
Can Health Care Costs be Reduced By Functional Foods Dietary Supplements

SMI Symposium

January 17th. 2004

London, UK

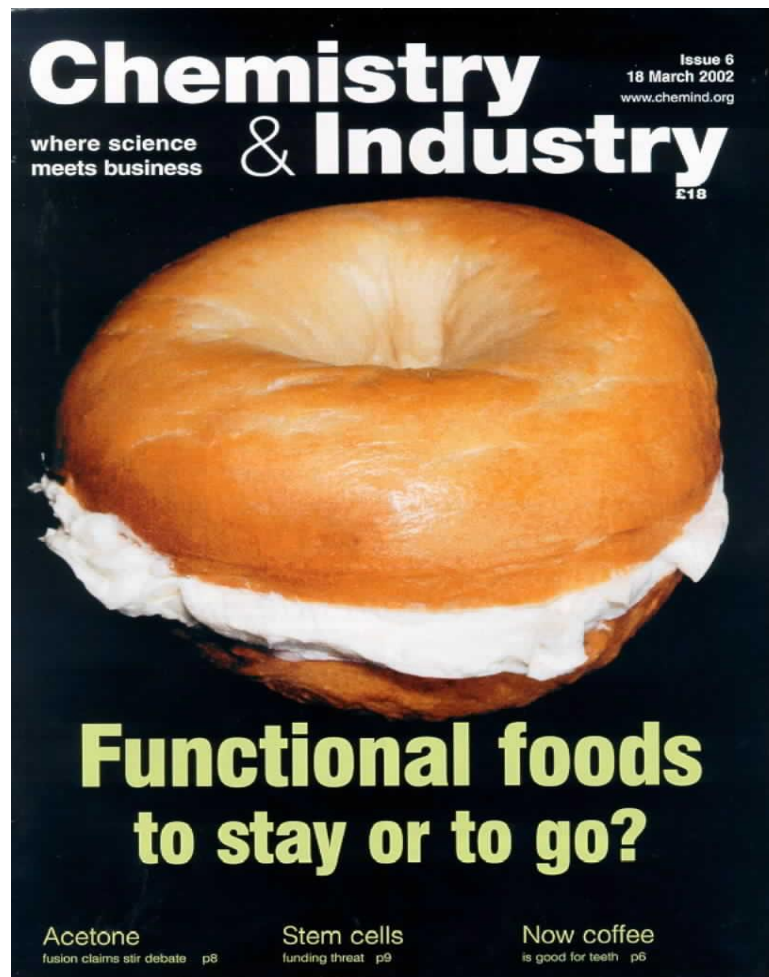
**Ian Newton,
Director, Business Development and Regulatory
Affairs,
DSM Nutritional Products Inc.
Parsippany. NJ**

Functional Foods: Here Today Gone Tomorrow?

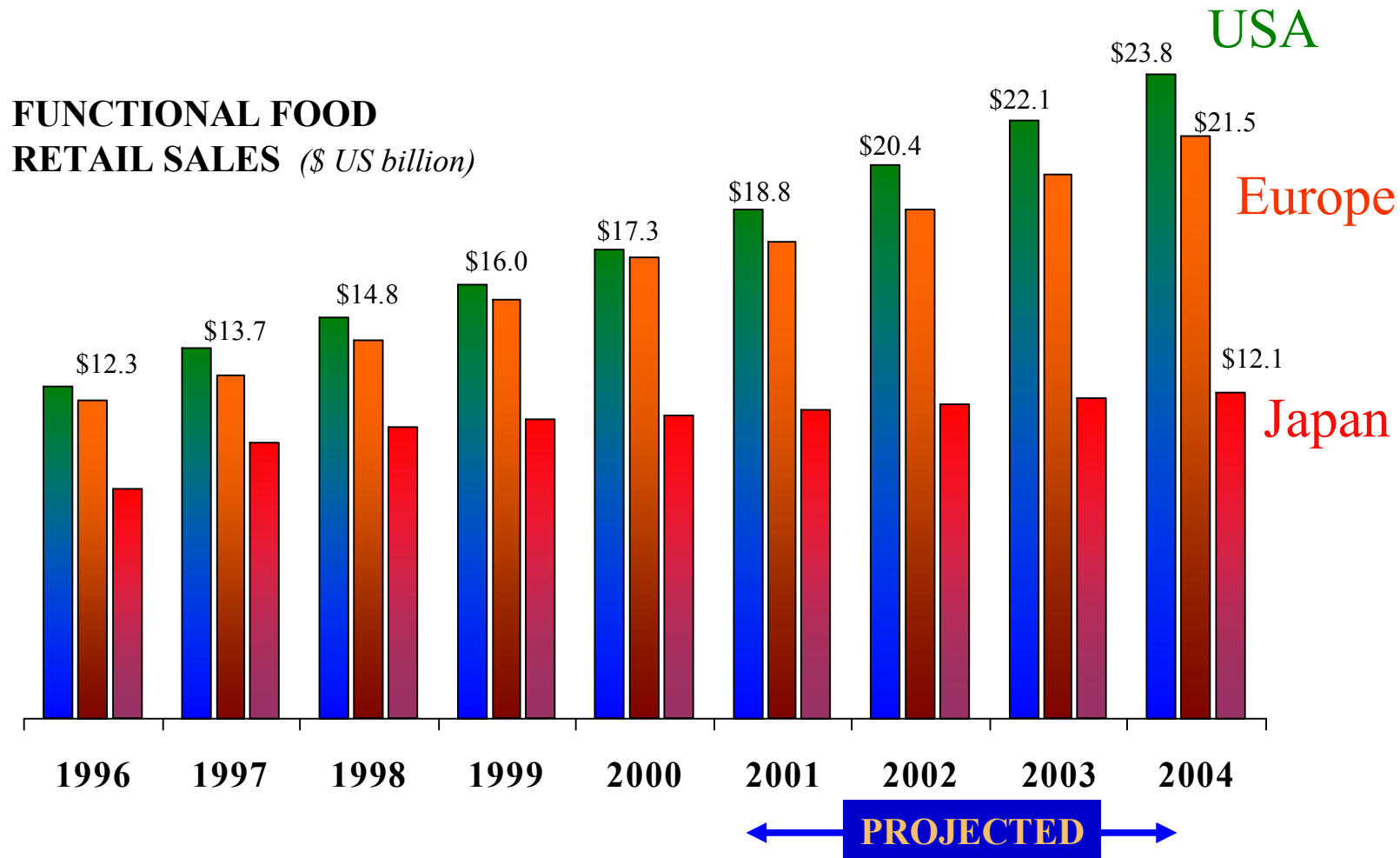
- Most people would argue that they are here to stay

Rationale/Drivers

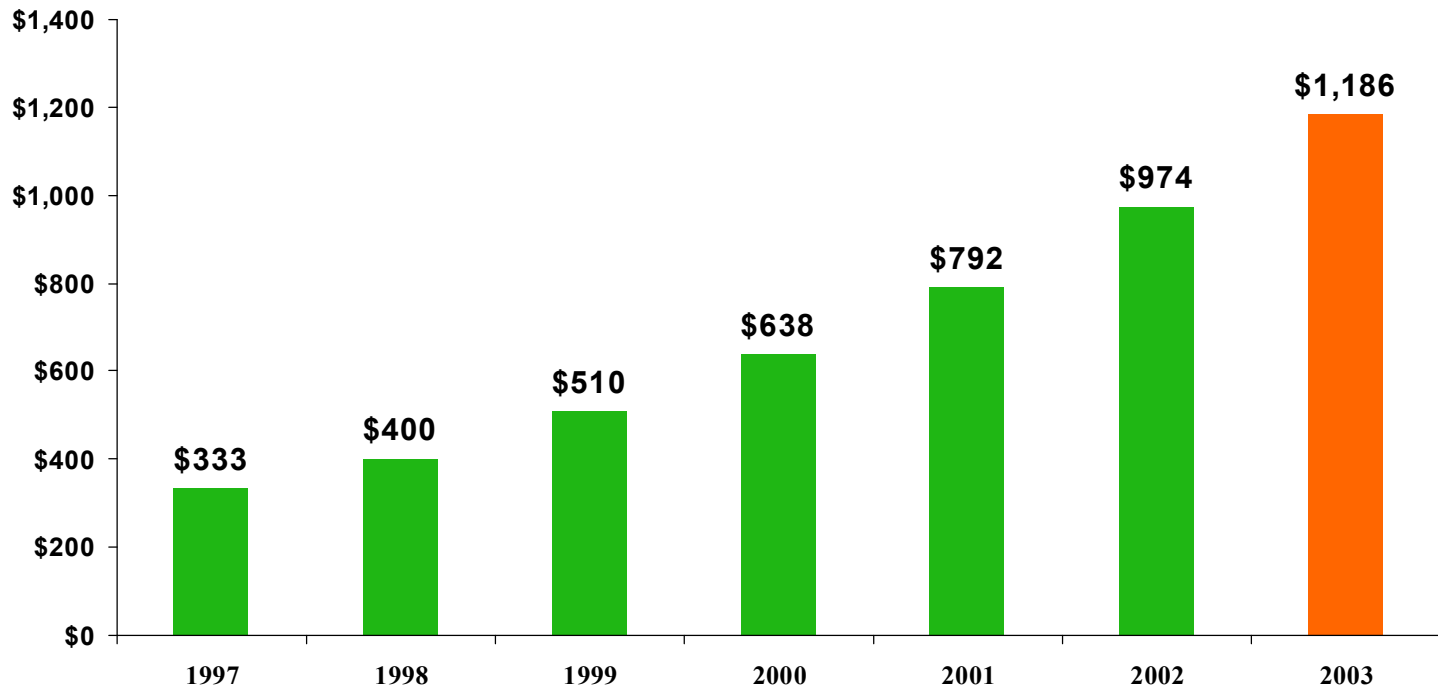
- Aging population
- Chronic disease epidemic
- New nutrition science
- Consumer choice for healthier foods, eating habits changing
- Rising health care costs
- Government regulations
- Food marketers looking for growth



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.

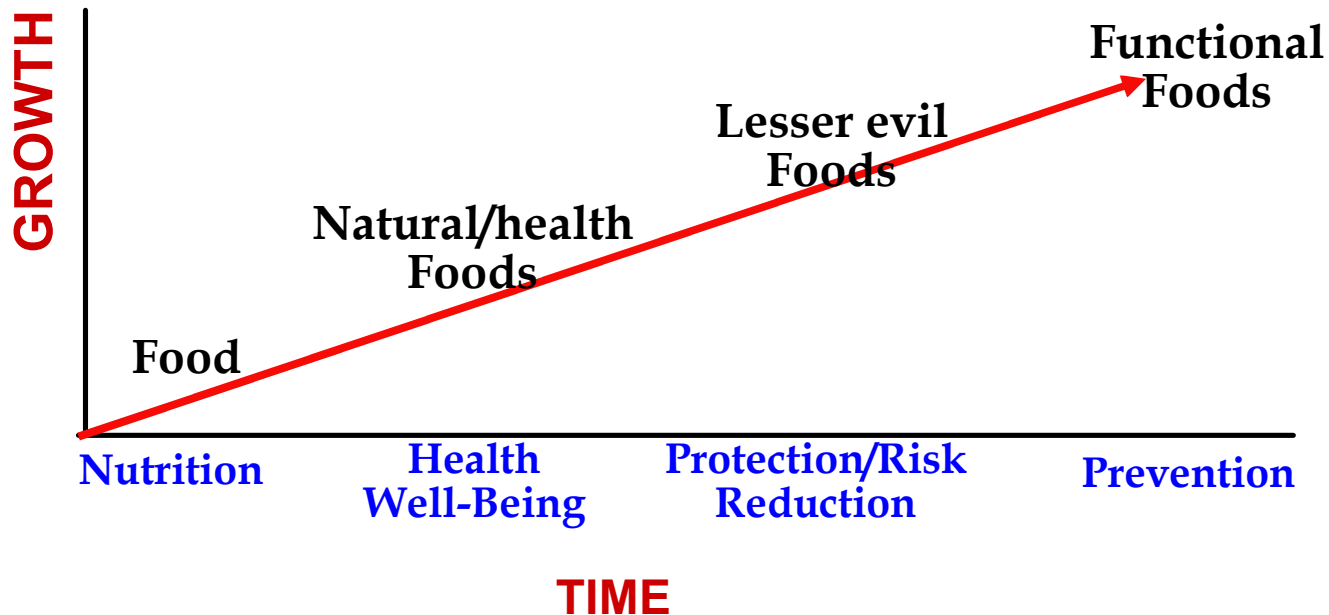


Transformation/Evolution of Foods

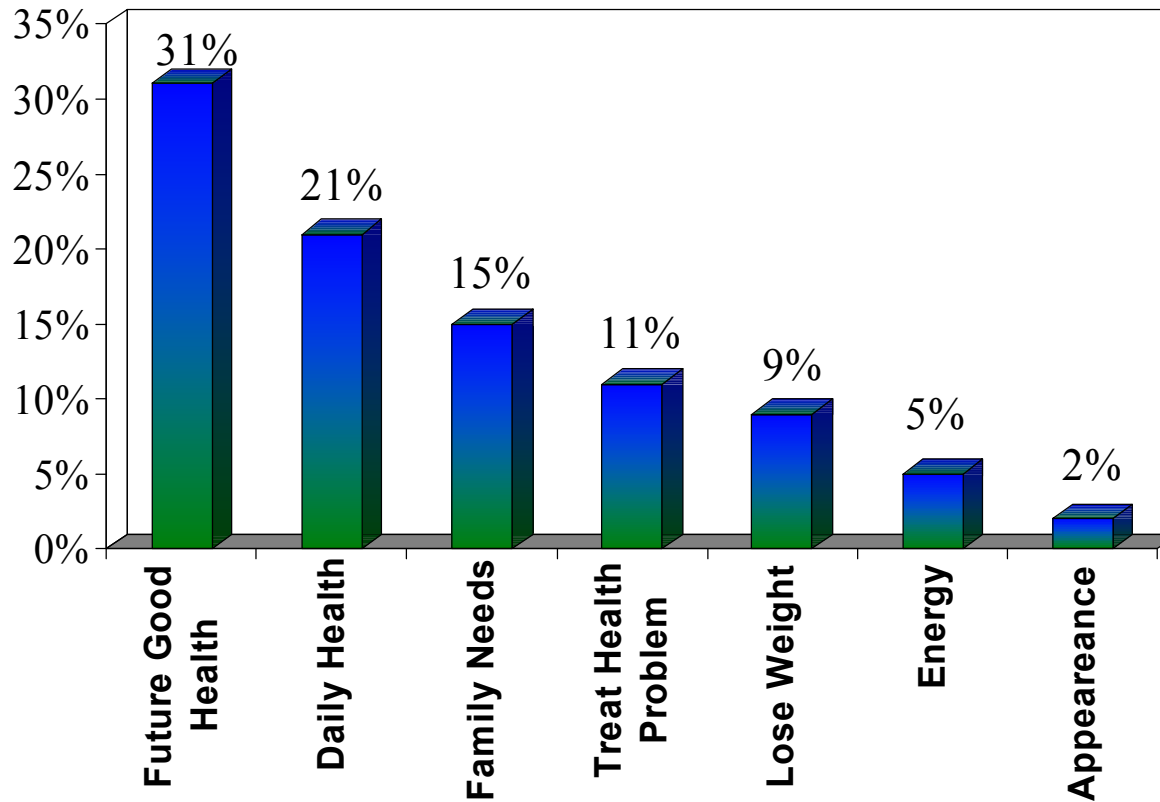
Eating Traditional Food \longrightarrow Healthy Eating / Functional Food



Developing Nutrition Science



Why Do People Purchase Healthy Foods/Beverages

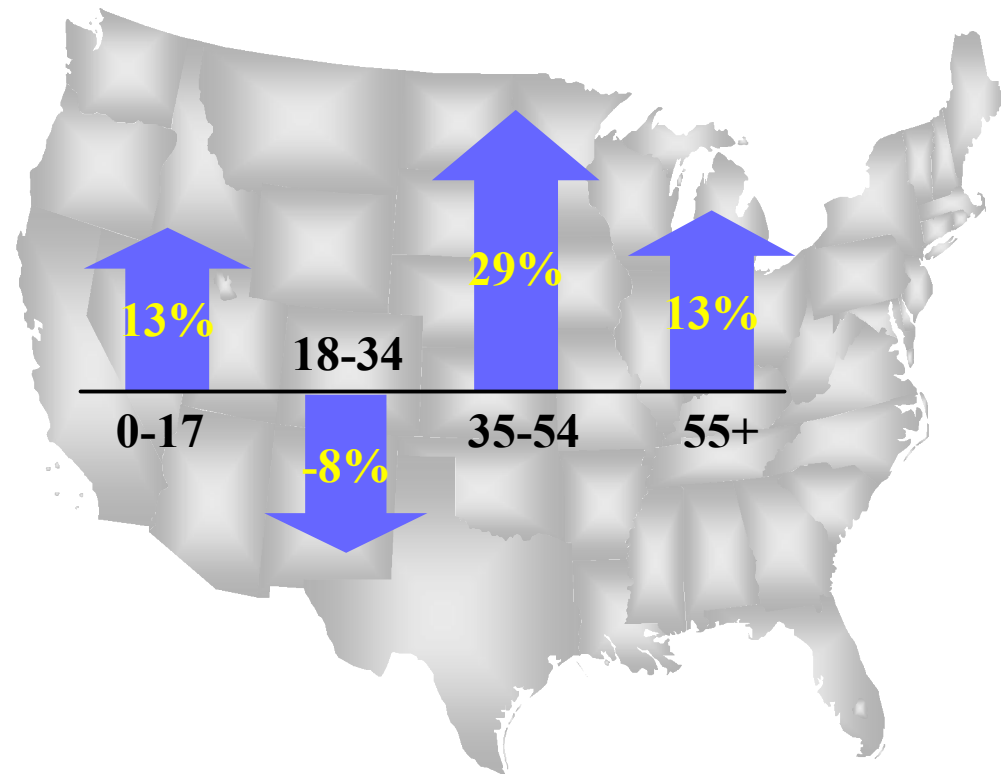


Population Growth and Chronic Disease

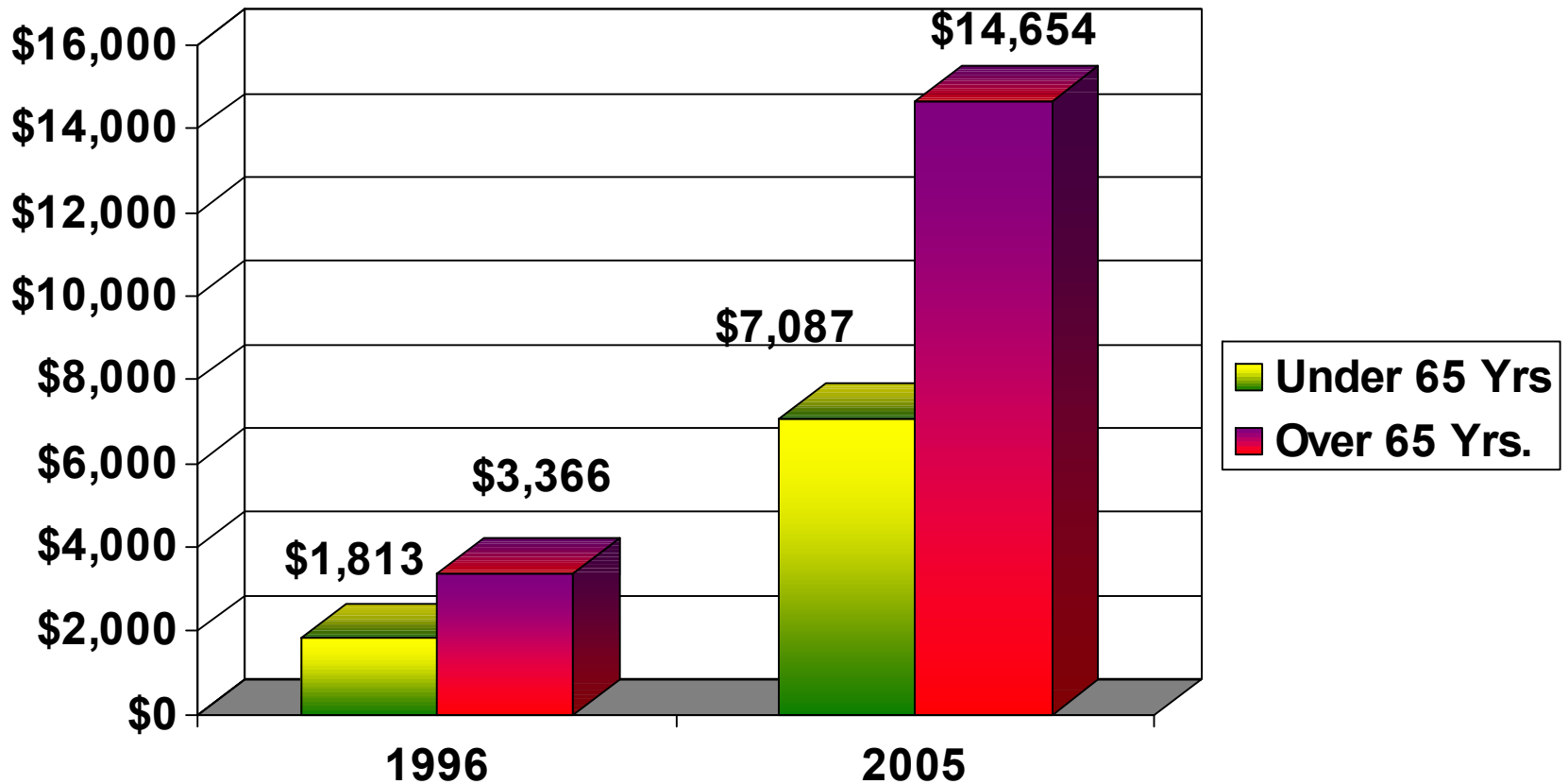
By 2005.....

- 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

Population Growth Trends 1990 - 2000



USA Per Capita Health Care Spending 1996-2005



Health Care Costs - Retirees to Pay More

Atlanta Journal-Constitution: ajc.com: Future retirees likely to pay most or all health care co - Microsoft Internet Explorer

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Future retirees likely to pay most or all health care costs

Leigh Strope - Associated Press
Monday, September 16, 2002

Washington --- Future retirees should expect to cover substantially more, if not all, of the costs of their health care not covered by Medicare as employers increasingly reduce retirement medical benefits.

Few workers today are getting ready for this significant change and may have to consider putting off retirement, says an author of a new study on the issue. By 2031, companies are expected to pay less than 10 percent of total medical expenses for retirees as part of actions already taken, says the report being released today by Watson Wyatt Worldwide, a human resources consulting firm that works with employers.

Large employers now typically pay more than half of total retiree medical expenses. But increasing health care costs are forcing companies to scale back how much they are willing to offer.

"The burden on future retirees to pay for their own medical costs is increasing

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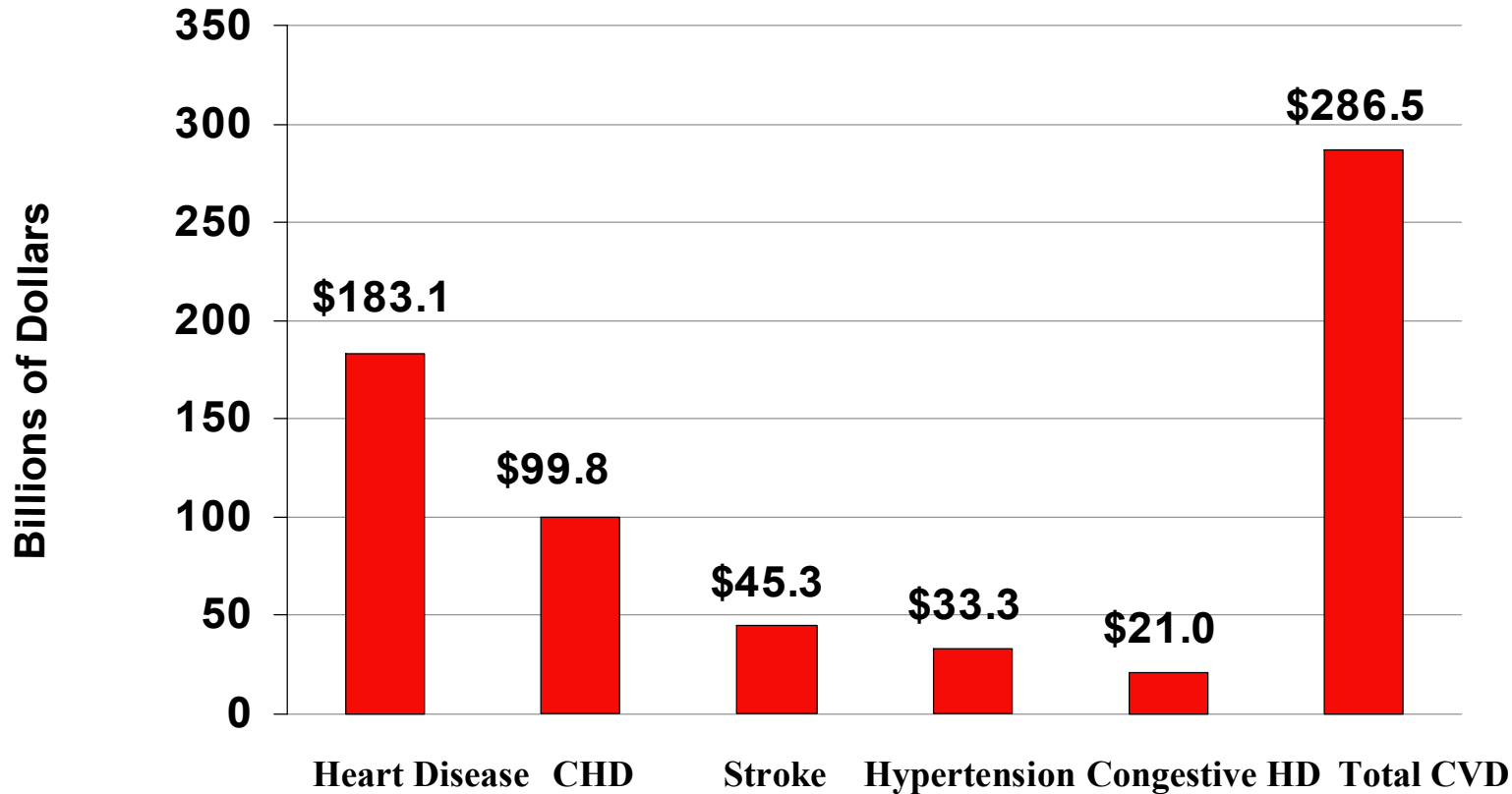
Internet

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 nutrition 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.

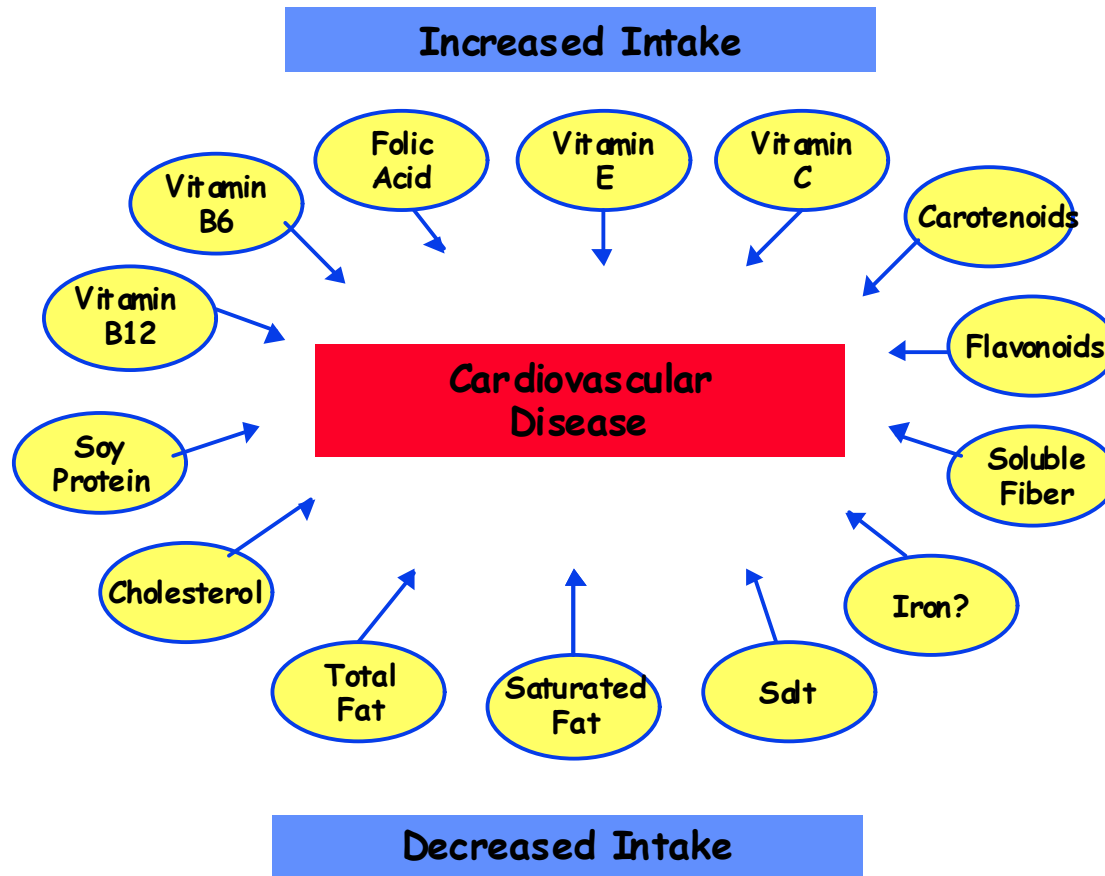
Estimated Direct and Indirect Costs of Cardiovascular Diseases and Stroke

(United States : 1999)



Am. Heart Assoc.

Convergence of Various Factors in CVD

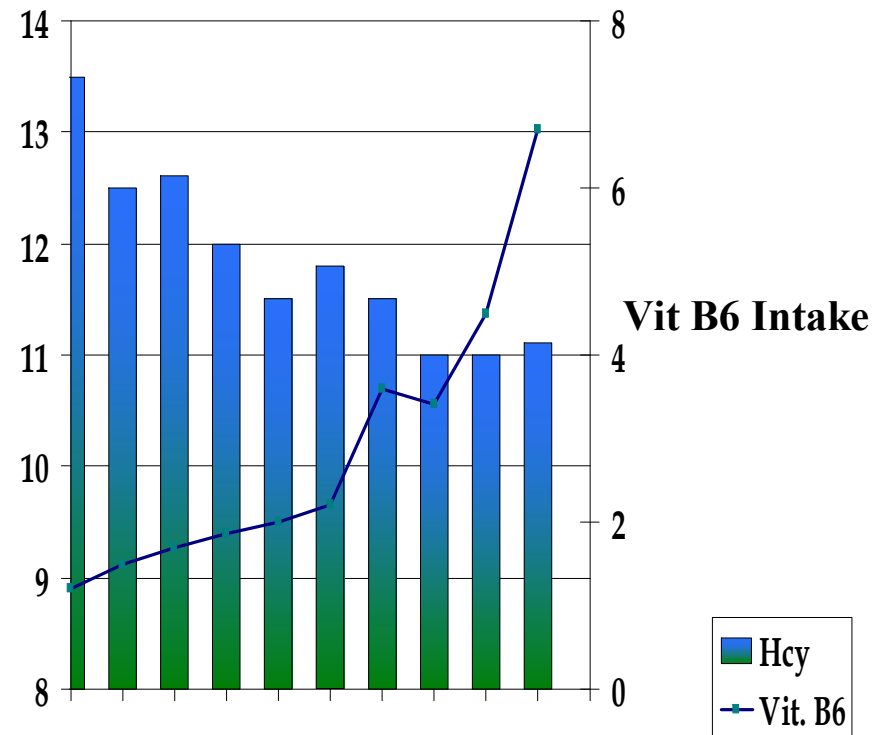
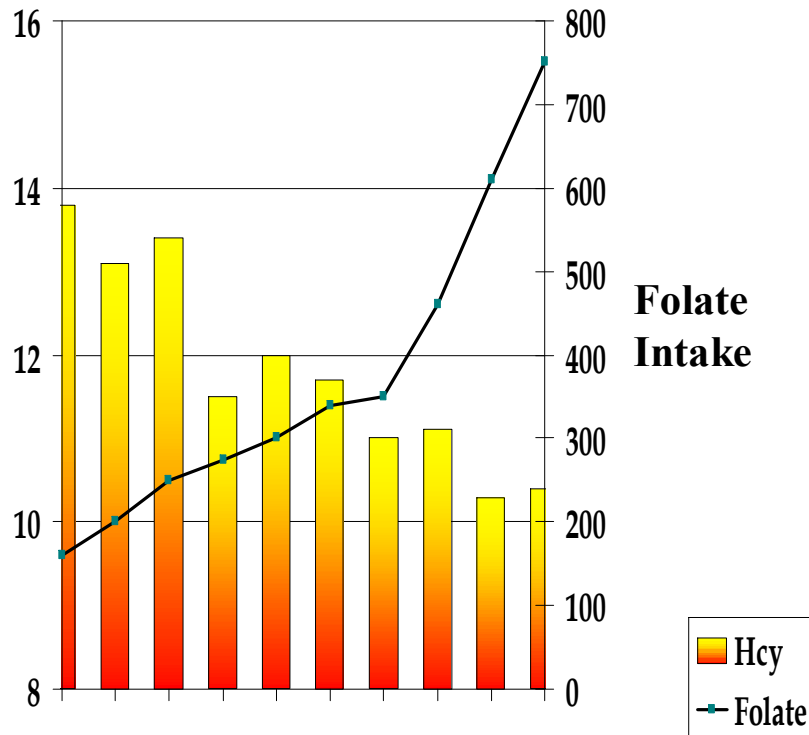


Plasma Homocysteine As A Risk Factor

- 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.

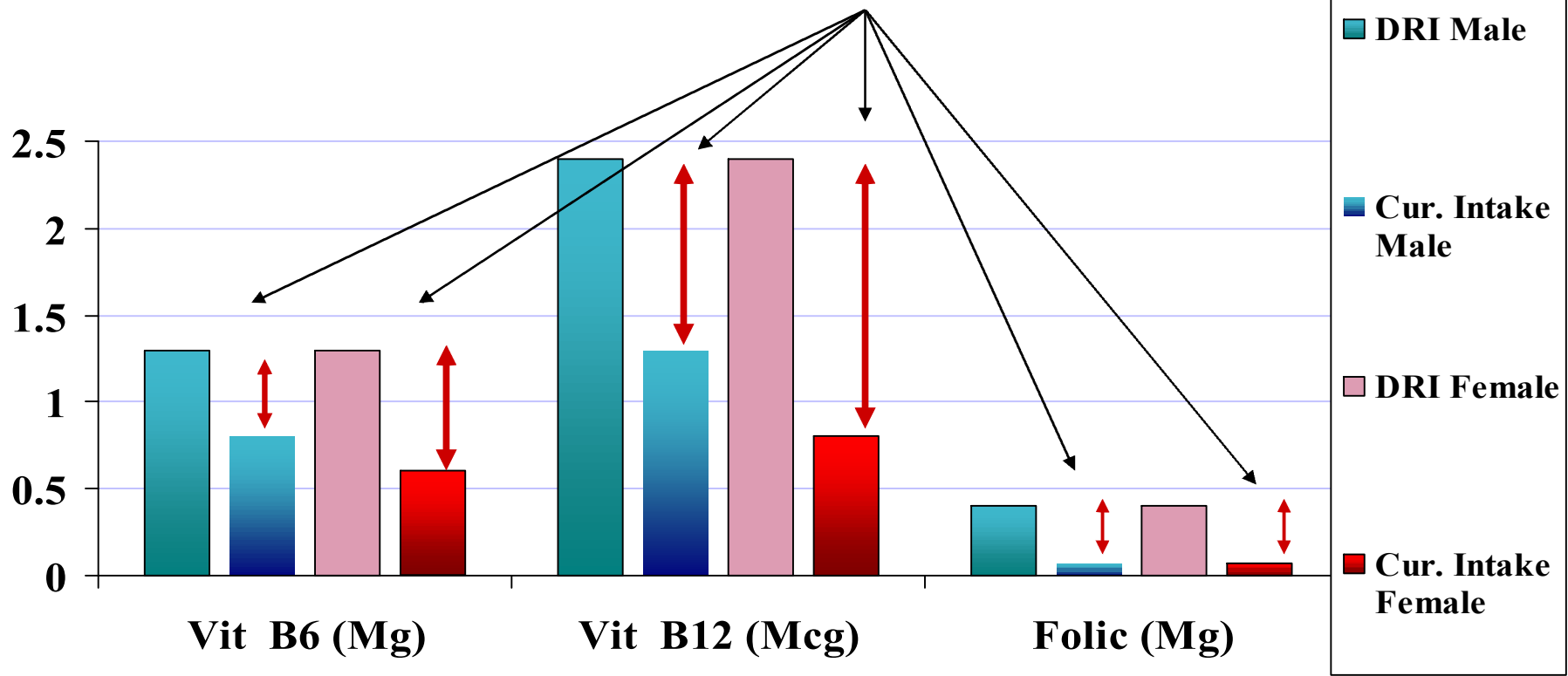
In general ~20% reduction in Homocysteine levels
lower CAD/stenosis ~30%

As Vit. B6 and Folate Intake Rise Hcy Declines



Comparison of DRI's and Intakes (USA)

Dietary Gaps in All Vitamins



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

40% for birth defects

60% LBW babies

38% CHD

Estimated Savings

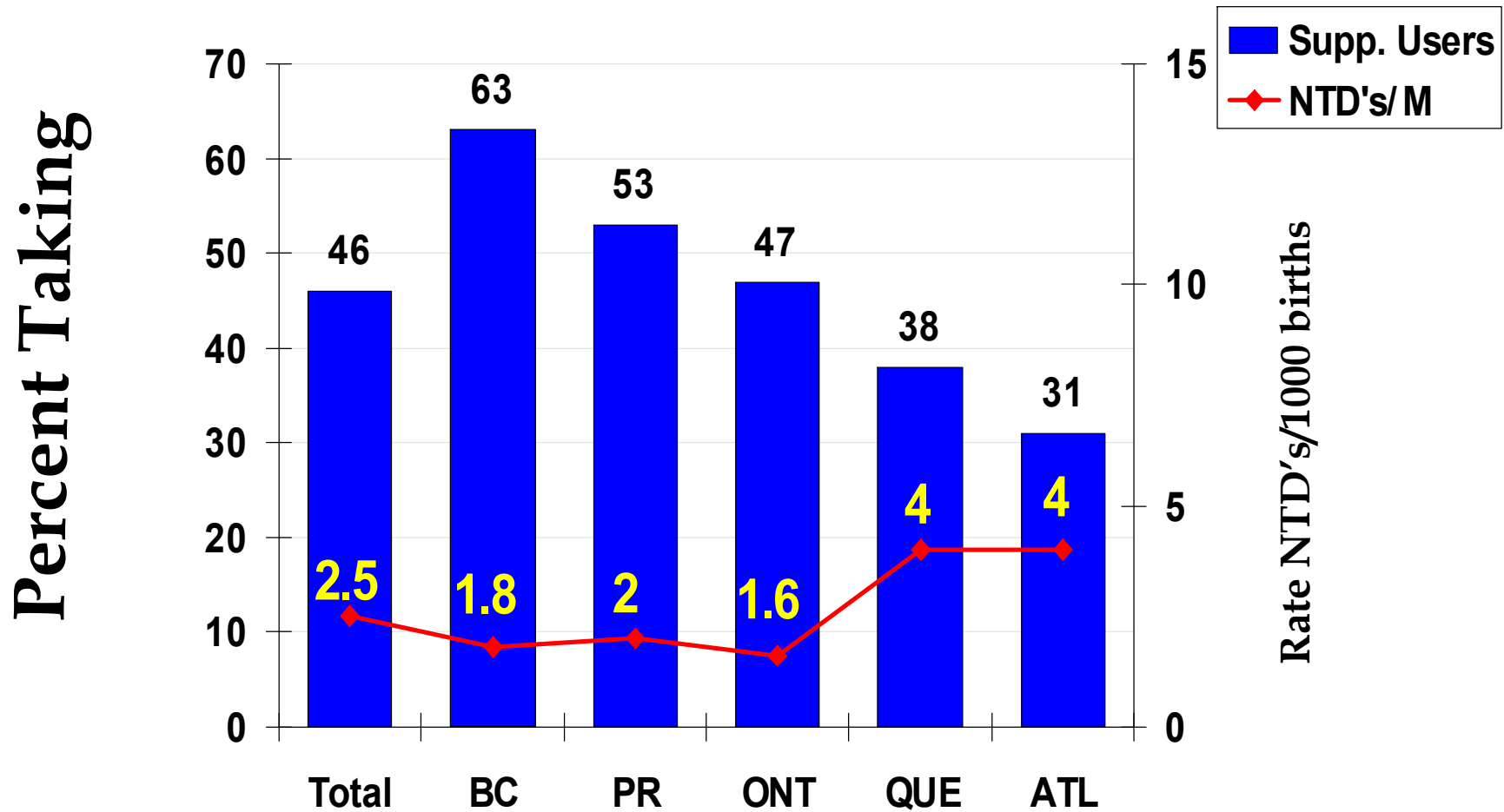
\$90 million

\$1.5 billion

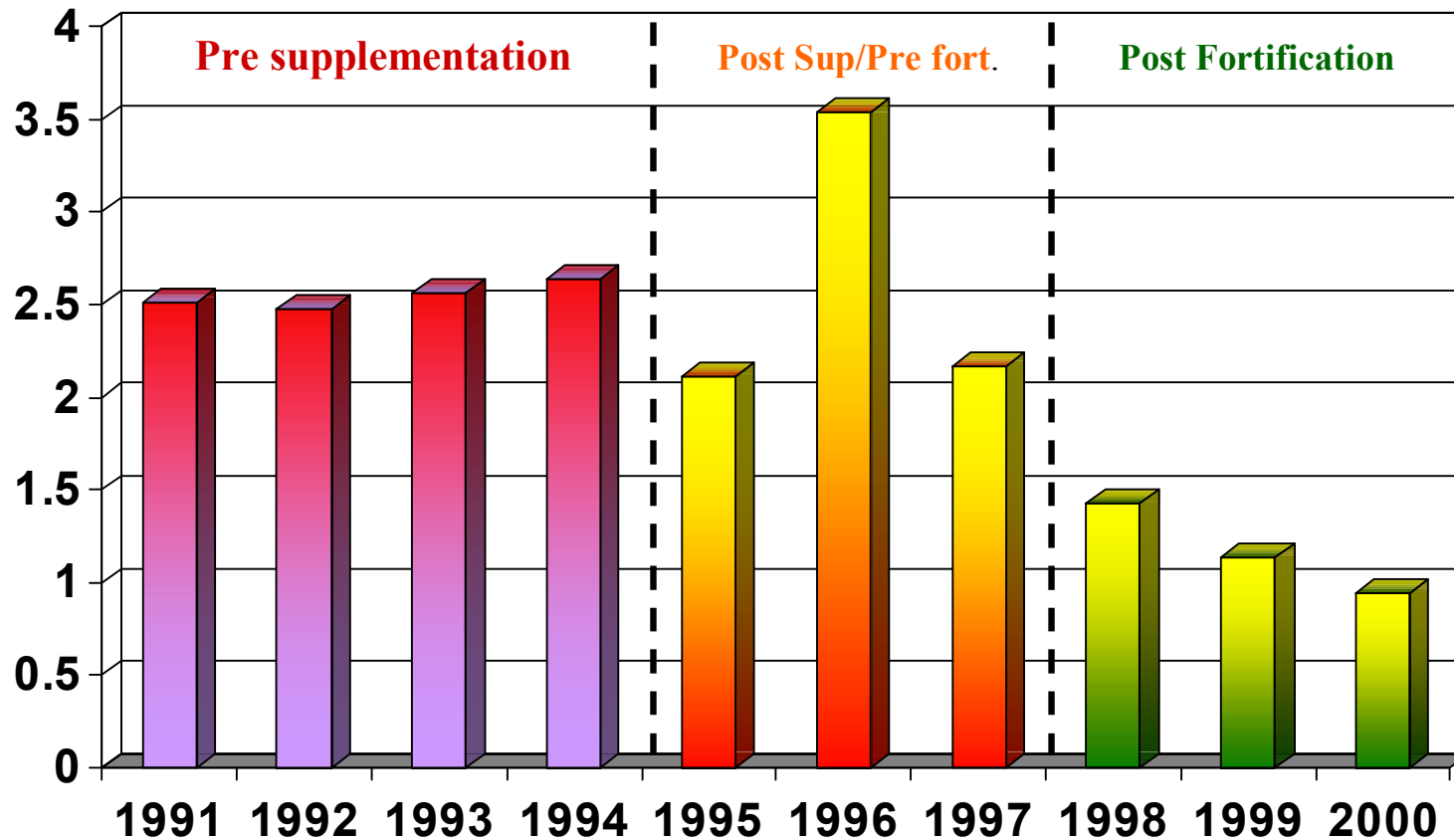
\$1.6 billion

Total cost savings: ~\$3 Billion by use of folic acid and zinc containing multivitamins

VM Supplement Use and NTD's in Canada



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

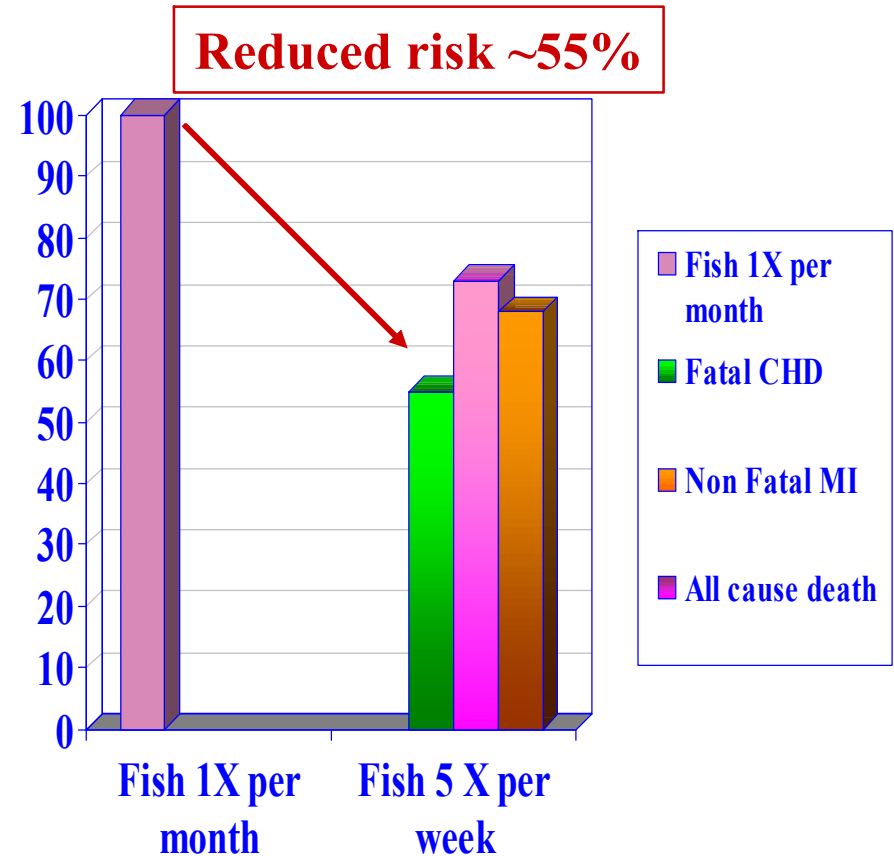
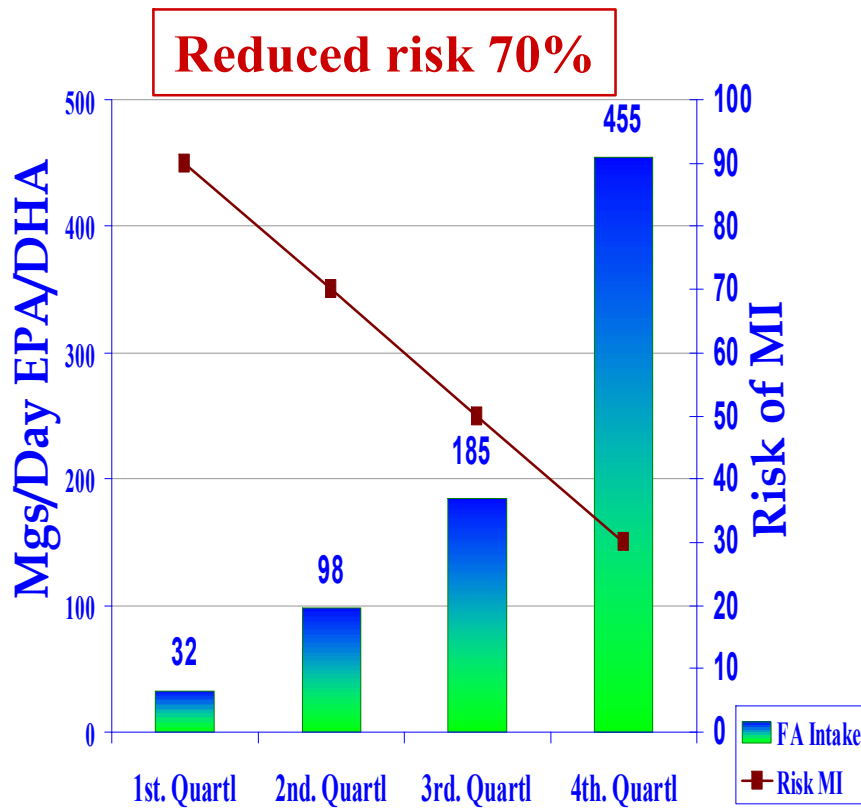


NTD's 1.13/1000

NTD's 0.58/1000

Ray, J Lancet 12/2002

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

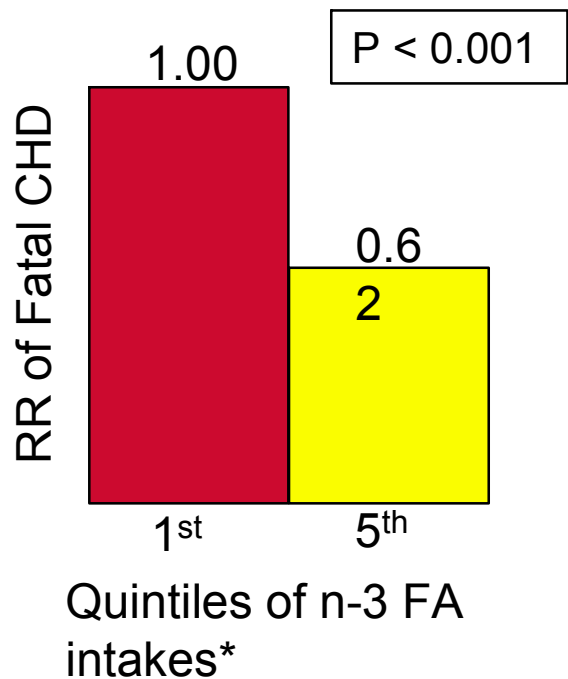


Omega-3 Fatty Acid Protection Against CHD and Sudden Death

Nurses' Health Study

84,688 Females

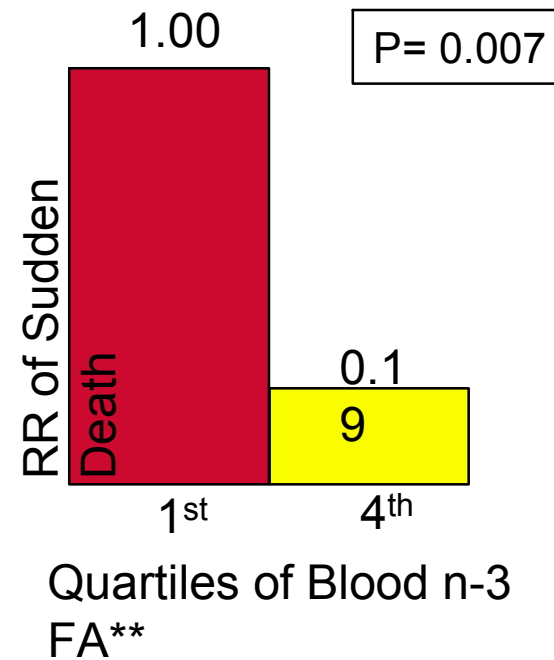
16-year longitudinal follow-up



Physicians' Health Study

22,071 Males 17-year follow-up

Nested case-control analysis

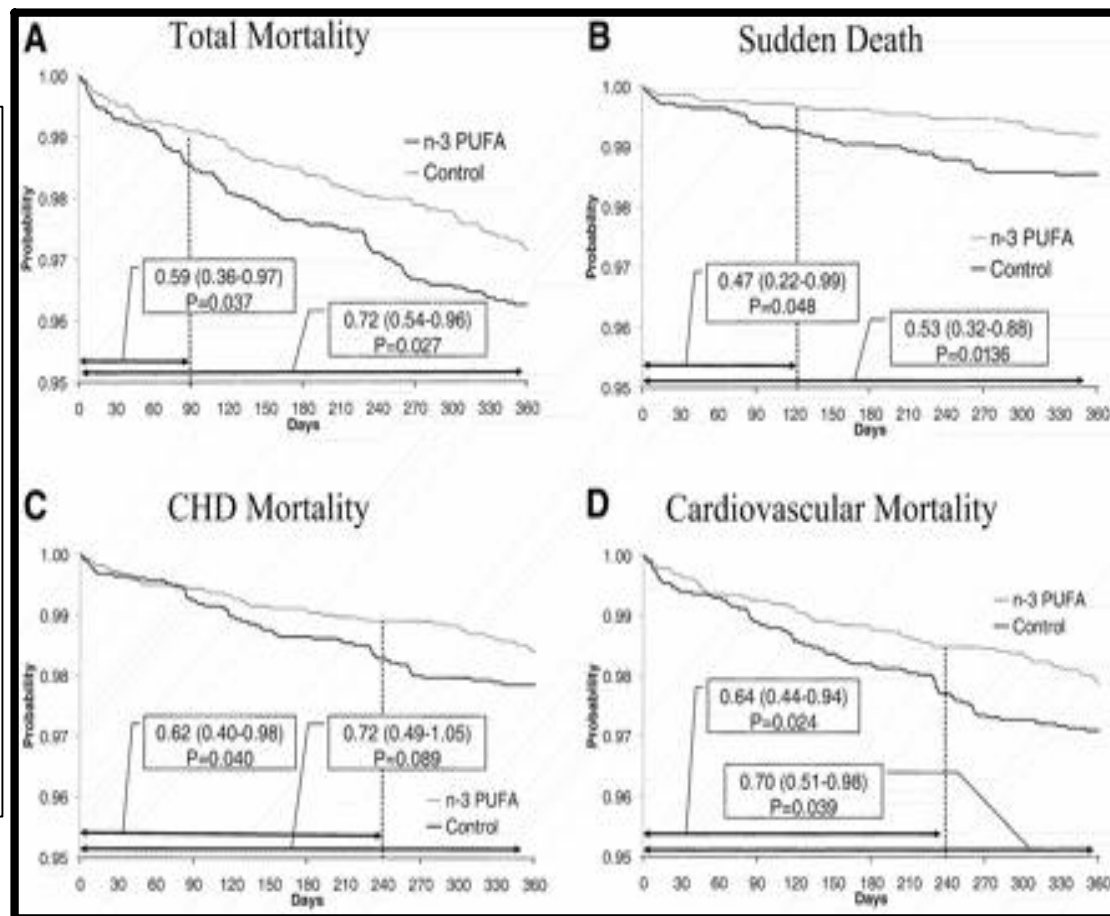


*Hu et al, JAMA 2002; 287:1815-1821.

**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

Studies	Nutritional Risk Gp.	Not at Risk Gp.	Other
Malnutrition %	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

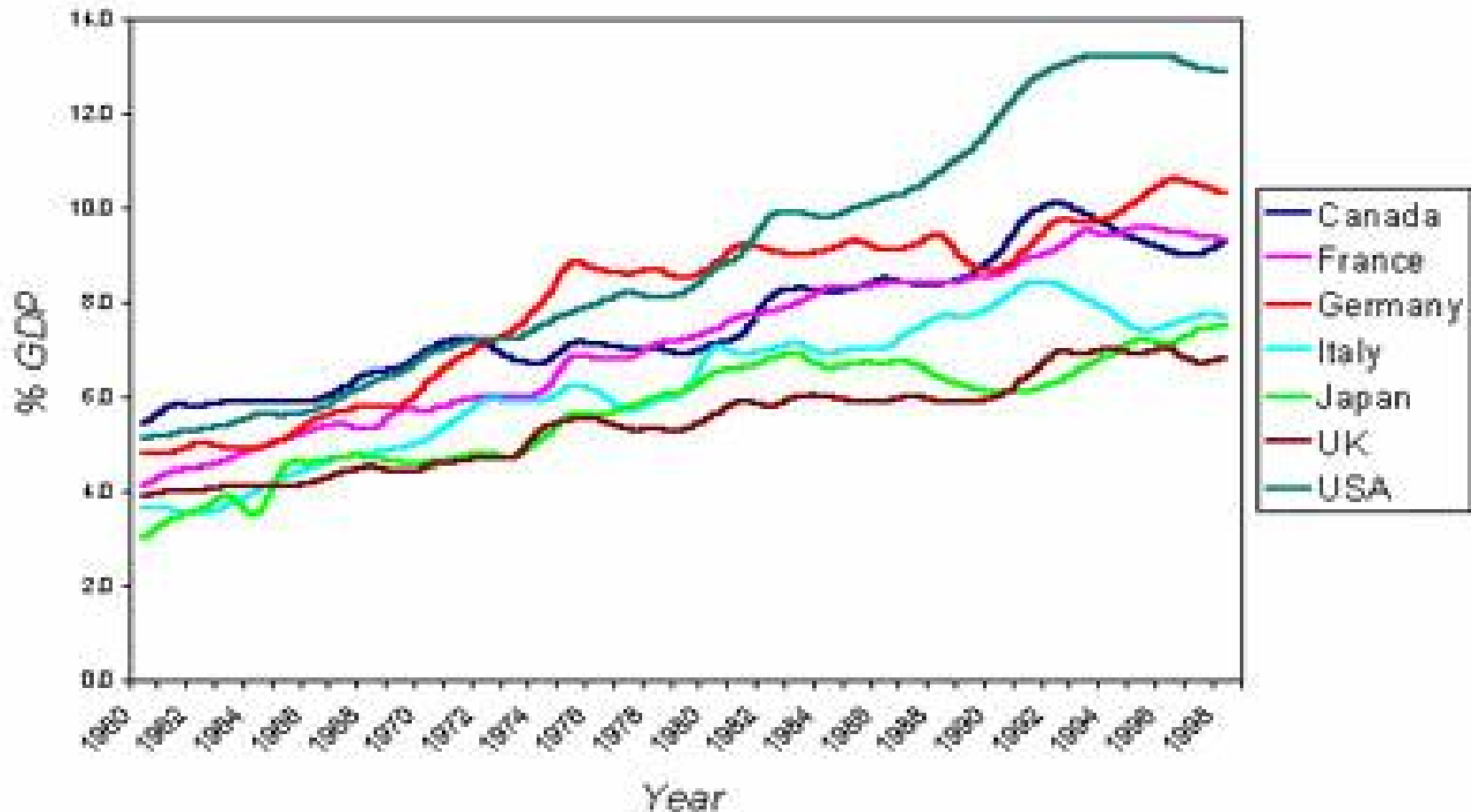
Vitamin and Trace mineral Supplements on Immunity/Infection

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

Cost Benefit \$28 dollars saved for every dollar spent

Health Care Costs Rising Globally

G7 Nation's Expenditures on Health Care



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

<u>Cause</u>	<u>Deaths</u>		<u>Annual Cost Billions</u>
CHD	739,860	32.6%	\$56.3 (others \$250)
Cancer	530,870	23.4%	\$104.0
Stroke	149,740	6.6%	\$19.7
Diabetes	55,110	2.4%	\$40.0
Obesity	NA		\$2.4 (total \$117.0)
Hypertension	NA		\$17.4
Osteoporosis	NA		\$10.0
TOTAL		65%	\$250 BILLION!

Researchers estimate proper diets could forestall 20% of deaths

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

<u>Cause</u>	<u>Annual Costs</u>	<u>% Diet</u>	<u>Potential</u>
	<u>Billions</u>	<u>Related</u>	<u>Saving Bio</u>
CHD	\$13	40-50%	\$6
Cancer	\$20	80%	\$8
Diabetes	\$10	35-50%	\$1
Dementia's/Alz	\$5-6	?	n/a
Kidney	\$3	?	n/a
Arthritis	\$11	20%	\$0.5
Psychiatric	\$3	?	n/a
Other	\$44		
TOTAL	\$100		\$19 Billions

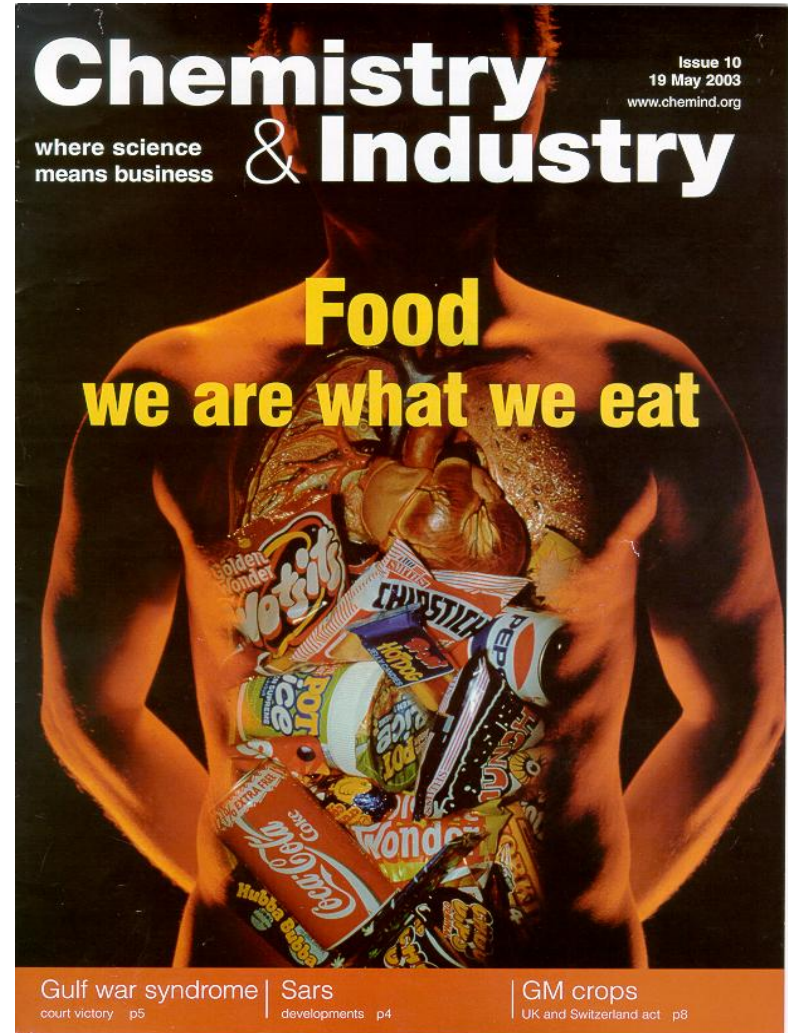
Per Capita spending; \$3,174, Seniors \$10,854

Foods

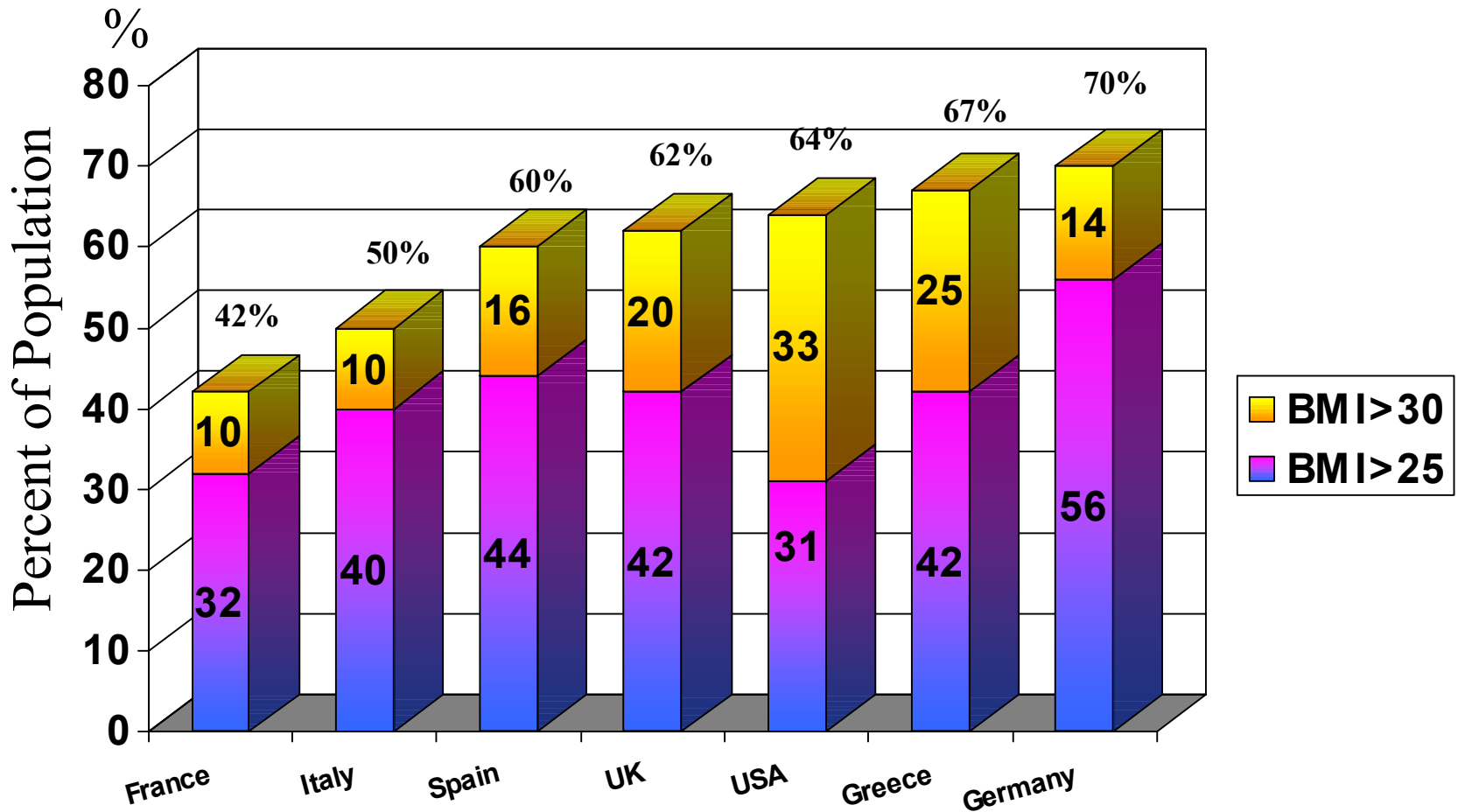
We Are What We Eat.....

Obesity Facts.....

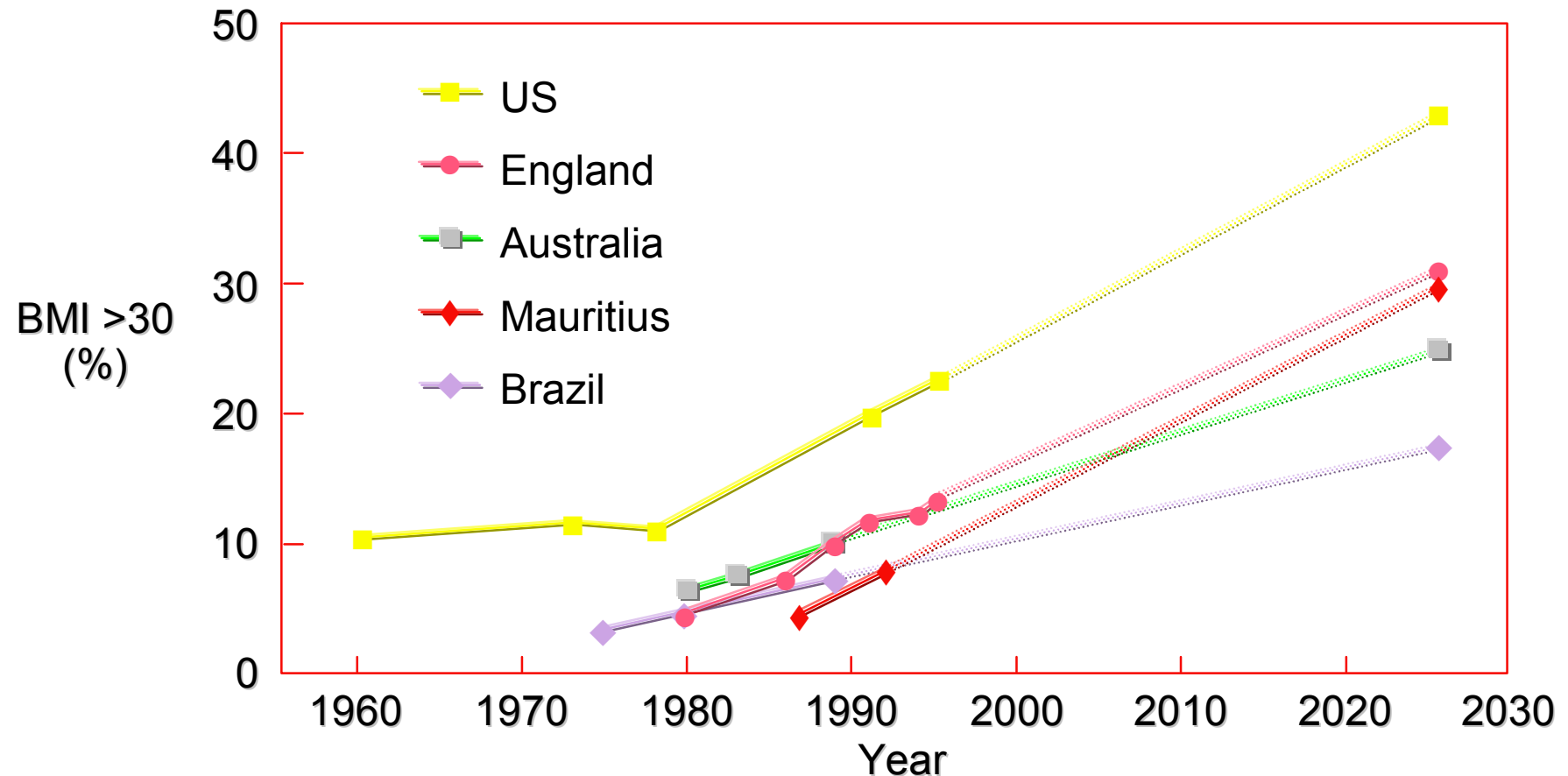
- One billion people worldwide obese/overweight (AHA, JAHA 2002)
- 64% of population in USA, (obese 31%, overweight 33%) 120 million PERSONS
- Percent obese:
 - 1976-80 15%,
 - 1988-94 23%,
 - 1999 27%
- Three times as many teens overweight vs. 1980 and twice as many children
- 300,000 deaths, 7% of total health care spending



Prevalence of Obesity & Overweight Globally



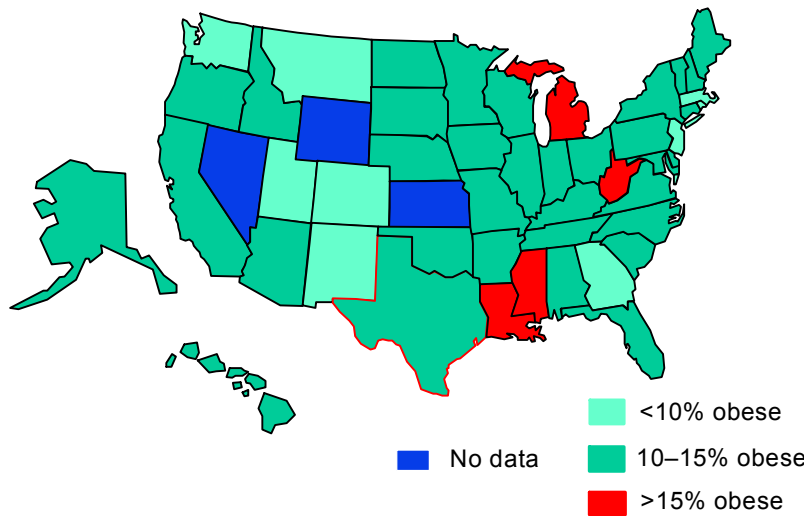
Obesity Rates Could Double in 30 Years



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

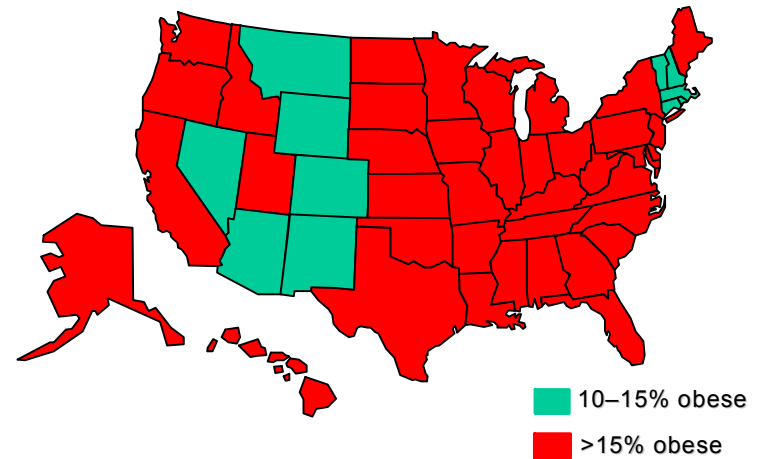
Prevalence of Obesity in USA 1991-1998

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)

	<u>Inactivity</u>	<u>Obesity</u>
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
Total Billions	\$24.3	\$70.0 billion
% of Health Costs	2.4%	7.0%

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

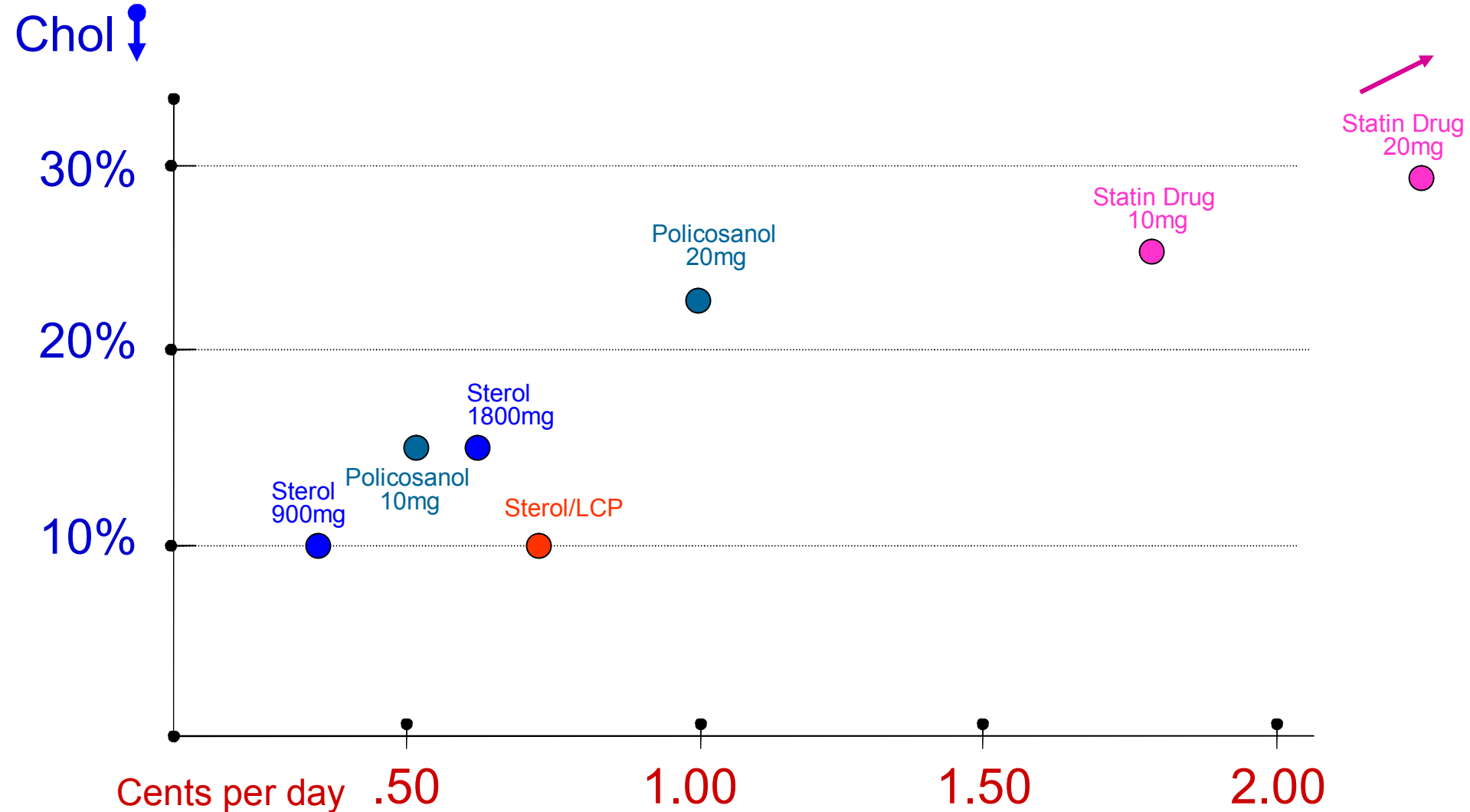
(Canada 2002)

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	\$2..72 billion

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
Prostate Cancer				
Selenium (0.2 mg)	5 cents	63%	\$18	\$315 million
Gross savings of \$2.4 billion dollars per year for selected cancers				

Cost Effectiveness Cholesterol lowering Agents

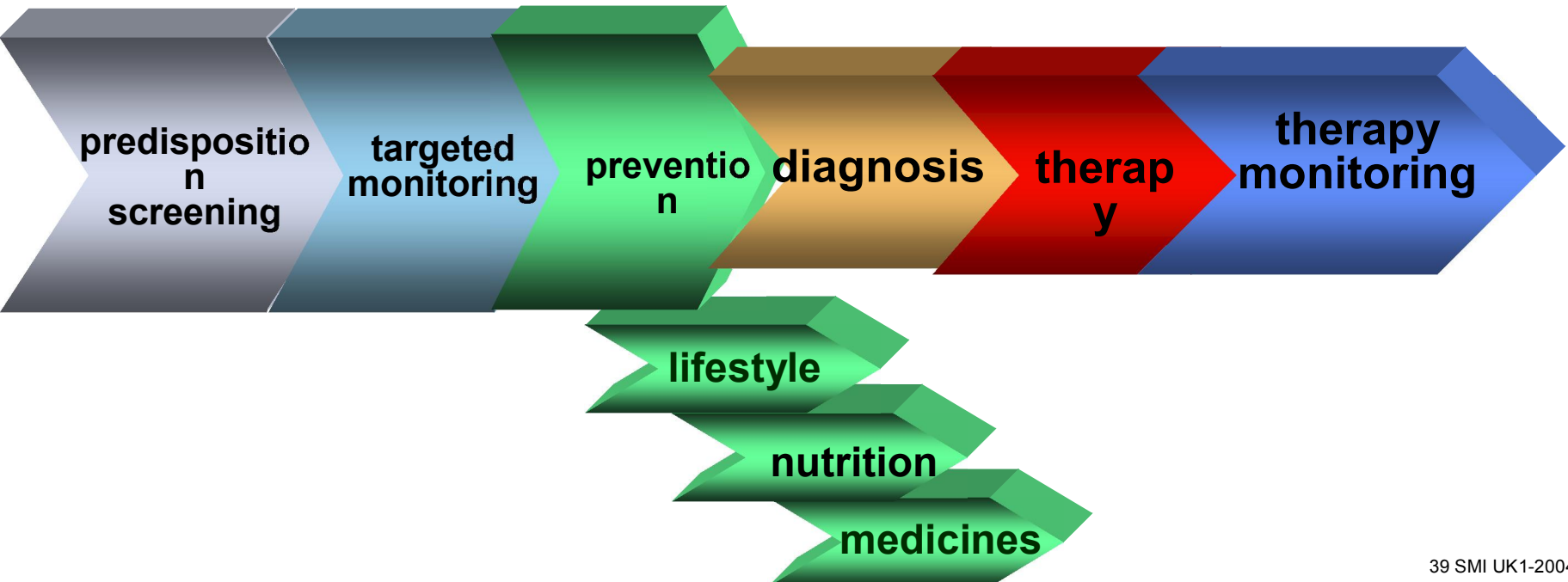


Integrated Healthcare Concepts

*from
today...*



...into the future



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 !

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

<u>Claim</u>	<u>Food</u>	<u>DS</u>	<u>CANADA</u>
- Saturated Fat and cholesterol and CHD (CFR 101.75)	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	
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		X	

INDUSTRY OF WELLNESS FOODS

LEGISLATION/REGULATION

CONSUMER AWARENESS

HEALTHCARE COSTS

MEDIA COVERAGE

PROF.INTEREST/SUPPORT

SCIENCE DATA-EFFICACY/SAFETY

Thank You

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Affairs,
DSM Nutritional Products Inc.**

Parsippany, NJ