – which they often are.
- Extensive regulations, enforced by U.S. FDA and FTC, regulate their formulation, manufacturing, labeling and marketing.



# Why Supplements Should Be Regulated Differently than Drugs



- Dietary ingredients are found in foods or have extensive history of use; they are not novel compounds.
- Natural compounds have little intellectual property/patent protection.
- Lack of exclusivity means less incentive to invest funding in drug-like studies.
- Nutrients have more subtle, long-term effects vs. immediate, life-saving results – they get less interest from researchers.
- Studying risk reduction and prevention vs. treatment and cure are more costly, time consuming and more arduous; RCTs may pose ethical issues.





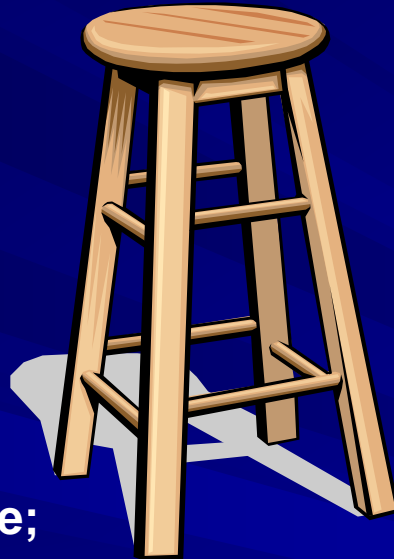
# Regulation is a Four-Legged Stool

## *Ingredient Safety*

1. The ingredients are safe.

## *Claims Evaluation*

4. The ingredients are effective; i.e., the product does what the marketer says it will do.



## *Manufacturing Controls*

2. The product is manufactured in a manner that assures quality.

## *Post-Market Surveillance*

3. Someone is monitoring the product in the marketplace.



# Ingredient Safety

- An ingredient that was on the market in 1994, when DSHEA was enacted, is presumed to be safe unless the FDA demonstrates that it is not.
- Twenty years later, we have additional usage data to further support the safety of these “old” ingredients.
- New dietary ingredients (introduced since 1994) must be “noticed” to FDA at least 75 days before entering the market.
- Mfrs must describe the ingredient with specificity and provide FDA with evidence that the ingredient, and product that would contain it, are “reasonably expected to be safe.”
- FDA can remove ingredients or products from the market if they pose a significant or unreasonable risk of illness or injury – and has used that authority.





# Manufacturing Controls

- Dietary supplements are subject to their own Good Manufacturing Practices (GMPs) regulations, effective for industry since 2010.
- GMPs govern all aspects of dietary supplement production, from identity testing of raw ingredients to testing of the final products.
- Mfrs must register their facilities with FDA every two years.
- FDA routinely inspects dietary supplement facilities, completing over 500 inspections in 2013.
- Warning letters for uncorrected violations are posted on FDA's website.



# Post-Market Surveillance

- 2006 law imposed mandatory adverse event reporting – with support of the industry.
- All serious adverse events reported to a company must be reported to FDA within 14 days of receipt. No determination of causality: all reports go to FDA.
- Companies must preserve all adverse event reports for six years; FDA has access upon request.
- These adverse event reports have proven helpful to identify manufacturing problems, safety concerns for ingredients and discrepancies in labeling.



# Claims Are Regulated by FDA and FTC

- Disease Claims are prohibited – Foods and dietary supplements may not claim to treat, prevent, mitigate, cure or diagnose a disease.
- Other claims must have substantiation that they are true – competent and reliable scientific evidence to support the claim.

# Advertising vs. Labeling

- The FDA regulates DS labeling – anything affixed to the product, or that would appear
- The Federal Trade Commission (FTC) oversees all consumer advertising, including DS – print ads, television, radio.
- Both FDA and FTC claim jurisdiction over internet – websites, banner ads, search engine tools, blogs, social media, etc.

# Why Claims Are Important

- Claims inform the consumer about safe use of the product and provide information about its ingredients.
- Educate consumers available options for their health interests.
- Claims communicate to FDA the intended use of the products.
  - Is it a food, drug or supplement?
- They support and facilitate marketing of products.

# Types of Allowable Dietary Supplement Claims

- Nutrient Content Claims
- Nutrient Deficiency Claims
- Structure / Function Claims
- Health Claims – includes Qualified Health Claims

**These can all be used for either dietary supplements or conventional foods**



# Disease Claims Are **NOT** Permitted

- A disease claim is a claim that the product prevents, treats, cures, mitigates or diagnoses a disease.
- Making a disease claim transforms the product into a DRUG.



# What is a “disease”?

- ...damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

# Nutrient Content Claims

- Characterize the level of a nutrient in the product.
- Examples:
  - “High in antioxidants”
  - “Good source of calcium”
  - “Excellent source of Vitamin C”
- Limited to those nutrients authorized by FDA.
- Product must contain the prescribed amount.



# Nutrient Deficiency Claims

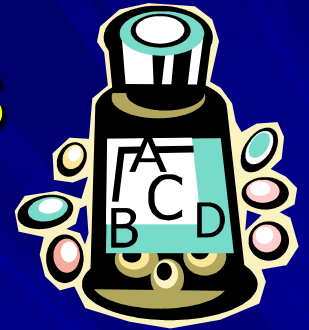
- Very limited claims related to a known deficiency-related disease.
- Must also provide the known prevalence of the disease in the general population.
- Examples:
  - Vitamin C – scurvy
  - Vitamin D – rickets

As a practical matter, these are rarely used in the U.S.

# Structure/Function Claims

- Describe the effect of a product on the (normal) structure or function of the body, and also include:
  - Claims that describe the effect of the supplement on general well-being.
- Manufacturer must notify FDA the claim is being made.
- Manufacturer must have substantiation that the statement is truthful and not misleading.

# Examples of Structure/Function Claims



- “Helps build strong bones”
- “Helps support a healthy Immune function”
- “Use for weight management”
- “For eye health”
- “Maintain a healthy circulatory system”
- “Helps build muscle – get strong and toned”

# Structure/Function Claims

## ■ Key Features:

- May not claim or imply diagnosis, prevention, treatment or cure of a disease

## ■ Label must bear an FDA disclaimer:

**These statements have not been evaluated by the Food and Drug Administration.  
These products are not intended to diagnose, treat, cure, or prevent any disease.**

These statements have not been evaluated by the Food and Drug Administration.  
These products are not intended to diagnose, treat, cure, or prevent any disease.

***Disclaimer has two purposes:***

1. To distinguish structure/function claims from health claims, which are evaluated by FDA.
2. To distinguish structure/function claims from drug claims, which do refer to preventing or treating disease.



# Case Study – *Immunity*

- “A good source of antioxidant vitamins C and E.”
- “Supports a healthy immune system.”
- “Supports a healthy respiratory system.”
- “Enhances your natural resistance.”
- **BUT NOT:** *Prevents colds, allergies or fights sinus infection*



**With Extra<sup>†</sup> C:**

- A COMPLETE MULTIVITAMIN WITH 10 ESSENTIAL NUTRIENTS
- SUPPORTS A HEALTHY IMMUNE SYSTEM\*
- CONTAINS AS MUCH VITAMIN C AS 3 ORANGES

A FLINTSTONES MULTIVITAMIN WITH NUTRIENTS YOUR CHILD NEEDS TO:\*

- SUPPORT THE IMMUNE SYSTEM with Vitamin C, Vitamin E, and Beta Carotene
- SUPPORT HEALTHY EYES with Vitamin A, Vitamin C, and Vitamin E
- AID IN THE RELEASE OF ENERGY FROM FOOD with Vitamin B6, Vitamin B12, Thiamin, Riboflavin, and Niacin
- HELP ABSORPTION OF CALCIUM FOR STRONG BONES AND TEETH with Vitamin D

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.  
†Compared to FLINTSTONES™ Complete.

Children's Multivitamin Supplement

Pediatricians' #1 Choice  
For Children's Chewable Vitamins

# FLINTSTONES™

Plus IMMUNITY SUPPORT\*

60 CHEWABLE TABLETS

**Green Giant.**

**New!**

## immunity boost

naturally rich in antioxidants  
Vitamins A & C to help  
support a healthy  
immune system

Broccoli Florets, Julienne Carrots and Red & Yellow Sweet Pepper Strips in a Garlic-Herb Infused Extra Virgin Olive Oil Seasoning

NET WT. 7 OZ (198g) KEEP FROZEN

SERVING SUGGESTION ENLARGED TO SHOW DETAIL



# Substantiating Structure/Function Claims

- ALL Claims require competent and reliable scientific evidence for support.
- FDA provides flexibility in the amount and type of evidence while helping to preserve consumer confidence.
- Support should relate to the specific product and claim, be scientifically sound, and adequate in the context of the surrounding body of evidence.

Source: *FDA Guidance: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act*

# “Competent and Reliable Scientific Evidence”

To meet this standard, companies should consider:

- 1) The **meaning** of the claim(s) being made
- 2) The **relationship** of the evidence to the claim
- 3) The **quality** of the evidence
- 4) The **totality** of the evidence

*...does not necessarily require blinded, randomized clinical trials.*

- Randomized-controlled trials (RCTs) are the “gold standard” -- but they may not be appropriate for nutrients and food components.
- Prevention/health maintenance is difficult to “prove” because benefits are realized over time.
- Nutrient effects may be subtle, and multi-functional.
- Observational data may be used.
- RCTs may be costly, impractical or unethical.

...so FDA uses a flexible approach  
to substantiating claims.



# Health Claims

- Discuss the relationship between the ingredient and the reduction of risk of a disease.
  - Reduction of risk in NOT prevention.
- Health claims require prior approval of FDA.
- Use the standard of “substantial scientific agreement” with the proposed claim.

# Health Claim Examples

- “Calcium and vitamin D can reduce the risk of osteoporosis.”
- “A diet rich in fiber may reduce the risk of heart disease.”



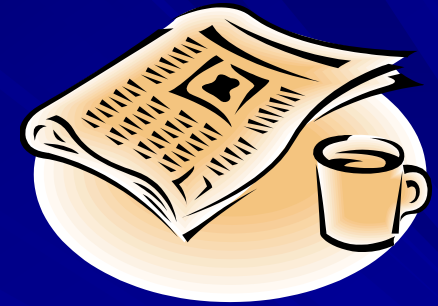
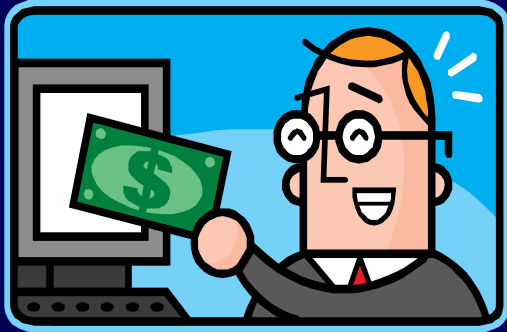


# Qualified Health Claims

- The result of court decisions in the U.S., not found in the statute.
- FDA cannot prohibit the dissemination of truthful but not conclusive evidence of health benefits.
- Authorizes FDA to create qualifications to a health claim to give consumers accurate understanding of the strength of the claim.

# Qualified Health Claim Examples

- “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.”
- “Selenium may reduce the risk of prostate cancer. Scientific evidence concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer.”
- “Scientific evidence suggests, but does not prove, that eating 1.5 ounces per day of most nuts, such as almonds, as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease.”



# Regulation of Advertising Claims

# Federal Trade Commission



- FTC has primary responsibility for claims in most consumer advertising
  - Includes TV, radio, Internet, newspaper ads
- Requires that dietary supplement manufacturers should be familiar with the requirements under both DSHEA (for labeling) and the Federal Trade Commission Act (for advertising)

# FTC Standard for Advertising

Same standard as FDA:

- Advertisers must have substantiation that advertising claims are truthful and not misleading.
- Requires competent and reliable scientific evidence to support advertising claims.
- FTC does not categorize claims (nutrient, S/F, health) – holds all claims to same standard.

# Issues for Advertising

- Looks at implied as well as express claims.
- Testimonials and endorsements are claims.
- Blogs, social media (Facebook, Twitter, etc.) can be claims if controlled by the advertiser.



# Summary

- Dietary supplements in the U.S. are subject to comprehensive, robust regulations to promote safe responsible production and use of these products.
- The U.S. system of claims review is flexible and allows consumers to make informed choices and to have access to a wide variety of products.



# Smart Prevention— Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements





# Introduction–The Problem

**Americans spend too much money on healthcare.** As the population ages, both the actual dollars spent and the percentage of GDP targeted to health care spending are expected to increase.



- ❖ 75% of health care spending goes to addressing preventable diseases.
- ❖ Only 3% of every health care dollar spent is used for prevention.
- ❖ Numerous, rigorous studies demonstrate that the targeted use of certain dietary supplements can actually help to reduce the risk of some chronic diseases.

***What if dietary supplements could contribute to reducing overall healthcare expenditures?***

# The Hypothesis

We hypothesized that if the selected dietary supplement regimens were taken at the same preventive levels as used in the clinical research by those at-risk populations, there would be a cost savings to the health care system and to individual providers and payers from reduced medical expenses associated with those lower risks of disease.

# The Research

## Objectives:

- To critically review the research literature which examines the association between dietary supplement intake and disease risk reduction to quantify the risk reduction; and then
- To determine the potential net health care cost savings from the use of those dietary supplements as a result of avoided disease-related medical events.



# Research Scope



- Coronary heart disease (CHD) and the potential net health care cost savings when using omega-3 fatty acids, three B vitamins (folic acid, B6, and B12), phyosterols and psyllium dietary fiber.



- Diabetes and the potential net health care cost savings from diabetes-attributed CHD when using chromium picolinate.



- Osteoporosis and the potential net health care cost savings when using the combination of calcium and vitamin D or when using magnesium.



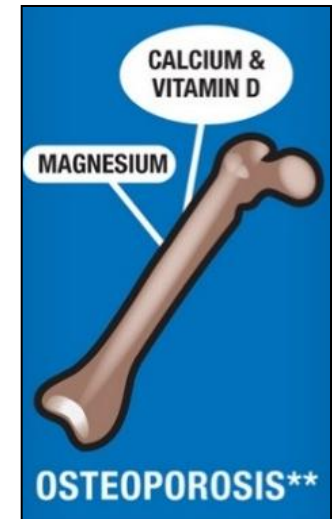
- Age-related eye disease (AREC), specifically age-related macular degeneration and cataracts, and the potential net health care cost savings when using lutein and zeaxanthin.

# Overarching Research Methodology– Part 1: Analytical Process to Ascertain Disease Risk Reduction

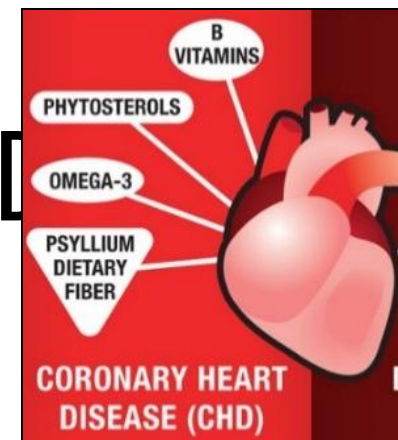


# Osteoporosis

- In 2012, 1.2 million fracture events related to osteoporosis.
- Average treatment cost: \$11,020 per event.
- More than \$14 billion in annual direct health care costs.
- **Calcium and vitamin D utilization yields:**
  - 18.6% relative risk reduction.
  - An average of 151,053 avoided events per year.
  - 1,208,422 avoided events accumulated through 2020.
- **Magnesium utilization yields:**
  - 6.0% relative risk reduction.
  - An average of 68,536 avoided events per year.
  - 548,284 avoided events accumulated through 2020.

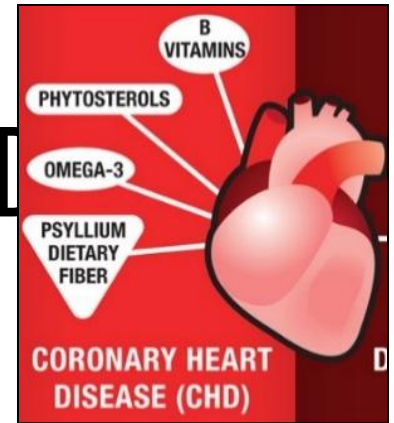


# Coronary Heart Disease (CHD)



- 16% of adults over 55 with CHD will experience a CHD-related medical event each year.
- Average cost of CHD-related inpatient procedures and emergency room visits = \$13,317.
- Between 2013 and 2020, average direct health care costs related to CHD events among adults over 55 = \$77.92 billion a year.

# Coronary Heart Disease (CHD)



- **Omega-3 utilization yields:**
  - An average of 137,210 avoided events per year.
- **B vitamins utilization yields:**
  - 808,225 avoided events accumulated through 2020.
- **Psyllium dietary fiber utilization yields:**
  - 11.5% relative risk reduction.
- **Phytosterol utilization yields:**
  - An average of 283,389 avoided events per year.



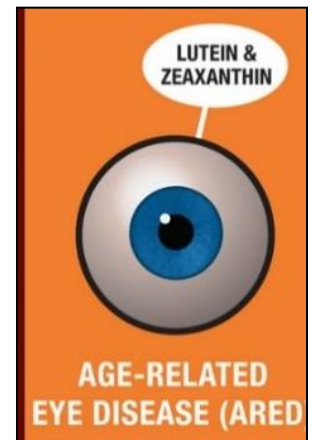
# Diabetes-Related CHD



- Over 17 million U.S. adults have Type II Diabetes.
- Of them, over 6.9 million have diabetes-related CHD and 1.9 million experienced a diabetes-attributed CHD-related inpatient procedure and/or visited the emergency room in 2012.
- Average expenditure per person = \$13,317.
- **Chromium picolinate utilization yields:**
  - 10.2% relative risk reduction.
  - An average of 81,243 avoided events per year.
  - 649,944 avoided events accumulated through 2020.

# Age-Related Eye Diseases (AREDS)

- Through 2020, an average of 4.8 million people over the age of 55 will experience an AMD or cataract event.
- Total cumulative health care costs related to ARED events: more than \$164.4 billion—an average annual cost of nearly \$20.60 billion.
- **Lutein and zeaxanthin utilization yields:**
  - 23.0% and 15.3% relative risk reduction of AMD and cataracts, respectively.
  - An average of 971,724 avoided AMD and cataract events per year.
  - 7,773,791 avoided events accumulated through 2020.



# Part 2: Determination of Health Care Cost Savings

Once the expected risk reduction factor is derived from the literature review, the potential cost savings derived from increasing dietary supplement intake among a given high risk population can be calculated.

**Determine Hospital Utilization Costs in the Current State**



**Avoided Hospital Utilization Costs Given 100% Use of Dietary Supplement Regimen at Preventive Intake Levels**



**Revised Hospital Utilization Costs Accounting for Dietary Supplement Usage**

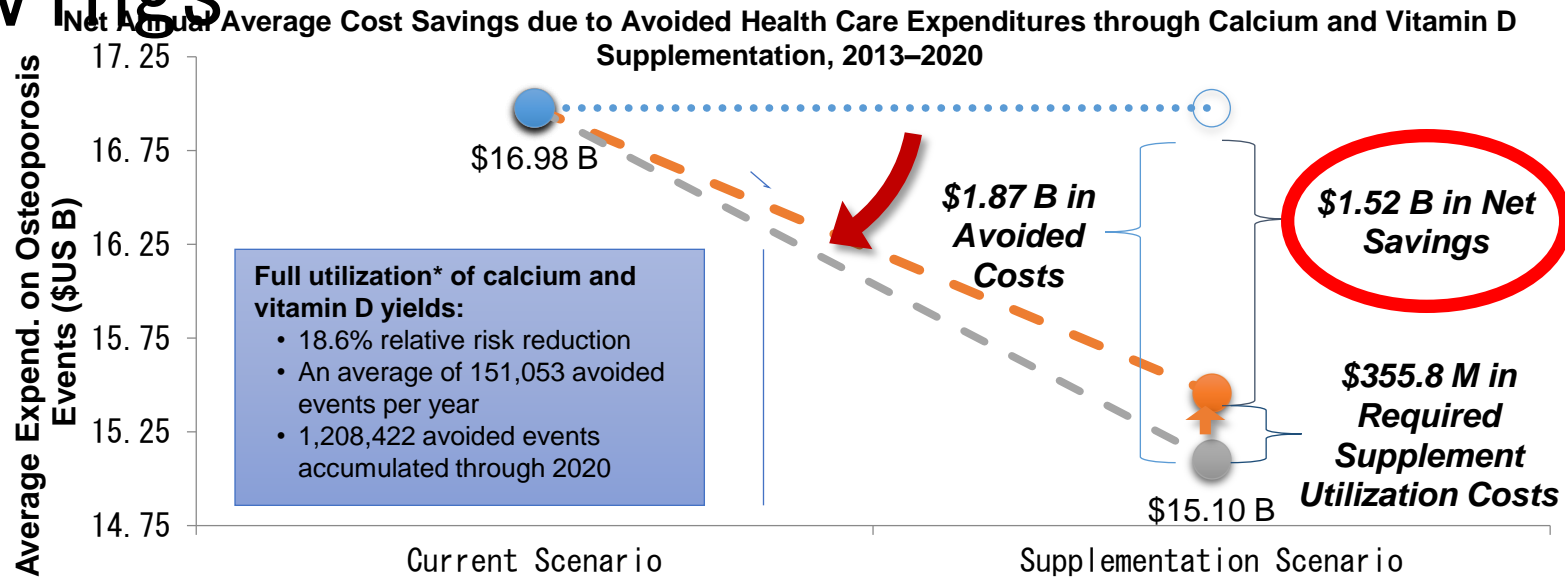


**Costs of Dietary Supplement Utilization**

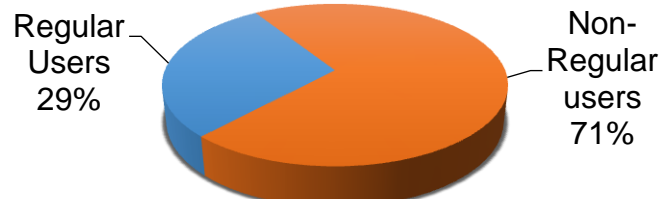


**Potential Net Cost Savings from Dietary Supplement Usage**

# Benefits of Calcium and Vitamin D— Potential Osteoporosis—attributed Cost Savings



Proportion of Target Population\* that are Regular Users of Calcium and Vitamin D, 2012



Source: Ipsos Public Affairs



**Cost Savings Yet to Realized:**

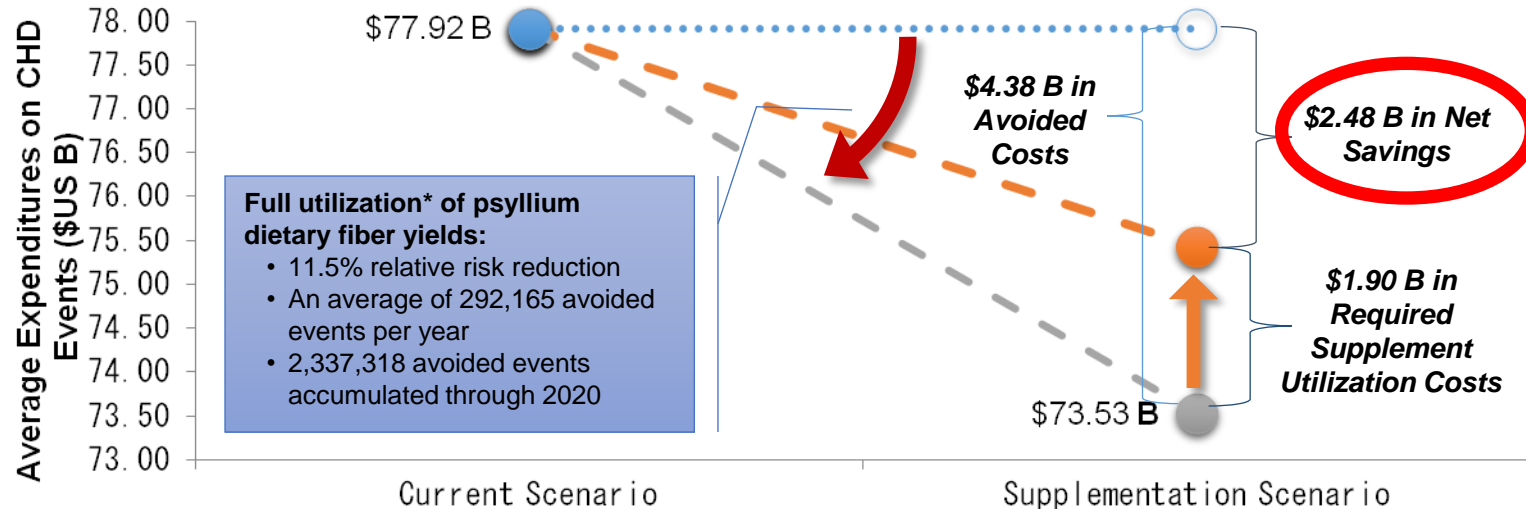
- 107,248 avoided events per year
- \$1.08 B in savings per year

Note: \* Among all females over the age of 55 with Osteoporosis, \*\*Time horizon = 2013 to 2020

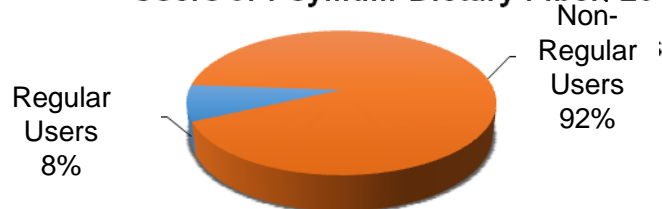
Source: Frost & Sullivan analysis.

# Benefits of Psyllium Dietary Fiber—Potential CHD Cost Savings

Net Annual Average Cost Savings due to Avoided Health Care Expenditures through Psyllium Dietary Fiber Intervention, 2013–2020



Proportion of Target Population\* that are Regular Users of Psyllium Dietary Fiber, 2012



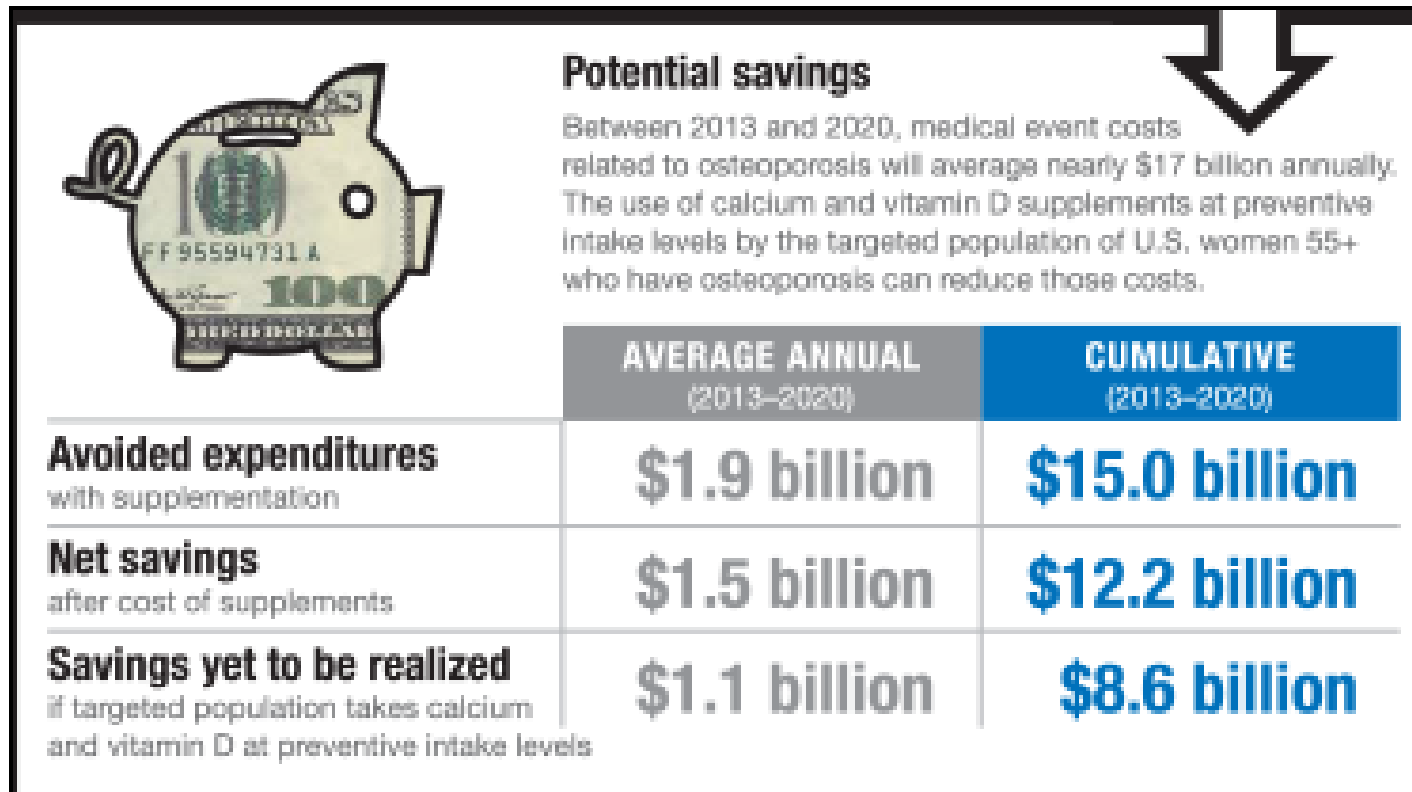
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**Cost Savings Yet to Realized:**

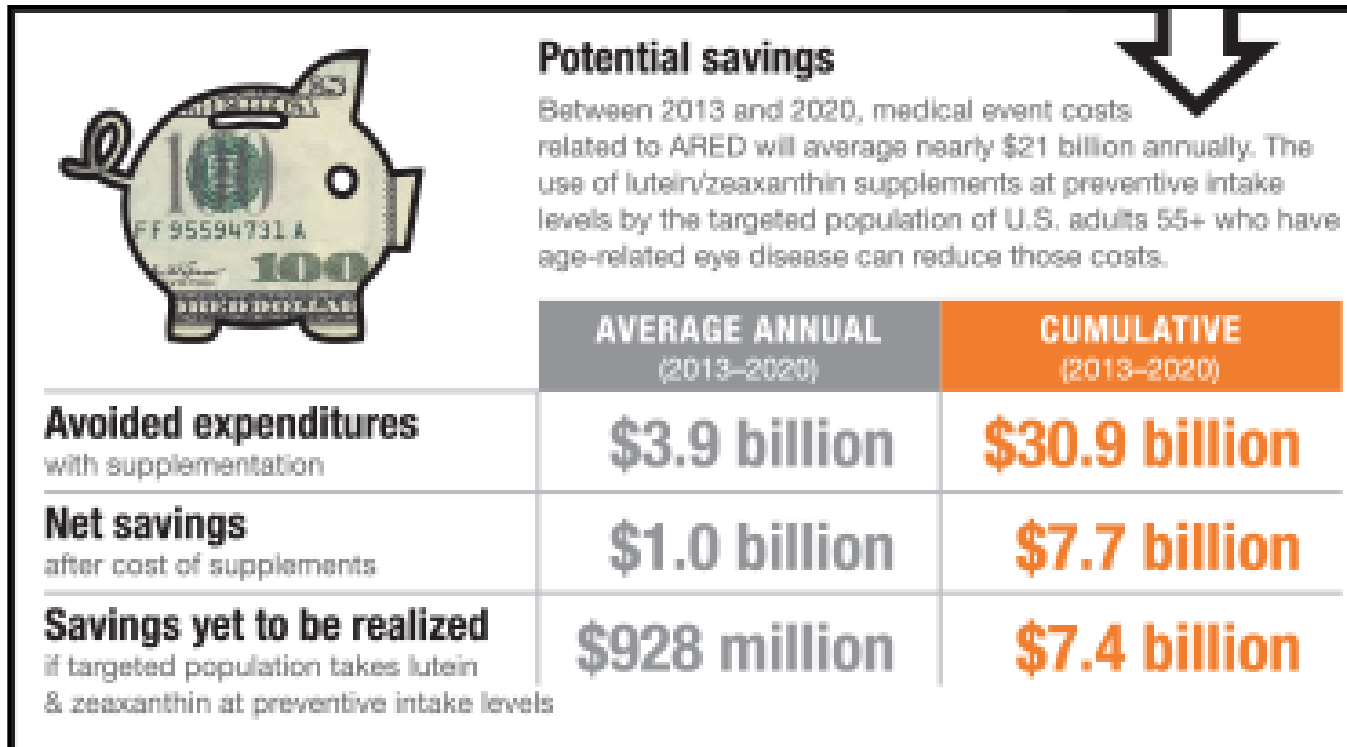
- 268,647 avoided events per year
- \$2.28 B in savings per year

Note: \* Among all adults over the age of 55 with CHD, \*\*Time horizon = 2013 to 2020  
Source: Frost & Sullivan analysis.

# Benefits of Calcium and Vitamin D— Potential Osteoporosis-attributed Cost Savings



# Benefits of Lutein and Zeaxanthin— Potential Age-related Eye Disease Cost Savings



# Benefits of B Vitamins— Potential CHD Cost Savings



## Potential savings

Between 2013 and 2020, CHD-related medical event costs will average nearly \$78 billion annually. The use of vitamin B dietary supplements at preventive intake levels by the targeted population of U.S. adults 55+ who have CHD can reduce those costs.



	AVERAGE ANNUAL (2013–2020)	CUMULATIVE (2013–2020)
<b>Avoided expenditures</b> with supplementation	<b>\$1.5 billion</b>	<b>\$12.1 billion</b>
<b>Net savings</b> after cost of supplements	<b>\$654 million</b>	<b>\$5.2 billion</b>
<b>Savings yet to be realized</b> if targeted population takes B vitamins at preventive intake levels	<b>\$562 million</b>	<b>\$4.5 billion</b>



# Benefits of Phytosterols— Potential CHD Cost Savings



## Potential savings

Between 2013 and 2020, CHD-related medical event costs will average nearly \$78 billion annually. The use of phytosterol dietary supplements at preventive intake levels by the targeted population of U.S. adults 55+ who have CHD can reduce those costs.



	AVERAGE ANNUAL (2013–2020)	CUMULATIVE (2013–2020)
<b>Avoided expenditures</b> with supplementation	<b>\$4.2 billion</b>	<b>\$34.0 billion</b>
<b>Net savings</b> after cost of supplements	<b>\$3.3 billion</b>	<b>\$26.6 billion</b>
<b>Savings yet to be realized</b> if targeted population takes phytosterols at preventive intake levels	<b>\$3.3 billion*</b>	<b>\$26.5 billion*</b>

# Benefits of Chromium Picolinate– Potential Diabetes–attributed CHD Cost Savings



# Outcomes

Understanding the link between smart prevention and health care cost savings will help key stakeholders, including patients, health care professionals, governments, insurance companies and employers, make better-informed decisions on the best course of action that minimizes current and future health care costs and maximizes long term potential benefits.



- A significant amount of scientific research has been conducted involving dietary supplements and many studies demonstrate a positive impact on reducing the risk of a disease event through supplement use.
- Disease events require costly treatment services, but until now there has been little effort to effectively calculate the cost-effectiveness of such supplement use.
- This report demonstrates that significant cost savings can be realized through the smart use of scientifically-substantiated dietary supplements among high risk populations.

# Research Caveats

- The results from these eight regimens may not be generalizable to all supplements.
- This report is not intended to be a prescription for everyone to begin these eight regimens.
- Results of each supplement regimen should not be summed together for overall cost-savings effect.
- Results of each regimen are not comparable to one another for either:
  - Absolute savings, or
  - Cost/benefit ratio,although each regimen independently demonstrates significant cost savings for that supplement.



## Calcium & Vitamin D Dietary Supplements and Osteoporosis

## Lutein and Zeaxanthin Dietary Supplements and Age-Related Eye Disease (AREd)

## Psyllium Dietary Fiber Supplements and Coronary Heart Disease (CHD)

## Omega-3 Dietary Supplements and Coronary Heart Disease (CHD)

## Vitamin B Dietary Supplements and Coronary Heart Disease (CHD)

## Phytosterol Dietary Supplements and Coronary Heart Disease (CHD)

## Magnesium Dietary Supplements and Osteoporosis

## Chromium Picolinate Dietary Supplements and Diabetes-Attributed Coronary Heart Disease (CHD)

A new economic report shows that taking specific dietary supplements can provide significant individual and societal healthcare savings, by reducing the number of hospitalizations and other costly medical events associated with chronic diseases. This infographic demonstrates the cost savings that can be realized through the utilization of phytosterol supplements among all U.S. adults over the age of 55.

**6.0%**  
How magnesium works: Magnesium works to support bone health and can help reduce the risk of fractures. It can also help with blood sugar control and blood pressure.

**9¢ Daily cost**  
Median cost of preventive intake levels, 2013

**15¢ Daily cost**  
Median cost of preventive intake levels, 2013

**16% Event rate**  
% of targeted population that will experience a medical event

**11.2%**  
Relative risk reduction  
Taking phytosterols at preventive intake levels can reduce the risk of having a CHD-related medical event.

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**7,774,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with age-related eye disease.

**2,337,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

**998,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

**808,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

**109,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

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### HEALTH CARE COST SAVINGS Dietary Supplements for Smart Prevention

A new economic report shows that taking specific dietary supplements can provide significant individual and societal healthcare savings, by reducing the number of hospitalizations and other costly medical events associated with chronic diseases. The report looked at eight dietary supplement regimens and four conditions in a targeted population of U.S. adults 55+ who have the specific conditions or are at high risk for the disease.

**Supplements as interventions**  
Taking any of these eight dietary supplements at preventive intake levels has been shown to reduce the occurrence of medical events related to these four diseases in high risk populations.

**Event rate**  
% of targeted population that will experience a medical event per year

Supplement	Event Rate
PHYTOSTEROLS	16%
OMEGA-3	3.3%
PSYLLIUM DIETARY FIBER	11.5%
VITAMIN B	12%
CHROMIUM PICOLINATE	10.2%
LUTEIN & ZEAXANTHIN	33%
MAGNESIUM	6.0%
CALCIUM & VITAMIN D	15%

**Relative risk reduction**  
The risk of having a medical event is reduced by taking these supplements.

Supplement	Relative Risk Reduction
PHYTOSTEROLS	3.3%
OMEGA-3	11.5%
PSYLLIUM DIETARY FIBER	10.2%
VITAMIN B	23.0%
CHROMIUM PICOLINATE	15.3%
LUTEIN & ZEAXANTHIN	10.6%
MAGNESIUM	10.6%
CALCIUM & VITAMIN D	10.6%

**2013-2020 Cumulative Stats**  
Medical events avoided: 808,000 to 2,337,000 (CHD), 650,000 (Diabetes & CHD), 7,659,000 (AREd), 548,000 to 1,208,000 (Osteoporosis).  
Avoided expenditures with supplementation: \$12.1-\$35.1 billion (CHD), \$9.8 billion (Diabetes & CHD), \$31.0 billion (AREd), \$6.8-\$15.0 billion (Osteoporosis).  
Net savings after cost of supplements: \$3.9-\$26.6 billion (CHD), \$7.8 billion (Diabetes & CHD), \$7.7 billion (AREd), \$4.8-\$12.2 billion (Osteoporosis).  
Savings yet to be realized if targeted population takes supplements at preventive intake levels: \$2.8-\$26.5 billion (CHD), -\$7.8 billion\*\*\* (Diabetes & CHD), \$7.4 billion (AREd), \$4.2-\$8.6 billion (Osteoporosis).

**2,337,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

**998,000**  
Events avoided  
between 2013 and 2020 among the target population of U.S. adults over 55 with CHD.

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# Implications

- What does this report mean for those interested in reducing health care spending?
  - For Employers, Insurers and the Prevention Community
  - For Healthcare Practitioners
  - For Policy Makers
  - For Consumers





**Thanks for listening!**