### Flipping the Script on America's Heart Health:

## "Prescribe" Food Solutions to High Cholesterol

Supermarkets can serve as a first line of defense against cardiovascular disease (CVD) - the nation's leading cause of death every year since 1950, and a dire threat to one out of two Americans with risk factors. By emphasizing foods with phytosterols, which are proven to lower cholesterol, retail dietitians can place powerful natural solutions at shoppers' fingertips to help them prevent or manage CVD. Increasing knowledge and access to these foods can improve health outcomes, and shoppers will think of food stores as trusted wellness allies. ADDRESS 1334

Prescription: Eat foods with high levels of phytosterols. Such as oils, seeds, nuts and whole grains

Date ////8

Benecol



Cardiovascular Disease (CVD): America's Greatest Health Challenge

Second in a series of four white papers to inform food retailers of the vast scale, causes and deadly consequences of heart illness in the U.S. and the beneficial role supermarkets can play to help lower incidence, and help afflicted and at-risk customers eat smarter to enjoy healthier lives.

#### Slowing Down Cardiovascular Disease (CVD), the Nation's Most Pressing Health Issue:

What If Supermarkets Make Customers 'Cholesterol Savvier'?

More than half the U.S. population has at least one CVD risk factor, so heart-health is becoming a food-shopping priority: 28% seek 'low/lowers cholesterol' and 'heart healthy' package claims, yet 74% also concede what 'they eat could be healthier,' and about 1 in 5 households in every generation has obesity.<sup>1</sup> People needing guidance to prevent or manage CVD can turn to retail dietitians - trusted, accessible experts on food choices that can lower cholesterol and improve health outcomes.

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#### Introduction

The first Benecol<sup>®</sup> white paper, *Slowing Down Cardiovascular Disease (CVD), the Nation's Most Pressure Health Issue* (www.benecolusa.com/whitepapers), explained why CVD has been America's most potent killer each year since 1950,<sup>1</sup> and described health dangers millions don't know they harbor, so they don't treat. It also positioned grocery store dietitians as the ideal experts to help shoppers make smarter food choices to reduce high LDL and total cholesterol, a top 3 risk factor for CVD.

The heart-health challenge consumers face today is enormous, and the food-information gap seems equally vast. If retail dietitians, chefs, category managers, buyers and department heads collaborate to guide consumers to beneficial foods, they can help abate risk for some CVD risk factors, such as obesity, diabetes, and high total and LDL cholesterol.

#### **Recapping the Risk**

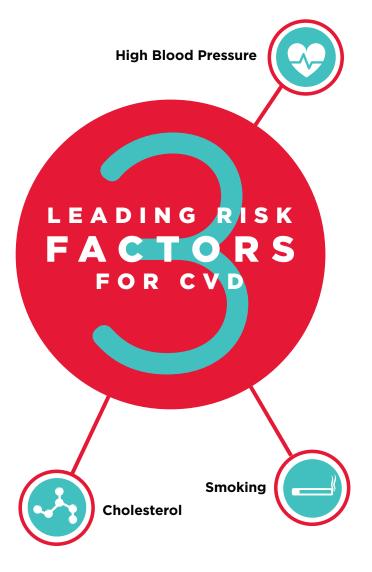
The three leading risk factors for CVD:

High cholesterol, high blood pressure and smoker status top the list of nine risk factors for CVD. <sup>2,3,4</sup> The Centers for Disease Control (CDC) says that half of Americans (49%) have at least one of these three. CVD risk compounds when more factors are present, notes the Framingham Heart Study.

# 4 IN 10 U.S. ADULTS

Nearly 4 in 10 U.S. adults – about 95 million people – have high total cholesterol.<sup>5</sup>

More than one-third of U.S. adults 20 years of age and older – 71 million people – have high LDL cholesterol; this includes 36% of males and 31% of females.<sup>6</sup>



#### What Consumers Don't Know Can Harm Them

Because CVD, a stealth killer, often presents no symptoms, people with high cholesterol are often unaware of their condition.<sup>7</sup> As a result, only half get treatment, and just one-third has the condition under control.<sup>8</sup> "People with high cholesterol have about twice the risk of heart disease as people with lower levels," said CDC.<sup>9</sup>

#### What Else May Contribute To The Low Rate Of Treatment & Control?

- Denial of condition.
- Unwillingness to improve eating habits or activity levels.
- Not knowing how to safely improve eating habits or activity level this is where retail dietitians and supermarkets can influence better behaviors.
- Fear of being on medications, or potential interactions with other medications, or inability to afford them.
- Uncomfortable side effects of statins. "Up to half of patients discontinue lipid-lowering medication within one year of treatment initiation, and adherence rates generally decrease over time,"<sup>10</sup> states a cardiovascular morbidity study in the American Journal of Therapeutics.



#### Time for Stores to Step Up, Visibly and Engagingly, Against Cholesterol

Public buzz about the risks of smoking and high blood pressure overshadows talk of cholesterol. Anti-tobacco public service messages are widespread. Blood pressure screening kiosks are common in retail pharmacies nationwide. And media covered CVS Health extensively when it ended its \$2 billion in annual tobacco products sales in 2014 to reinforce its image as a healthcare provider.

The chain documented the move's positive effect on public health. In states where it had at least a 15% share of the retail pharmacy market, cigarette pack sales across all retailers declined an additional 1% in eight months following the ban. Also, the average smoker in those states bought five fewer cigarette packs – a collective 95 million fewer packs sold in that same period. Consumer attempts to quit smoking apparently rose too, as nicotine patch purchases rose 4%, and the average number of MinuteClinic 'Start to Stop' smoking cessation visits conducted per month nearly doubled.<sup>11</sup>

#### In states where CVS/Pharmacy has greater than 15% market share:





over the 8 months following the tobacco removal



Source: CVS Health, September 3, 2015

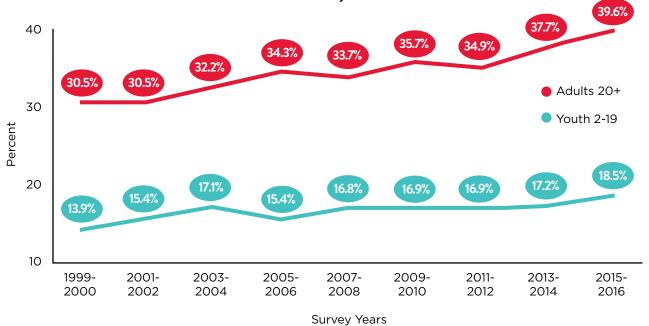
#### **Action Can Lead To Results**

Imagine what retail dietitians and supermarkets could achieve for cholesterol management by committing to foods with phytosterols, educating customers about them, and making them readily available year-round.

This would compare well with CVS's flight from tobacco. Healthdriven grocers that establish a higher profile for phytosterols could help millions of customers prevent cholesterol issues before they begin, and help millions more abate their high-cholesterol condition through retail dietitian-led programs – using functional foods, Food as Medicine themes, Medically Tailored Meals, signs, store maps, recipes and more.

#### Why Supermarkets Are the Right Place at the Right Time to Share Heart-Healthy Insights and Foods With Conflicted Consumers

- People need the expert guidance of dietitians, who are collaborating with in-store chefs, category managers and buyers. While 28% of consumers polled by Food Marketing Institute and Hartman Group seek 'low/lowers cholesterol' and 'heart healthy' package claims, 74% admit what 'they eat could be healthier.'<sup>12</sup>
- Obesity among U.S. adults and youth has reached an all-time high, state new data from the National Center for Health Statistics. Nearly 40% of adults and 19% of youth are obese. That's a 30% increase in adult obesity and 33% increase in youth obesity between 1999-2000 data and 2015-16.<sup>13</sup> Obese adults have a Body Mass Index (BMI) of 30 or more. Obese youths have a BMI of greater than or equal to the age- and sex-specific 95th percentile of the 2000 CDC growth charts.<sup>14</sup> (See chart C-1 for trends.)
- Affordable insurance options are in flux due to possible health reform. This may motivate consumers to engage with dietitians in supermarkets about food solutions to help avoid or manage health conditions requiring doctor and hospital visits.



#### C-1. Trends in obesity prevalence among adults aged 20+ and youth aged 2–19 years United States, 1999-2016

<sup>1</sup> Significant increasing linear trend from 1999–2000 through 2015–2016.

Notes: All estimates for adults are age adjusted by the direct method to the 2000 U.S. census population using the age groups 20-39, 40-59, and 60 and older. Source: National Center for Health Statistics, National Health and Nutrition Examination Survey, 1999-2016.

#### Why Supermarkets Are the Right Place at the Right Time (cont.)

- Retail dietitians can show how diverse foods with phytosterols enhance meal appeal as well as nutrition. Dietitians can also guide customers through the foods rich in cholesterol-lowering plant stanols.
- Such retail efforts could make customers personally accountable for their own heart health and dietary habits similar to the way smokers cut down on cigarettes after CVS Health adopted its anti-tobacco stance.
- Moreover, retail dietitians can amplify the goals and messages of the national Million Hearts public-private initiative to prevent 1 million heart attacks, strokes and other CVD events between now and 2022, following a similar five-year period that began in 2012. Within this initiative, the CDC and CMS (Centers for Medicaid & Medicare Services) co-lead evidence-based clinical and community interventions to improve cardiac health – aspirin as appropriate, blood pressure control, cholesterol management and smoking cessation.<sup>15</sup>
- 60% of retail dietitians engage in 50 or more shopper interactions each month; 18% have this
  many in one week.<sup>16</sup> These discussions are ideal to shape better eating habits, especially with
  Millennials (57% of the U.S. population by 2020), who are likelier than others to: ask experts for
  advice in grocery stores, be health-conscious, eat fresh and prepared foods, support healthrelated causes, and seek fortified foods.<sup>17</sup>

#### **Phytosterols: An Accessible Population-Level Food Solution for Health Care Practitioners and Patients**

#### **FDA Claim**

The Food and Drug Administration (FDA) identified dozens of intervention studies with strong scientific conclusions about the connection between phytosterol intake and risk of CVD, as related to common risk factors of CVD. The health agency recognized this relationship by issuing plant stanols and sterols the Significant Scientific Agreement (SSA) health claim. The SSA is an extremely strong statement as it identifies a proven, significant health-related relationship between an ingredient and a documented health condition.<sup>18</sup> The precise wording of the claim is as follows: *Foods containing at least 0.5 grams per serving of plant stanols or sterols eaten with meals or snacks for a daily total intake of 2 grams, as part of a diet low in saturated fat and cholesterol, may reduce blood total cholesterol and the risk of heart disease.* 

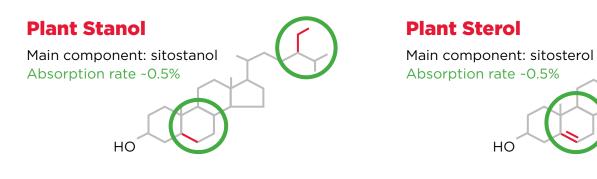
#### Why Plant Stanol Ester may be Better than Plant Sterol Ester

Phytosterols include plant sterols, plant stanols, and their esterified forms (plant sterol ester and plant stanol ester). Both are naturally occurring components of plant cell membranes. Both have a molecular structure similar to cholesterol, so they compete for absorption in the intestine, which in turn causes less cholesterol to be absorbed and lowers blood cholesterol levels.<sup>19,20</sup>

Both plant sterol ester and plant stanol ester effectively lower total and LDL cholesterol, while maintaining HDL levels. Yet studies suggest that plant stanol ester may perform better and be absorbed less by the body over the long term. A meta-analysis <sup>21</sup> of 113 published studies and one unpublished study report points to these advantages of stanol. While findings aren't fully conclusive, other research analyses tend to corroborate them with far lower daily intakes, which align with the FDA recommendation of 2 grams per day.<sup>22</sup>

- In a 16-week study of 18 familial hypercholesterolemia subjects "on statin therapy, plant stanol and sterol consumption (2g/day) lowered LDL cholesterol by 15.3% and 14.2%, respectively (Ketomaki et al., 2005). In our study – also a side-by-side comparison in subjects on stable statin treatment – LDL cholesterol was lowered by 12.6% in the plant stanol (2.5 g/day) and 8.1% in the plant sterol group (2.5g/day) as compared with the control group. This response is smaller than that in the studies of Ketomaki et al. (2004, 2005), whereas the intake of plant sterols and stanols was higher."<sup>23</sup>
- In a double-blind randomized trial of 54 subjects who also took statins over 90 weeks, LDL cholesterol lowered by 13.1% in the plant stanol group versus an 8.7% reduction in the plant sterol group, at a consumption of 2.5g per day.<sup>24</sup>

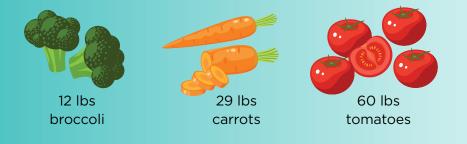
Phytosterols lower total and LDL cholesterol and can be part of a cholesterol-lowering strategy, alongside therapeutic lifestyle changes. In addition, these studies show incremental benefits among patients who take statins to help control their LDL cholesterol levels.





**Trace amounts of plant stanols are naturally present in foods such as cereals and grains, vegetables, fruits and legumes – but too little to achieve the desired cholesterol-lowering effect.**<sup>25</sup>

To consume the FDA's recommended 2 grams of plant stanols daily, one would have to eat 12 pounds of broccoli, 29 pounds of carrots, or 60 pounds of tomatoes each day – or easily add phytosterolfortified foods to the daily diet.



#### **Prescribe Food as Medicine: Phytosterols**

Globally, buttery spreads, yogurt, coffee creamers and orange juice are among functional foods fortified with plant stanols or plant sterols to lower cholesterol. Federal and international health bodies support phytosterol-fortified foods as a cholesterol-lowering strategy, which has been shown to be safe for most populations without side effects. Retail dietitians can confidently "prescribe" these to empower consumers with food solutions that are readily available and easy to integrate into daily diets. By doing so, retail dietitians further the theme of Food as Medicine, and help set the stage for individualized Medically Tailored Meals to help people manage specific health conditions and augment other healthcare practitioners' efforts.

#### Footnotes

<sup>1</sup> Heron M, Anderson RN. 'Changes in the leading cause of death: Recent patterns in heart disease and cancer mortality.' NCHS data brief #254. Hyattsville, MD: National Center for Health Statistics. August 2016.

<sup>2</sup> Mozzafarian D, Benjamin EJ, Go AS, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation.* 2016;133:e38-e360.

<sup>3</sup> D'Agostino, RB et al. 'General Cardiovascular Risk Pro le for Use in Primary Care,' The Framingham Heart Study. Circulation. 2008;117:743-753. Downloaded from http://circ.ahajournals.org October 6, 2016.

<sup>4,15</sup> US Department of Health and Human Services. Million Hearts initiative. Washington, DC: US Department of Health and Human Services; 2014. Available at http://millionhearts.hhs.gov/index.html.

<sup>5.7</sup> Heart Disease and Stroke Statistics 2017 At-a-Glance, American Heart Association annual update, pulled May 2017.

<sup>6,8</sup> Vital Signs: Prevalence, Treatment and Control of High Levels of Low-Density Lipoprotein Cholesterol – United States, 1999-2002 and 2005-2008". *CDC, MMWR*. 2011;60(4):109-114.

<sup>9</sup> Cholesterol Fact Sheet, CDC, updated April 30, 2015.

<sup>10</sup> Rublee DA, Chen SY, Mardekian J, Wu N, Rao P, Boulanger L. "Evaluation of cardiovascular morbidity associated with adherence to atorvastatin therapy." *Am J Ther.* 2012;19(1):24-32

<sup>11</sup> CVS Health Marks First Anniversary of Tobacco Removal With New Data on Decision's Impact, Extends Commitment to Creating Tobacco-Free Generation, CVS Health, September 3, 2015.

<sup>12</sup> U.S. Grocery Shopper Trends 2016, Food Marketing Institute, Hartman Group.

<sup>13</sup> Obesity among all US adults reaches all-time high, CNN, October 13, 2017.

<sup>14</sup> Ogden CL, Flegal KM. Changes in terminology for childhood overweight and obesity. National health statistics reports; No. 25. Hyattsville, MD: National Center for Health Statistics, 2010.

<sup>16</sup> Retail Dietitians Business Alliance survey, September 2017.

<sup>17</sup> Going to Market: A National Survey of Grocery Shoppers, Nielsen, 2016, conducted for the National Grocers Association.

<sup>18, 22</sup> Food Labeling; Healthclaim; Phytosterols and Risk of Coronary Heart Disease; Proposed Rule. 21 Code of Federal Regulations Part 101. 2010;75(235): 76526 - 76571

<sup>19</sup> Ostlund RE Jr. Phytosterols and cholesterol metabolism. Curr Opin Lipidol. 2004;15 (1): 37-41.

<sup>20</sup> Katan, Martijn B. et al.Efficacy and Safety of Plant Stanols and Sterols in the Management of Blood Cholesterol Levels. *Mayo Clinic Proceedings.* 2003;78 (8): 965 – 978.

<sup>21</sup> Musa-Veloso Kathy et al. A comparison of the LDL-cholesterol lowering efficacy of plant stanols and plant sterols over a continuous dose range: Results of a meta-analysis of randomized, placebo-controlled trials. *Prostaglandins, Leukotrienes and Essential Fatty Acids*. 2011;85(1):9-28.

<sup>23</sup> De Jong, Arienne et al. Effects of plant sterol and stanol ester consumption on lipid metabolism, antioxidant status and markers of oxidative stress, endothelial function and low-grade inflammation in patients on current statin treatment. *Eur J Clin Nutr.* 2008;62:263-273

<sup>24</sup> De Jong, Arienne et al. Effects of long-term plant sterol or stanol ester consumption on lipid and lipoprotein metabolism in subjects on statin treatment. *Brit J Nutr.* 2008;100(5):937-941

<sup>25</sup> Piironen, V., Toivo, J., Puupponen-Pimiä, R., and Lampi, A.M. Plant sterols in vegetables, fruits and berries. *J. Sci. Food Agric.* 2003;83:330-337.

Statistical figures throughout this White Paper are rounded to the nearest full digit.



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