# AOCS Special Oils Conference Cincinnati.

May 8th. 2004

# Can Functional Foods Reduce Health Care Costs

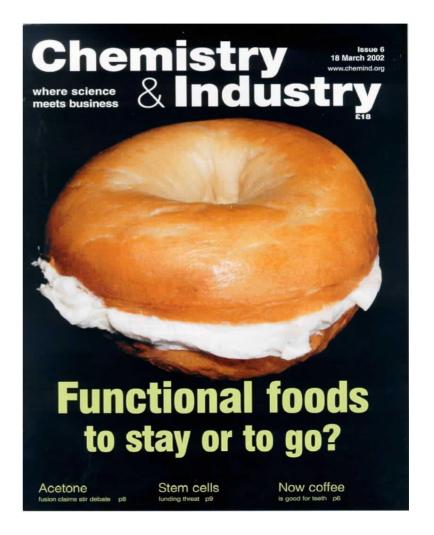
lan Newton, Ceres Consulting Toronto, Canada.

### Functional Foods: Here Today Gone Tomorrow?

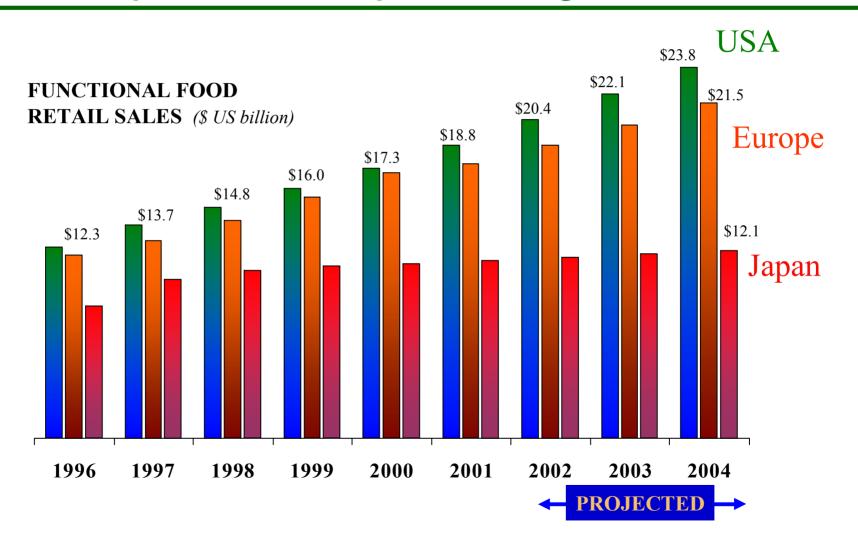
Most people would argue that they are here to stay

#### **Rationale/Drivers**

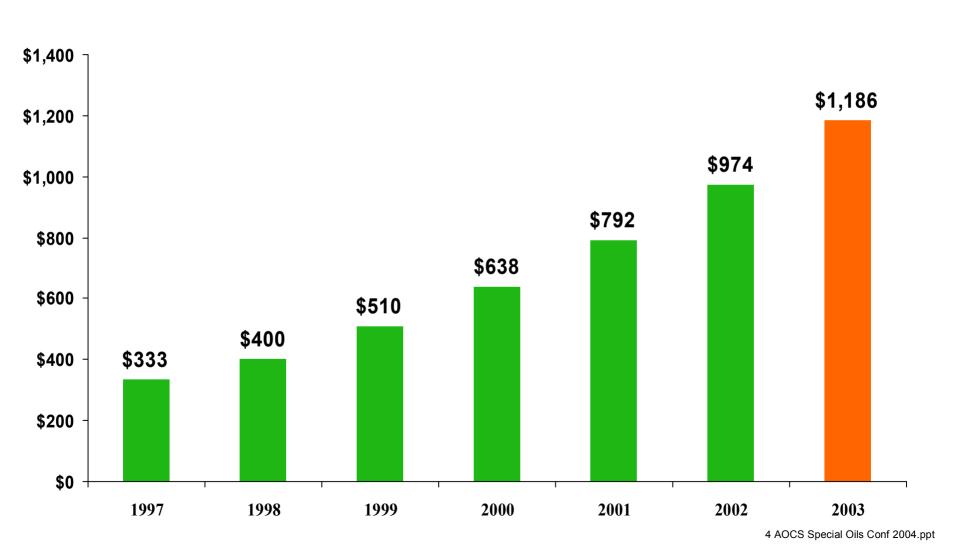
- Aging population
- Chronic disease epidemic
- New nutrition science
- Consumer choice for healthier foods, eating habits changing
- Rising health care costs
- Government regulations
- Food marketers looking for growth



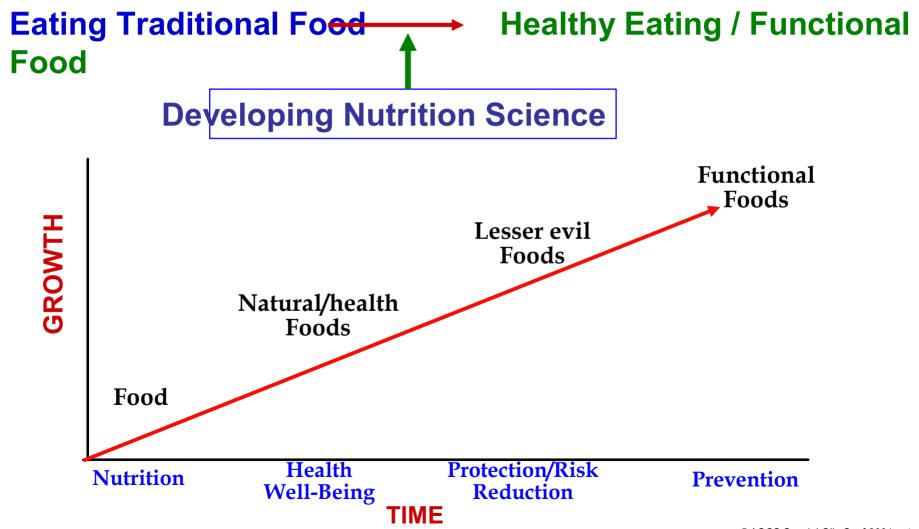
# The \$20.0 Billion U.S. Functional Food Market Is Expected to Grow at 8.3% Through 2004 Growth Expected in Eu, Japan Maturing



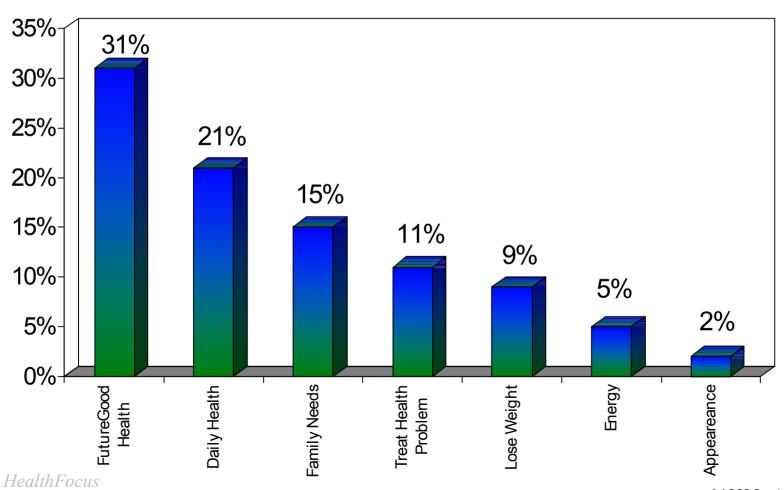
### US Soymilk Sales grew 23% in 2002 to \$970 million.



#### **Transformation/Evolution of Foods**



### Why Do People Purchase Healthy Foods/Beverages

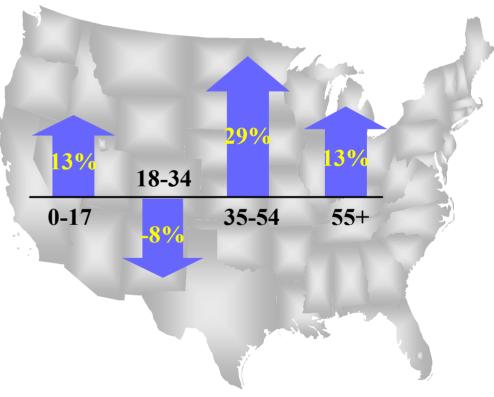


### Population Growth and Chronic Disease

#### By 2005.....

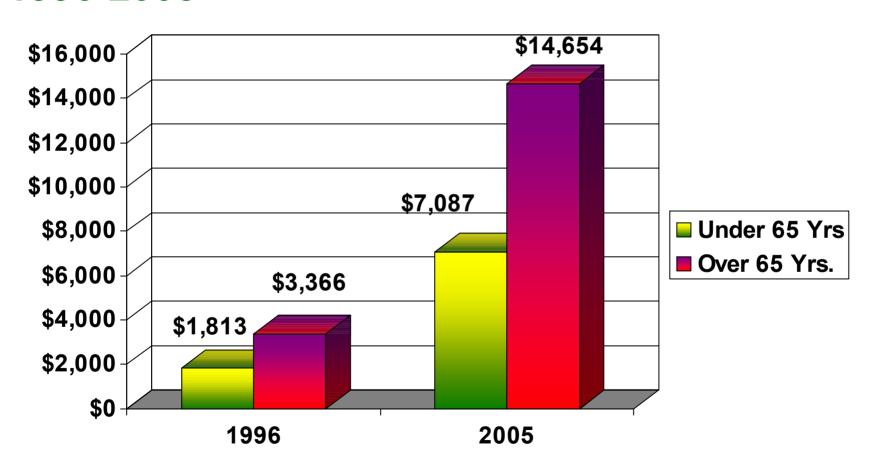
- 1.5 million suffers of Alzheimer's disease
- 20 million diabetics
- 46 million cases of Hypertension
- 6 million congestive Heart Failure cases
- 195 million overweight or obese
- 200 thousand reports of Prostate Cancer
- 247 thousand Breast Cancer patients
- 2 million cataract operations per year





## **USA Per Capita Health Care Spending**

1996-2005



# Health Care Costs Retirees to Pay More

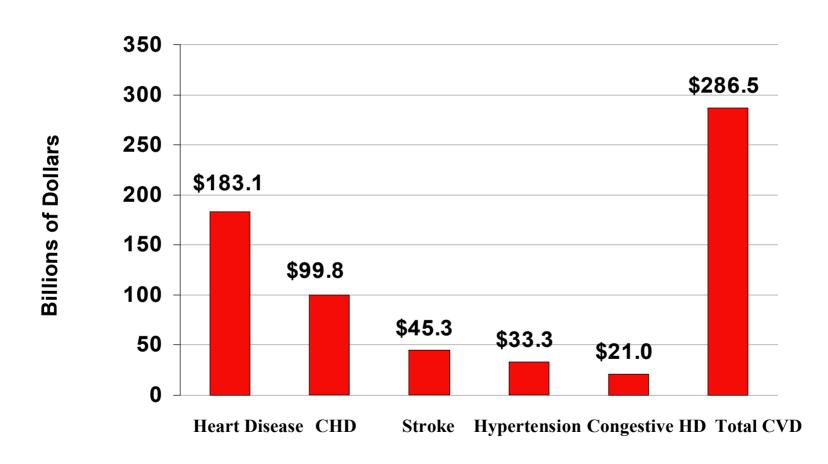


### **Rising Health Care Costs**

- Poor dietary health and activity #2 preventable cause of death in USA. (1993)
- Obesity and inactivity cost >\$100 billion annually
- Annual budget National Institutes of Health, ~\$20 billion
- 2000 Research budget for <u>nutrition</u> at NIH, \$400 million, dwarfed by the >\$250 BILLION annual cost of chronic disease in USA linked to poor nutrition
- Alzheimer's cost \$5.5 billion in Canada today,
- In USA Alzheimer's growing from 4 mio people today to 14 million by 2025 and costs expected to be \$100 billion.

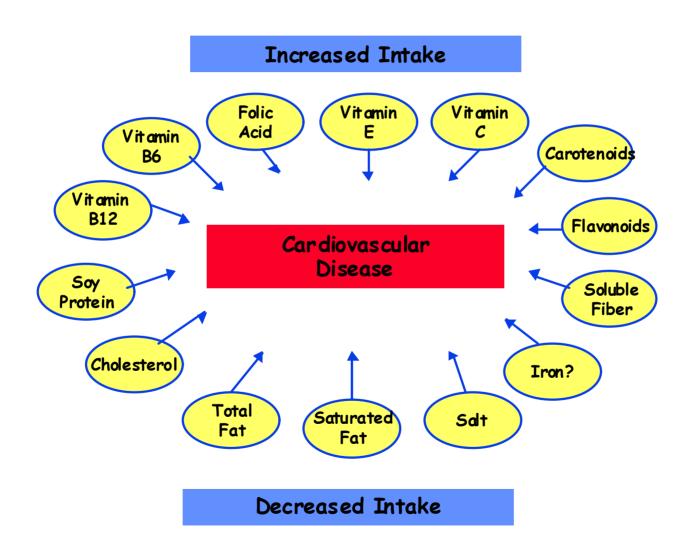
### **Estimated Direct and Indirect Costs of Cardiovascular Diseases and Stroke**

(United States: 1999)



Am. Heart Assoc.

### **Convergence of Various Factors in CVD**

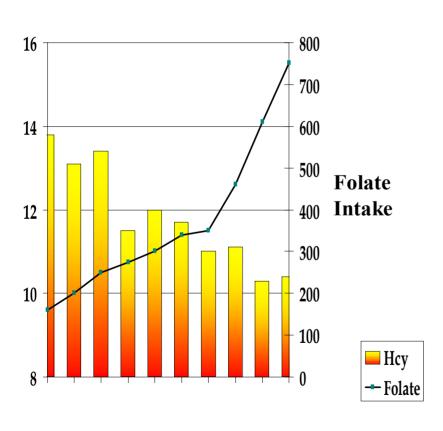


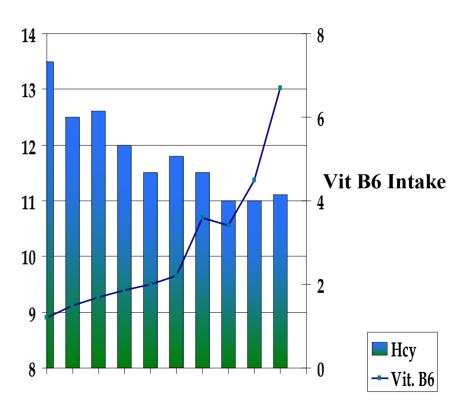
# Plasma Homocysteine As A Risk Factor

- Meta analysis of 27 studies, elevation in homocysteine (tHcy) an independent risk factor for arteriosclerosis.
- Every 5 mmol/l increase of tHcy, risk of CAD increases 60%-80% for adults
- 10% of population's CVD risk attributable to Homocysteine
- Two different Meta analyses of 21 studies on folate, showed reductions in Hcy risk.
- B12 alone was also effective in lowering Hcy.

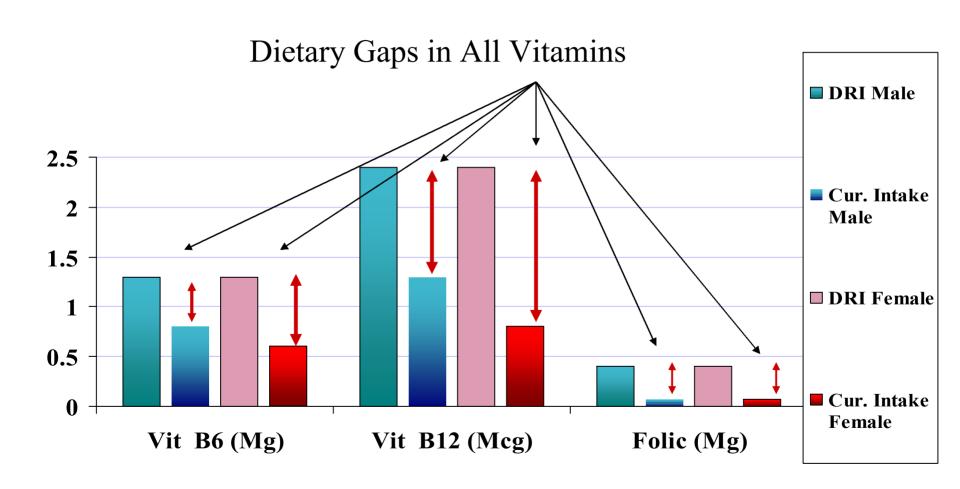
In general ~20% reduction in Homocysteine levels lower CAD/stenosis ~30%

# As Vit. B6 and Folate Intake Rise Hcy Declines





# Comparison of DRI's and Intakes (USA)



# **Economic Benefits of Multivitamin Supplementation and Birth Complications**

- Many studies show that use of folate prior to conception lowers NTD's ~50-70%
- Study reviewed birth defects, premature birth, CVD
- Utilized epidemiological and intervention studies with risk estimates
- Used hospital discharge data for codes and costs

Risk reductions Estimated Savings

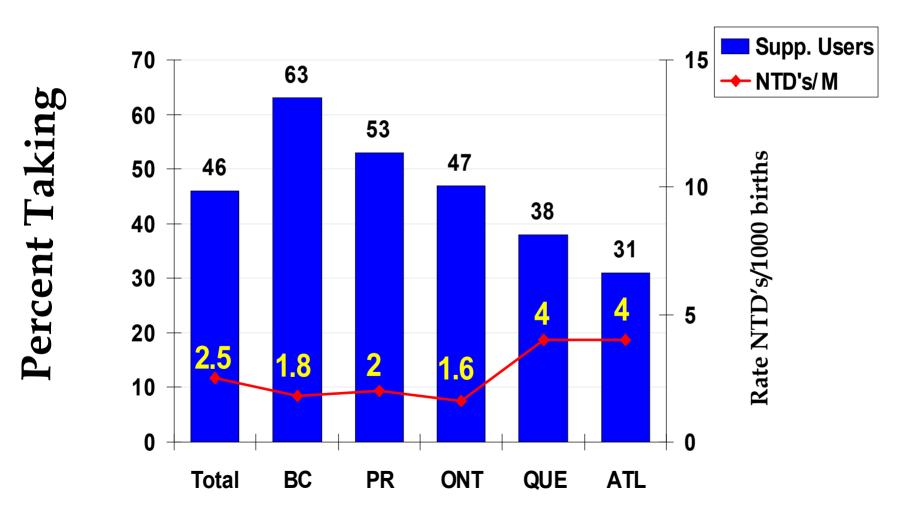
40% for birth defects \$90 million

60% LBW babies \$1.5 billion

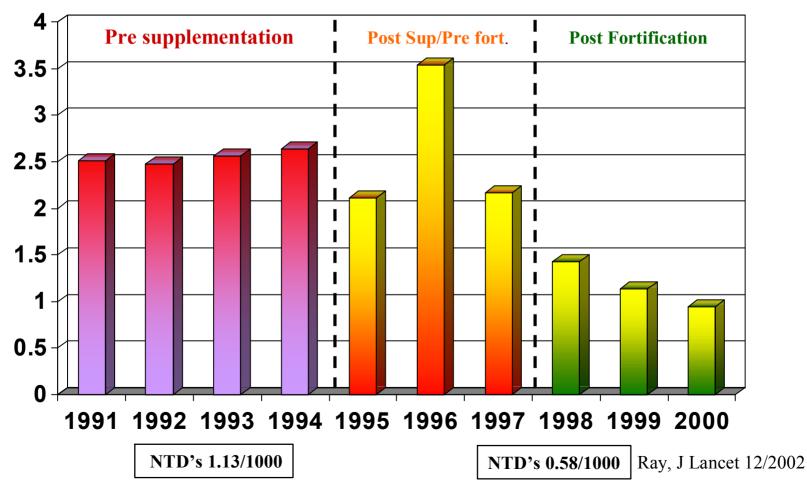
38% CHD \$1.6 billion

Total cost savings: ~<u>\$3 Billion</u>by use of folic acid and zinc

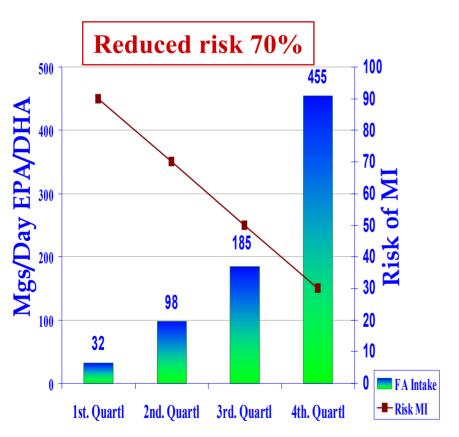
### VM Supplement Use and NTD's in Canada

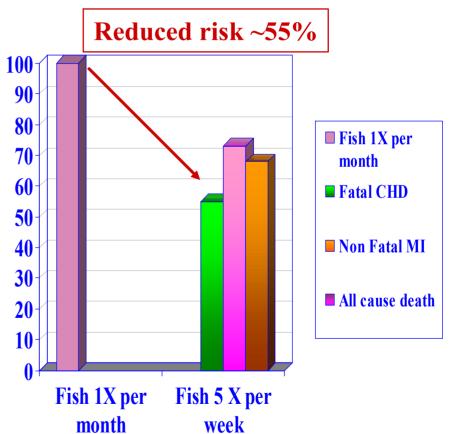


## Benefits of Folic Acid on Total NTD's, Nova Scotia



### Dietary Intake of Omega-3's and Risk of Cardiac Arrest



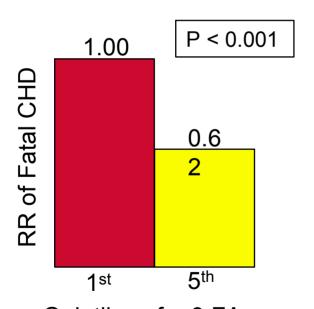


### Omega-3 Fatty Acid Protection Against CHD and Sudden Death

#### Nurses' Health Study

84,688 Females

16-year longitudinal follow-up

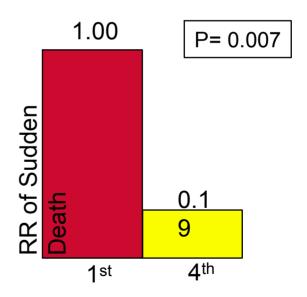


Quintiles of n-3 FA intakes\*

#### Physicians' Health Study

22,071 Males 17-year follow-up

Nested case-control analysis



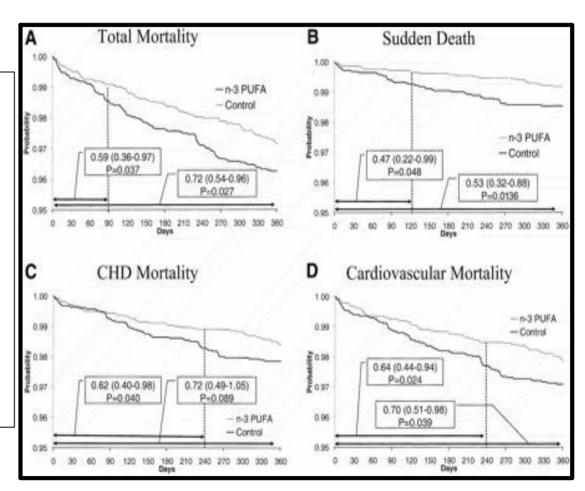
Quartiles of Blood n-3 FA\*\*

<sup>\*</sup>Hu et al, JAMA 2002; 287:1815-1821.

<sup>\*\*</sup>Albert et al, N Engl J Med 2002; 346:1113-1118.

# Protection Against Sudden Death, CHD and Cardiovascular Mortality by n-3 LC PUFA Supplementation

- A randomized clinical intervention, GISSI Prevenzione (11,323 MI patients)
- Intervention: Daily n-3 PUFA (~882 mg EPA & DHA, 1:2), or vitamin E (300 mg), or both, or control
- Follow-up: 3.5 years



## Hospital Costs Vs Nutritional Status (admissions)

Prevalence of malnutrition in hospitals significant, several studies show that 40-50% malnourished

Νι	ıtritional Risk Gp.	Not at Risk Gp.	Other
Studies			
<b>Malnutrition %</b>	46%	-	40-50%
Length of Stay Costs	\$6200 (+35%)	\$4600	2X
LOS	6D	4D	
Readmission	NS	NS	
Home services	31%	12%	

More Post Op complications, morbidity, mortality and higher complications, and costs 36% higher

### **Nutrition and the Elderly**

#### Nutrient deficiencies increase with age.

80% of the independent elderly over 79 yrs. consume inadequate amounts of 4 or more nutrients

- 75% too little folate
- < 63 % too little calcium
- Deficiencies also with vitamins E, B-6, C, Zn and Mg.

Vitamin/mineral supplementation trial with ~ one RDA of 18 vitamins, minerals and trace elements in free-living elderly over 65yrs..

**Measures:** Immune function

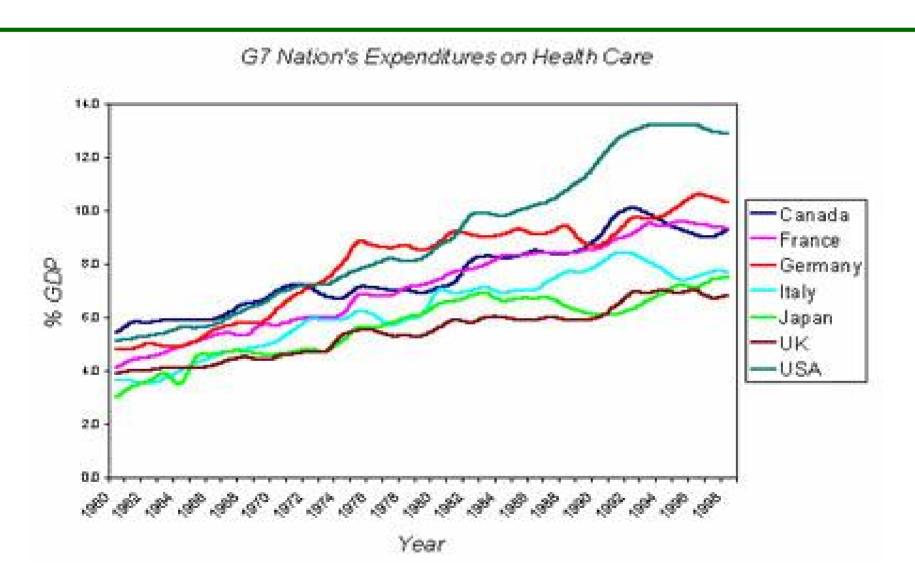
Infectious-related illness

### Vitamin and Trace mineral Supplements on Immunity/Infection

<b>Parameter</b>	Users	Non-Users
Deficiencies	Reductions for	No change
	A, BC,B6,C Fe,Zn	
<b>Immune Status</b>	Improvement	No change
	(Increased T4, NK, DTH	I, IL-2)
<b>Infection illness</b>	23 Days	48 Days
<b>Antibiotic Use</b>	18 Days	32 Days

Cost Benefit \$28 dollars saved for every dollar spent

### **Health Care Costs Rising Globally**



### **Costs Associated with 7 Major Diet Related Diseases in USA** (1995)

TOTAL		65%	\$250 BILLION!	
Osteoporosis	N/	4	\$10.0	
Hypertension	NA	4	\$17.4	
Obesity	NA	A	\$2.4 (total \$117.0)	forestall 20% of deaths
Diabetes	55,110	2.4%	\$40.0	estimate proper diets could
Stroke	149,740	6.6%	\$19.7	Researchers
Cancer	530,870	23.4%	\$104.0	
CHD	739,860	32.6%	\$56.3 (others \$250)	
<u>Cause</u>	<b>Deaths</b>		Annual Cost Billions	

Source: E.Frazao, 1995. USDA ERS

### **Costs Associated with Major Diet Related Diseases in Canada** (2001)

Cause	Annual Co	sts	% Diet		
Potential					
	Billions		Related	Saving	g Bio
CHD	\$13		40-50%	\$6	
Cancer	\$2	20	8	0%	\$8
Diabetes	\$10		35-50%	\$1	
Dementia's	s/Alz \$5-6		?		n/a
Kidney		\$3	?		n/a
<b>Arthritis</b>	\$11		20%	\$0.5	
<u>Psychiatric</u>	\$3		?	n/a	
Other	\$44				
TOTAL	Per Capha spend	ling; \$3	,174, Seniors \$10,8	§49 Billio	ns

Source: Holub, B 2002

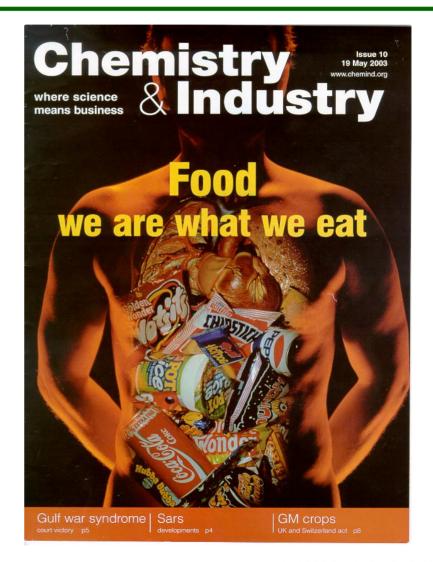
### Foods We Are What We Eat.....

#### **Obesity Facts.....**

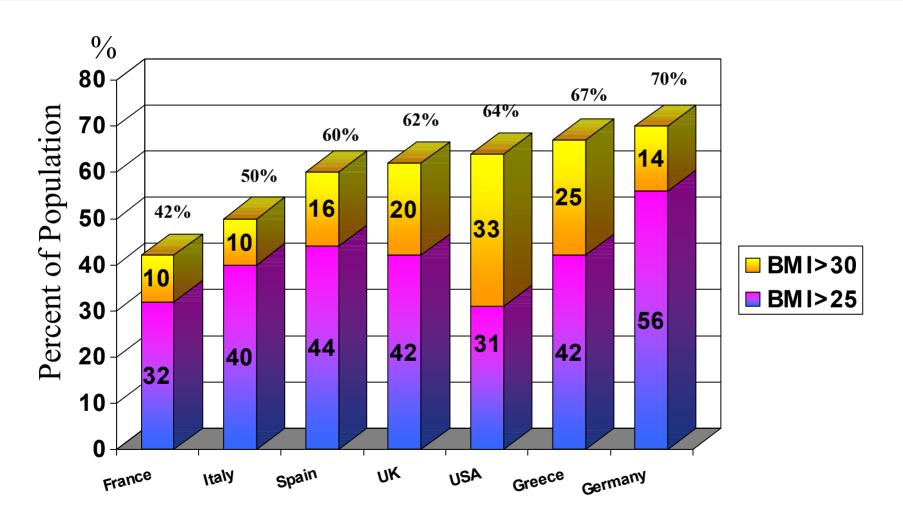
- •One billion people worldwide obese/overweight (AHA, JAHA 2002)
- •64% of population in USA, (obese 31%, overweight 33%) 120 million PERSONS
- •Percent obese: 1976-80 15%, 1988-94 23%,

1999 27%

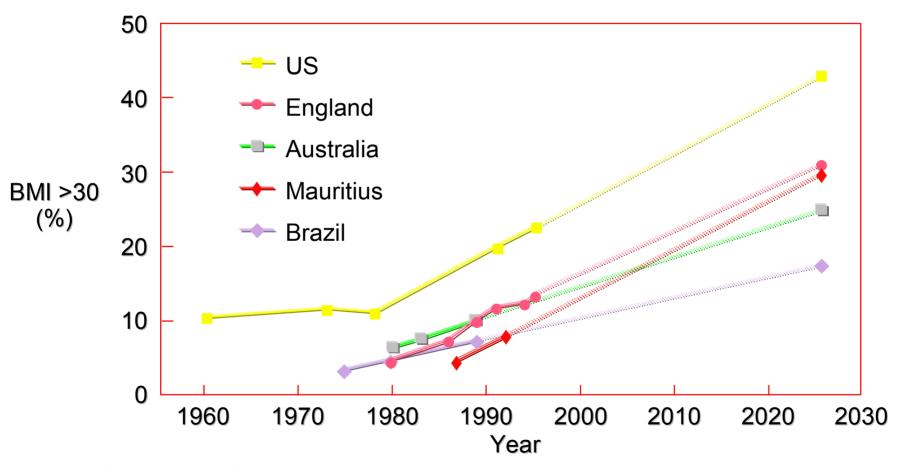
- •Three times as many teens overweight vs. 1980 and twice as many children
- •300,000 deaths, 7% of total health care spending



## Prevalence of Obesity & Overweight Globally



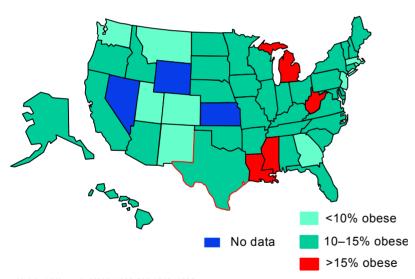
#### **Obesity Rates Could Double in 30 Years**



Adapted from International Obesity Task Force Web site. Available at: http://www.rri.sari.ac.uk/iotf/slides/graph12.gif.

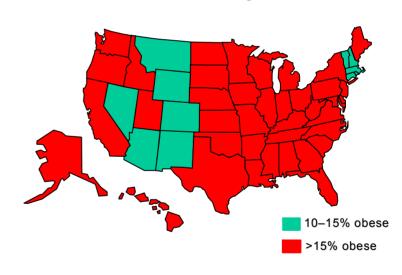
### Prevalence of Obesity in USA 1991-1998

#### Prevalence of Obesity - 1991



Source: Mokdad AH, et al. JAMA. 1999;282:1519-1522.

#### Prevalence of Obesity - 1998



Source: Mokdad AH, et al. JAMA. 1999;282:1519-1522.

### **Costs Associated with Obesity and Inactivity in USA (1995)**

]	<b>Inactivity</b>	<b>Obesity</b>
Diabetes II	\$6.4	\$36.6
CHD	\$8.9	\$16.2
Hypertension	\$2.3	\$7.6
Gall Bladder	\$1.9	\$4.3
Cancer		
Breast	\$0.38	\$0.53
Colon	\$2.0	\$0.89
Osteoporosis Fractures	\$2.4	\$3.6
<b>Total Billions</b>	\$24.3	\$70.0 billion
% of Health Costs	2.4%	<b>7.0</b> %

5.0% % of Health Costs Other Sources/Countries:USA

> France 2.0% NL 4.0%

Austral. 2.0%

#### The Bottom Line.....

### **Can Functional Foods Reduce Chronic Disease Costs?**

Is there a good rationale?

Is there supporting clinical data?

Is the ingredient safe for all populations/ages?

Is the food in a form the consumer wants?

Is the price premium reasonable?

Can you get health professionals support?

### Physicians Support for Vitamins and Their Health

#### **Benefits**

Majorities of physicians believe vitamins can be very or somewhat effective in reducing the risk or delaying the onset of:

Osteoporosis (92%)
Cardiovascular disease (85%)
High cholesterol (80%)
Cancer (76%)
Macular degeneration (67%)
Arthritis (66%)
Alzheimers (54%)
Cataracts (50%)

### Estimated Cost Savings from Sterol Spreads UK

- National Health Service Estimate
- Plant sterol spreads have potential to lower country costs by \$150 million dollars
- Due to lowering LDL cholesterol 10-15% as a part of healthy diet.
- Benefit also accrue to those persons on statin drugs.
- Annual cost to patients, \$70 with NO cost to NHS
- Additional savings in primary cost care

#### **Estimated Savings with Functional Foods for Cardiovascular Disease**

(Canada 2002)

Fibers	Wholesale cost/Day for 8% Chol reduction	Expected Decrease in risk	Reduced Expenditure (net)	
Citrus pectins	8 cents	20%	\$2.58 billion	
Guar Gum	7 cents	20%	\$2.65 billion	
Plant sterols	20 cents	20%	\$1.56 billion	
LC Omega Fatty acids. TG lowering by 15%	13 cents	20% women 7.5% men	\$1.6 billion	
Ingredient	Cost per Day for 20% Cholesterol Lowering	Cost per Year	Target Pop. Cost/Yr	Net Savings
STATIN Drug	\$1.50	\$913	\$4.97 billion	-
Cholestin,(red yeast rice)	\$1.50	\$548	\$2.98	\$2.0 billion
policosanol	\$1.50	\$548	\$2.98	\$2.0 billion
Ingredient	Cost per Day for TG Lowering	Cost per Year	Target Pop. Cost/Yr	Net Savings
Gemfibrozil	\$1.70	\$621	\$3.38 billion	-
LC Omega-3 Fatty acids	\$0.30	\$110	\$0.66 billion	\$272 billion
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Holub, B. 2002.

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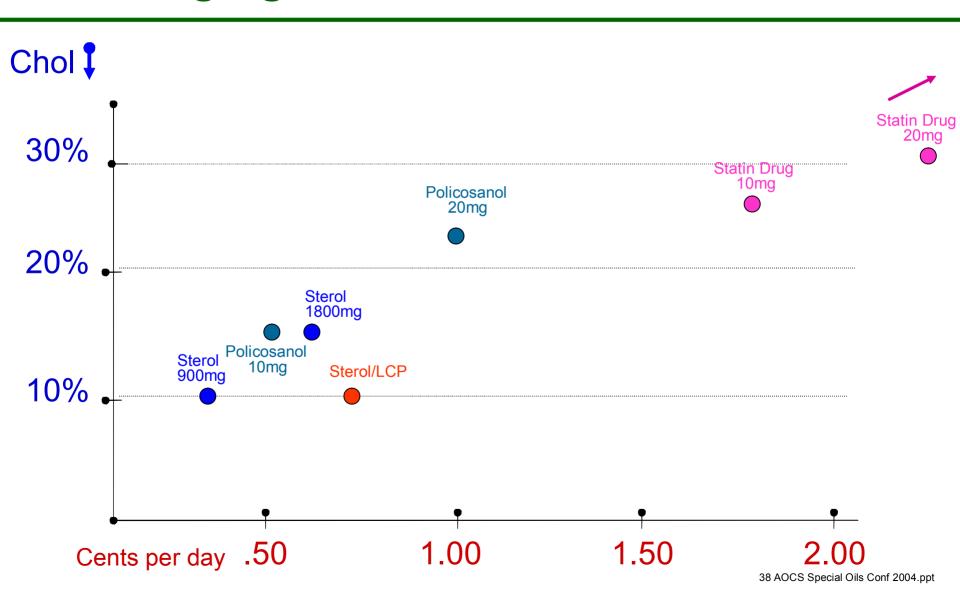
### **Estimated Savings with Functional Foods for Cancers** (Canada 2002)

Ingredient	Cost per Day for Nutraceutical	Expected Decrease in Cancer	Cost per Year	Reduced cancer Expenditure per year
Color-rectal Cancer				
Calcium (1.2g)	7 cents	15%	\$26	\$300 million
Selenium (0.2mg)	5 cents	58%	\$18	\$1.2 billion
Folic Acid (0.4mg)	3 cents	30%	\$1	\$600 million
<b>Prostate Cancer</b>				
Selenium (0.2 mg)	5 cents	63%	\$18	\$315 million

Gross savings of \$2.4 billion dollars per year for selected cancers

Holub, B 2002.

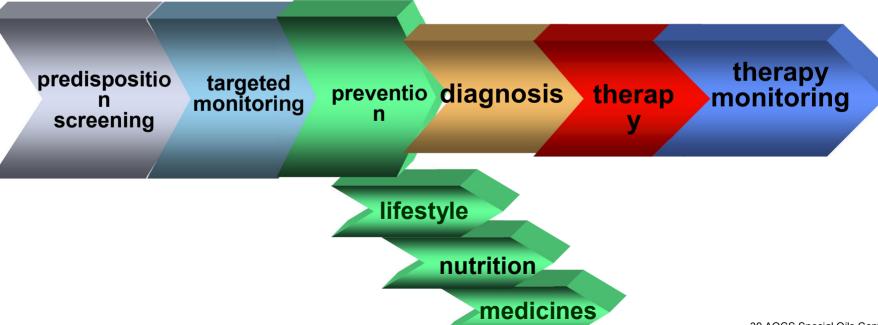
# Cost Effectiveness Cholesterol lowering Agents



### **Integrated Healthcare Concepts**

from today... diagnosis therapy monitoring

#### ...into the future



therapy

### Health Economics and Nutraceuticals

- 1. Potential cost effectiveness for Direct Medical Applications:
  - Bone fide treatments
  - Adjunct to support other treatments
- 2. Applications in Normal population
  - For "well-being" applications
  - Prevention of future conditions.
- Health care providers now in evidence-based medicine
- Efficacy and safety vital but practice now includes COST-EFFECTIVENESS
- Healthcare providers may pay for nutraceuticals if you can show:

**Clinical effectiveness** 

Low toxicity

**Cost-effectiveness** 

#### YOU NEED TO COLLECT THE EVIDENCE!

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# Estimated Costs to Obtain FDA Approved Health Claim (1999)

### dollars)

- B vitamins (B6, Folic, B12) for reduction of CVD: \$174 million
- Vitamin E for reduction CHD: \$58 million
- Omega-3 fatty acids for reducing CHD: \$58 million
- Antioxidants (A, C, E, BC, Lycopene, Lutein) for reduction in cancer: \$348 million
- Fiber for reduction colorectal cancer: \$116 million
- Folic acid for reduction in NTD: \$58 million

#### **US Health Claims Currently Permitted**

Claim	<u>Food</u>	DS	CANADA
<ul> <li>Saturated Fat and cholesterol and CHD (CFR 101.75)</li> </ul>	X		X
- Fat and cancer (CFR 101.73)	X		
- Fiber containing fruit, vegetables, grains and cancer (CFR 101.76)		X	
- Fiber containing fruits,vegetables,grains and CHD (CFR 101.77)		X	
- Fruits and vegetables and cancer (CFR 101.78)	X		
- Calcium and Osteoporosis (CFR 101.72)	X	X	X
- Folate and neural tube defects (CFR 101.79)	X	X	
- Potassium and blood pressure and stroke (FDAMA)	X		
- Whole grains and CHD and certain cancers (FDAMA)	X		
- Sodium and hypertension (CFR 101.74)	X		X
- Soluble fiber from psyllium or whole oats and CHD (CFR 101.81)	X	X	
- Sugar alcohol and dental decay (CFR 101.80)	X	X	X
- Soy protein and CHD (CFR 101.82)		X	X
- Stanol/Stanol esters and CVD (CFR 101.83)	X		
- LC Pufa and CVD (Q)		X	
- B Vitamins and CVD (homocystein) (Q)		X	
- Folic acid and neural tube defects (Q)			X
- AO vitamins and certain kinds of cancer May.2003		Х	42 AOCS Special Oils Conf 2004.pp

# INDUSTRY OF WELLNESS FOODS

#### LEGISLATION/REGULATION

CONSUMER AWARENESS

HEALTHCARE COSTS

MEDIA COVERAGE

ROF.INTEREST/SUPPOR

**SCIENCE DATA-EFFICACY/SAFETY** 

### **Thank You**

lan Newton, Ceres Consulting Toronto, Canada.