

Health Care Costs and Functional Foods

Worldnutra Conference Nov.19th. 2002

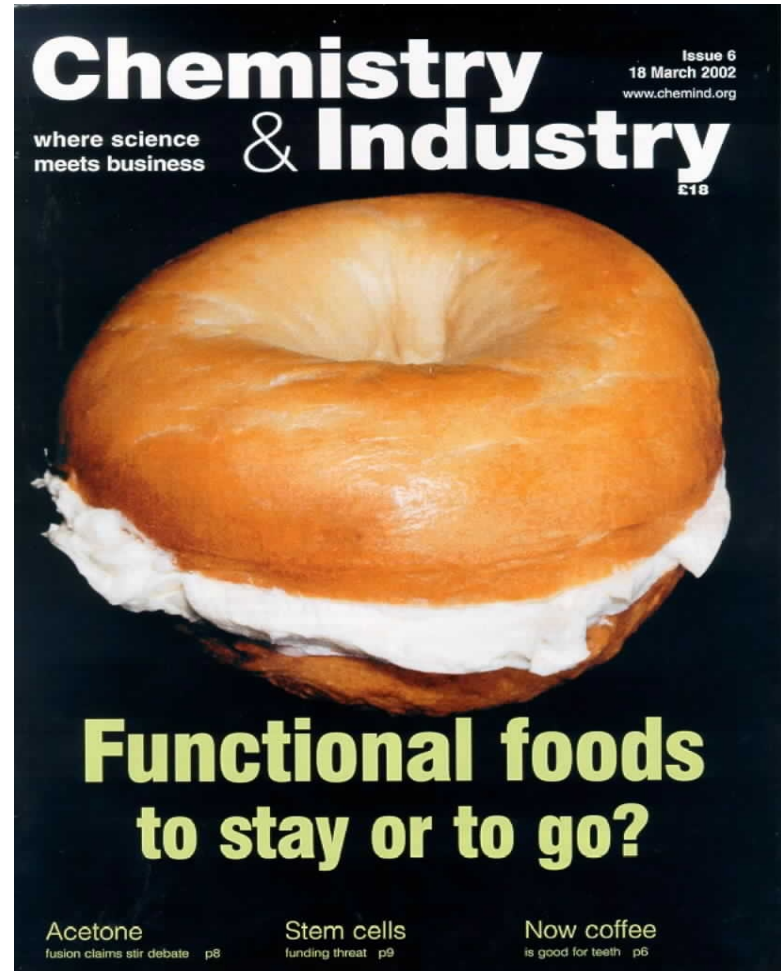
Ian Newton,
Director, Business Development and Regulatory
Affairs,
Roche Vitamins Inc.
Parsippany. NJ

Functional Foods: Here Today Gone Tomorrow?

- Most people would argue that they are here to stay

Rationale


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



Roche HMO Savings Program Ahead of It's Time





► Main Menu

Potential National Savings (Hospitalization)



Optimal Vitamin Intakes

Potential National Savings (Hospitalization) with Full Supplementation

Disease/Disorder	Potential Savings (\$000,000)	
Birth Defects (excluding NTD) *	\$ 1,075 - 1,771	
Neural Tube Defects *	\$ 163 - 179	
Low Birth Weight (short gestation) *	\$ 146 - 1,741	
Coronary Heart Disease ***	\$ 33,730 - 34,800	
Total Potential Savings (billions)	\$ 35,114 - 38,491	

* taking folic acid and zinc containing multivitamins for at least three months before conception and throughout pregnancy.
*** taking vitamin E supplements for a minimum of two years

Roche

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National savings for all Birth Defects and CVD: \$35-38.5 billion per year

Roche HMO Savings Program Ahead of It's Time

Potential Savings
 Vitamin E for Coronary Heart Disease

Enter Total HMO Enrollment: 1,000,000
 HMO Population at Risk: Estimate 255,000

ICD-9	Diagnosis	Gross Potential Hospital Savings	Vitamin Program Costs	Net Potential Hospital Savings
410-414	Coronary Heart Disease, Age Over 50	\$ 71,415,082		
Totals, Vitamin E Program, Age Over 50 (per year)		\$ 71,415,082	2,792,250	68,622,832
Per Enrollee (men and women over 50)		\$ 280.06	10.95	269.11

HMO Population at Risk: Estimate 206,000

ICD-9	Diagnosis	Gross Potential Hospital Savings	Vitamin Program Costs	Net Potential Hospital Savings
410-414	Coronary Heart Disease, Age 35 to 49	\$ 7,497,655		
Totals, Vitamin E Program, Ages 35-49 (per year)		\$ 7,497,655	2,255,700	5,241,955
Per Enrollee (men and women, ages 35-49)		\$ 36.40	10.95	25.45

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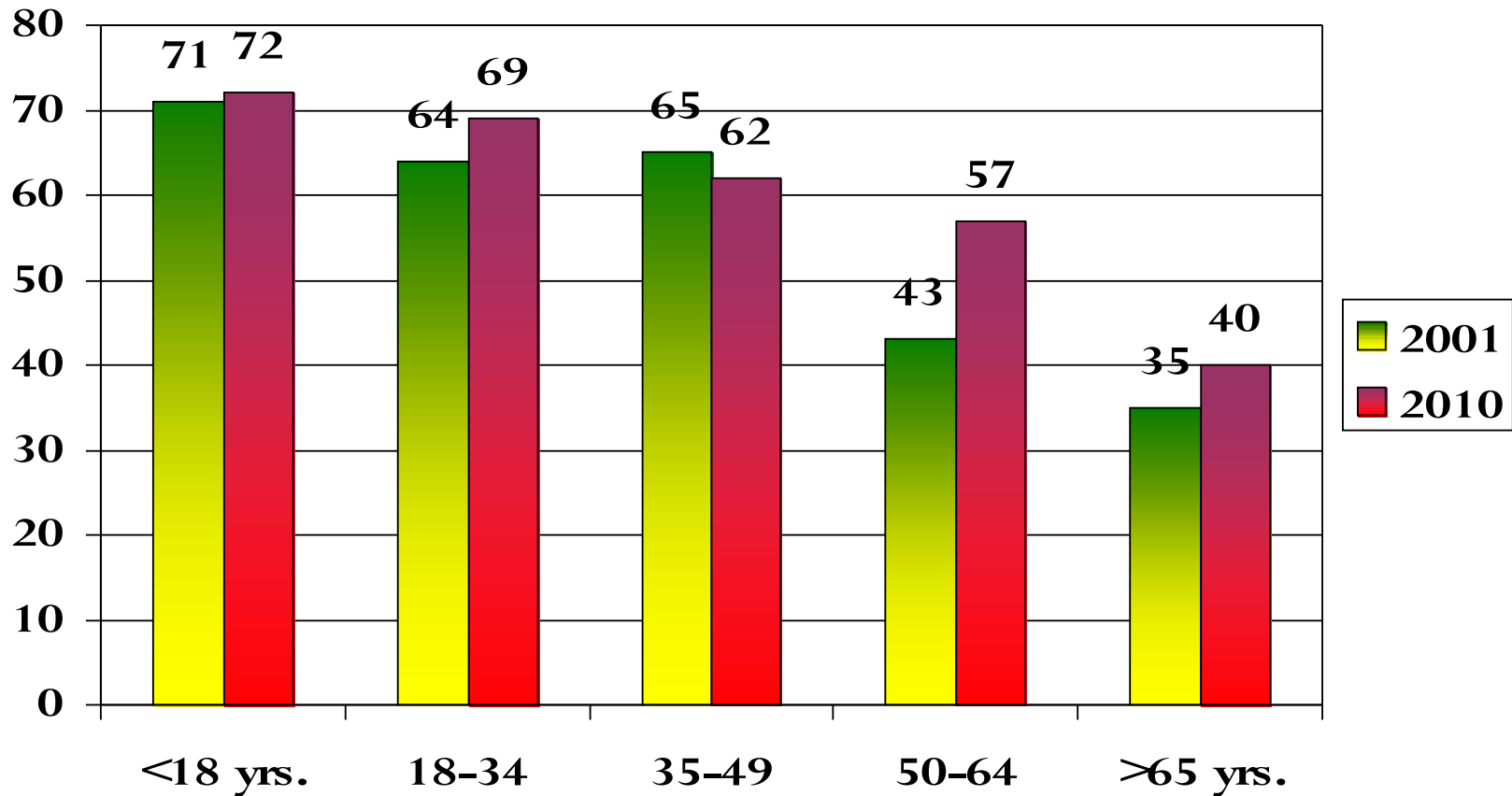
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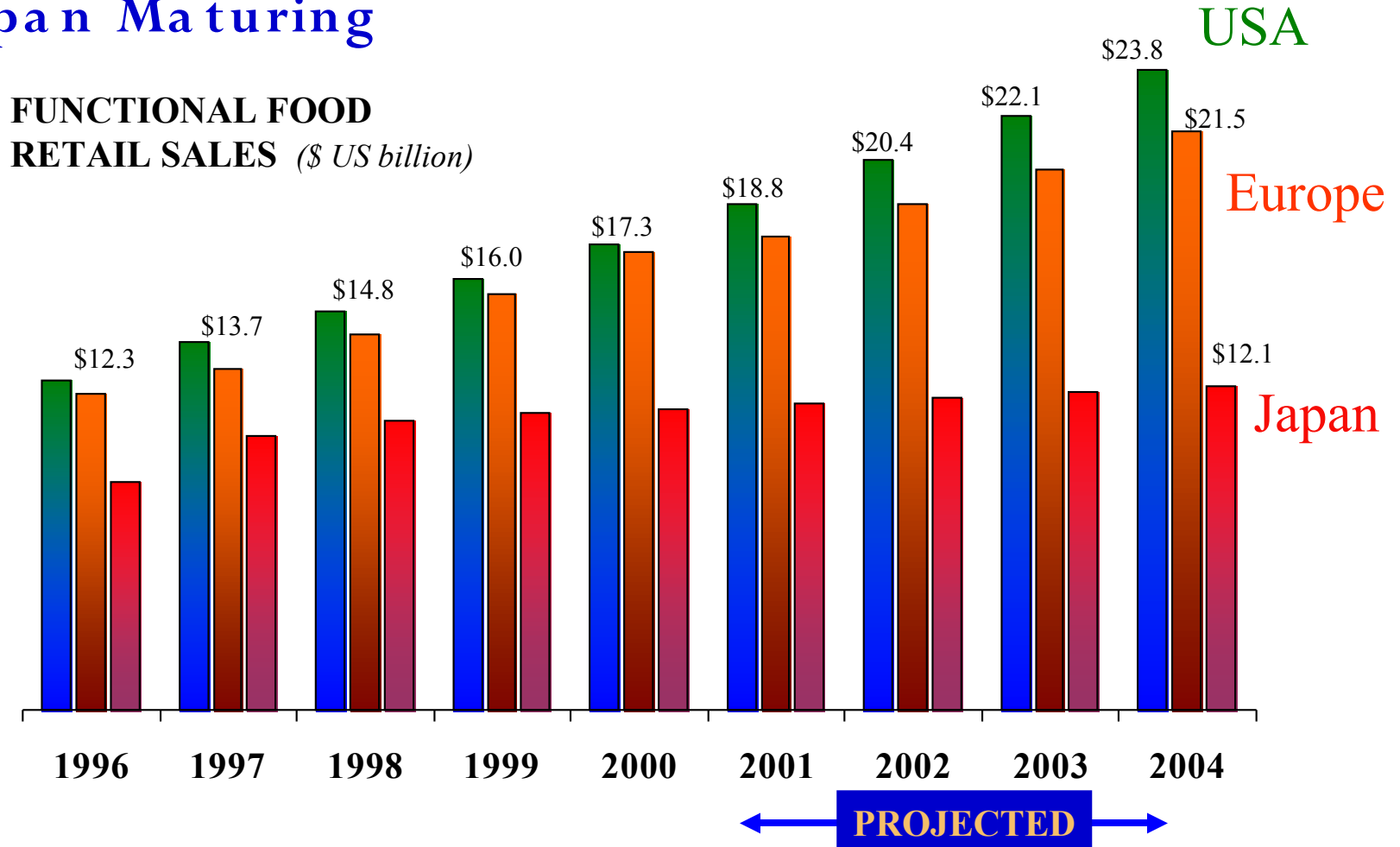
Savings of \$68.6 million dollars for \$2.792 million vitamin E costs for people over 50.

Population in US A By Age.

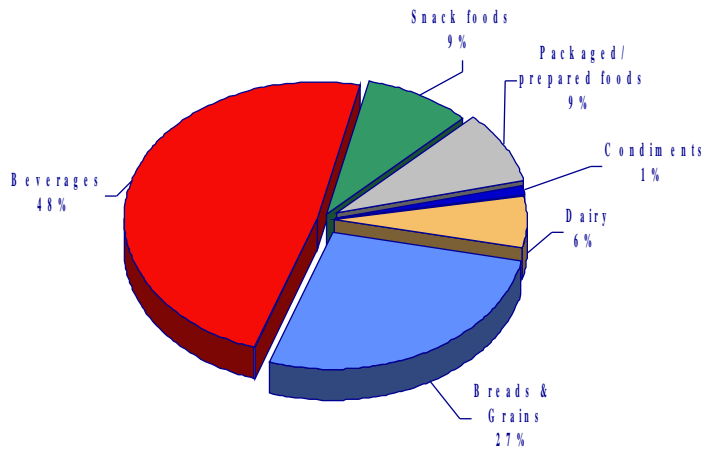
Total Population 2001: 278.1 mio.
Total Population:2010: 300 mio.



The \$18.0 Billion U.S. Functional Food Market Is Expected to Grow at 8.3% Through 2004 Growth Expected in Eu, Japan Maturing

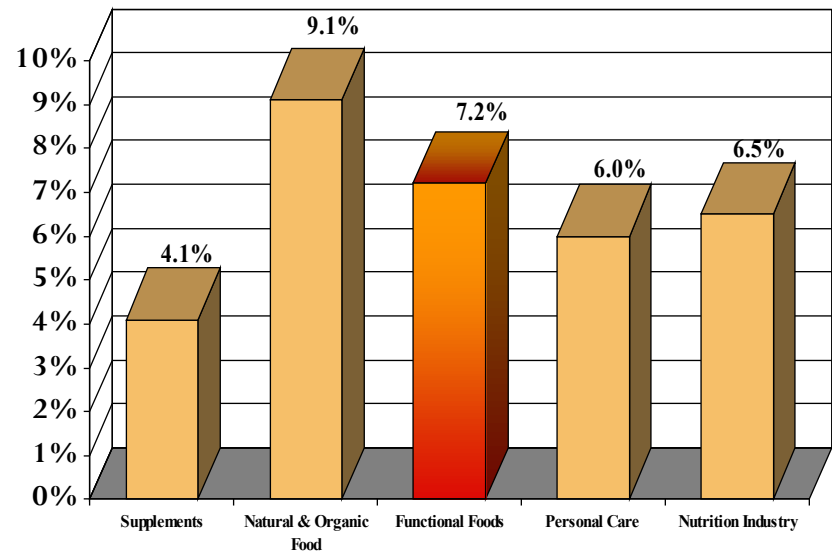


\$18.5B U.S. Functional Foods Market in 2001



Half the FF market is beverages, grains (bars) are an additional 25%.

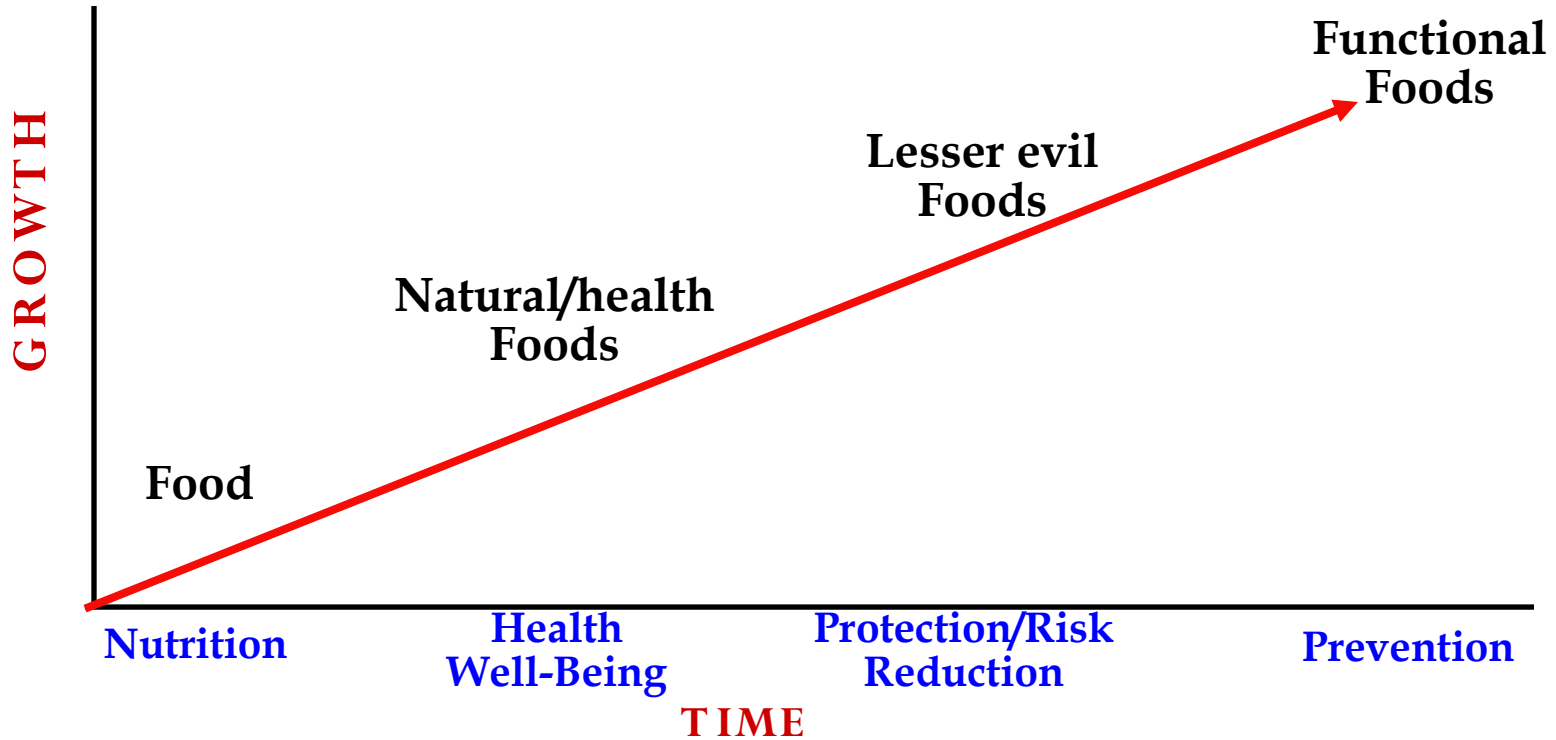
Functional foods grow at twice conventional food rates.



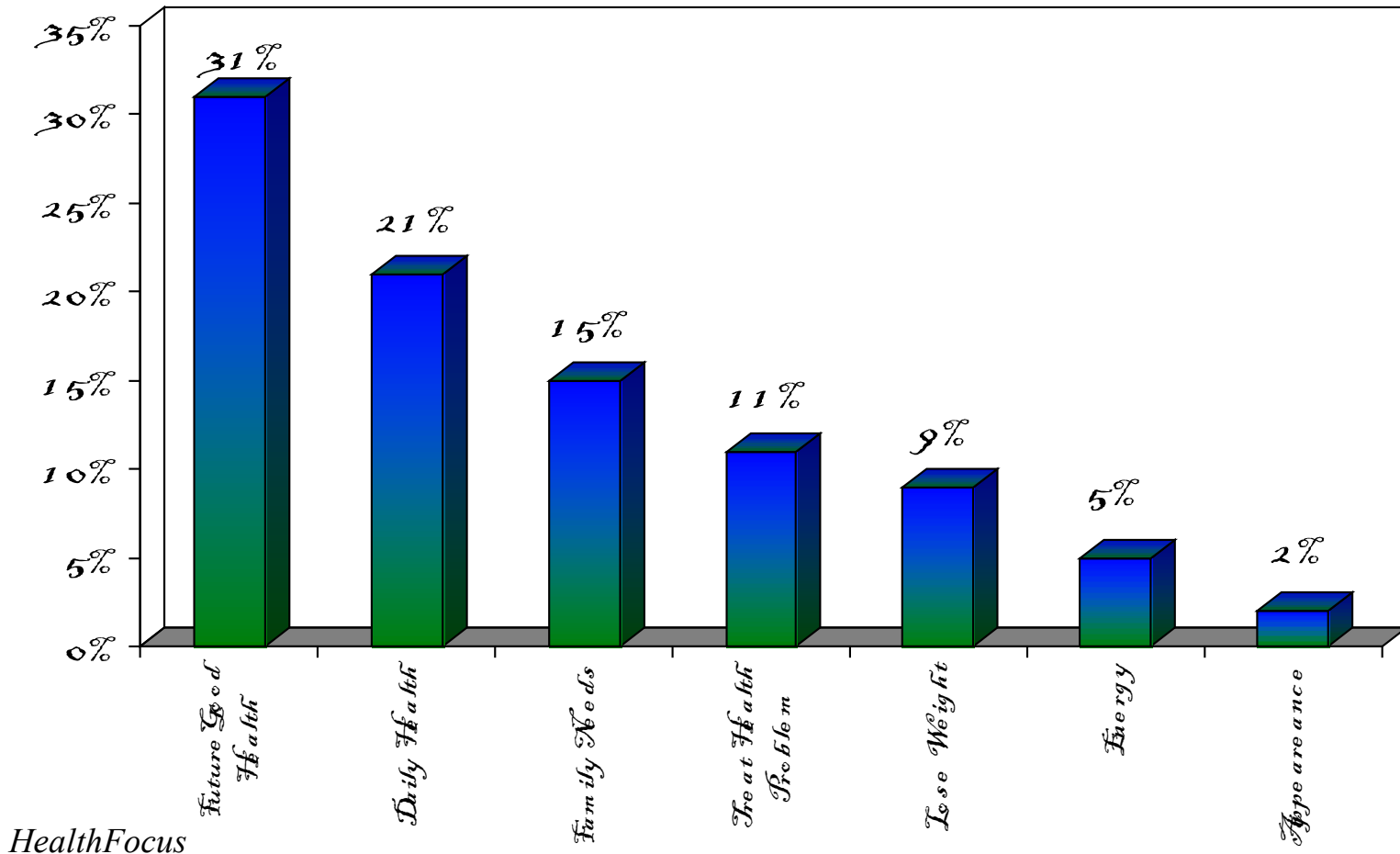
Transformation Evolution of Foods

Eating Traditional Food \longrightarrow Healthy Eating / Functional Food

Developing Nutrition Science

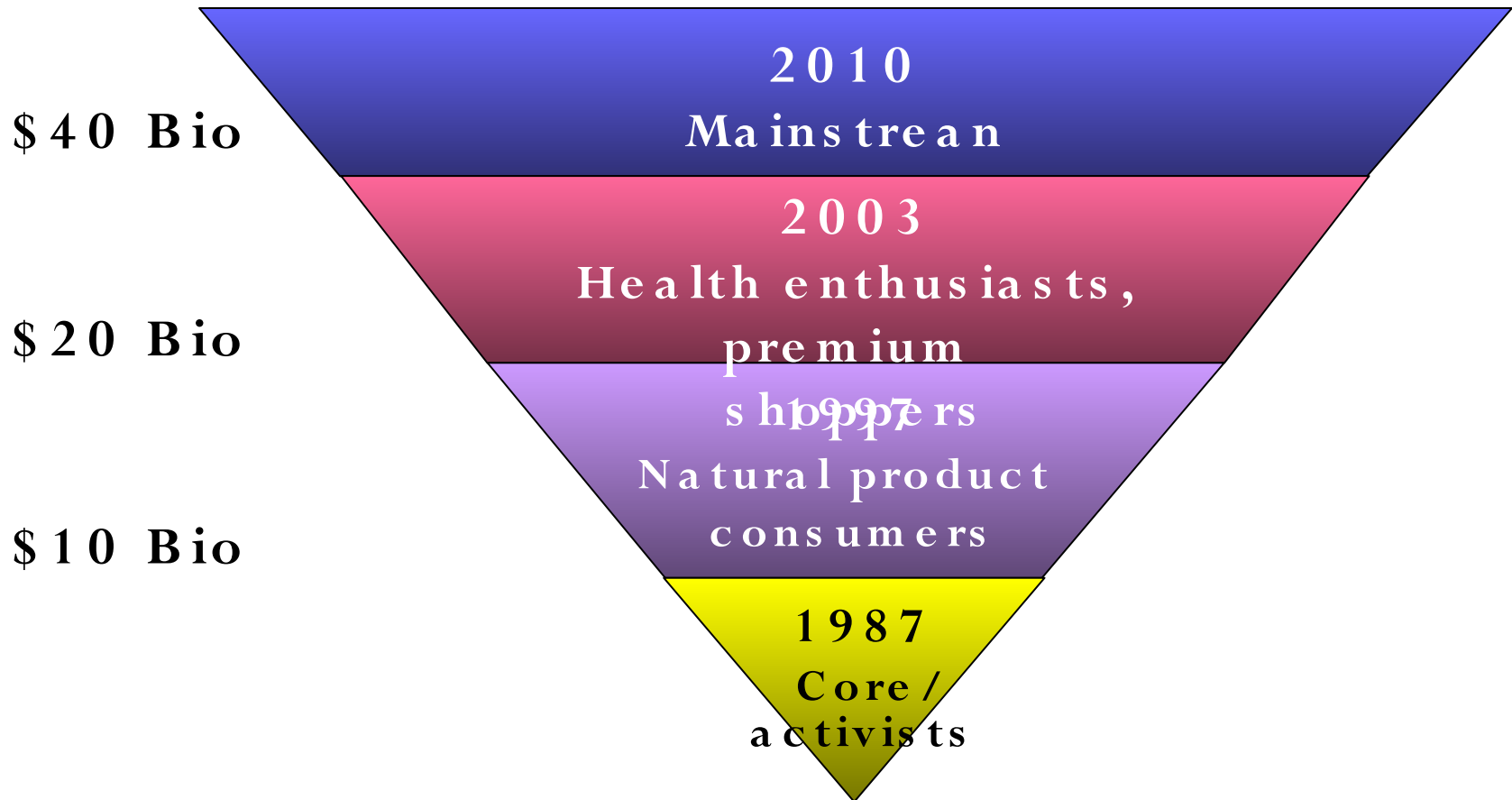


Why Do People Purchase Healthy Foods & Beverages

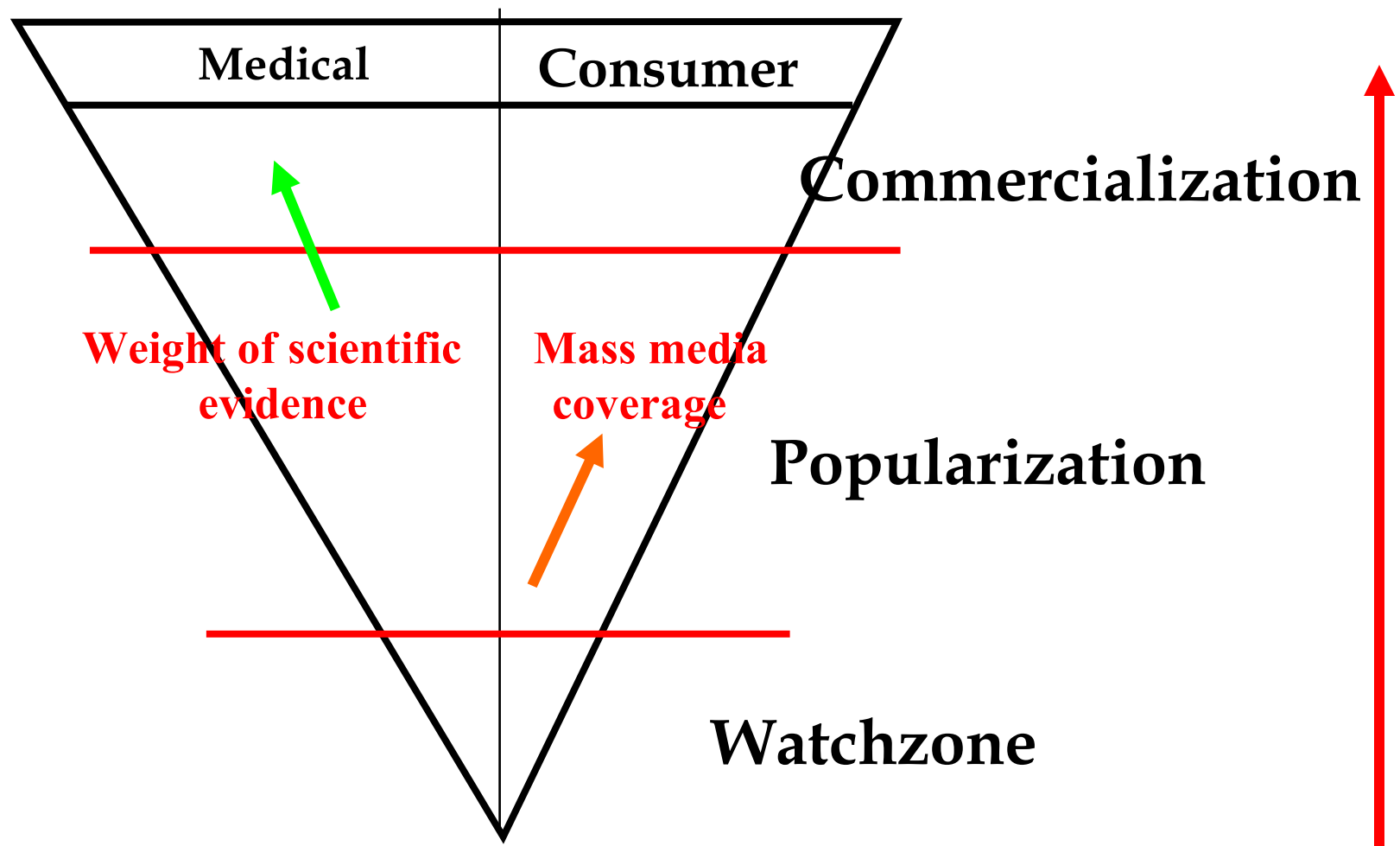


Functional Food Market Trend US A

Market Size



Trends in Functional Foods



Age Related DiseasesWhat will Influence one of the Largest Demographic Groups?

- 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

Health Insurance Cuts Hurt Retirees

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying <http://careers.usatoday.com/service/usa/national/content/news/economy/2002-10-02-retirees-health-ins>. The page content includes the USA TODAY logo, a navigation menu with links for Home, News, Money, Sports, Life, Tech, and Weather, and a sidebar with links for Job Seekers, Employers, and News & Information. The main article is titled "Health insurance cuts hurt retirees" and is dated 10/02/2002. The article text discusses how health insurance costs are increasing for retirees, with one retiree, Harry Nieman, paying \$600 a month for insurance coverage for himself and his wife. A sidebar titled "Life after retirement" contains links to "Career advice for mature workers", "Survey: Many plan to work past 65", and "Census report shows number of uninsured up". A "Search for jobs" section includes buttons for "Find a Job", "Post a Resume", "Save Agents", and "Save Jobs".

• **Only 34%** companies now offer health coverage, down from 60% in 1988

• **Only 5%** of companies with less than 200 offer coverage

• **Only 29%** of large companies offer early retirees coverage

• **Benefits for retirees declining and estimated by 2031 90% of health costs retirees will pay themselves**

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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MORE THAN \$160 IN SAVINGS THIS WEEK



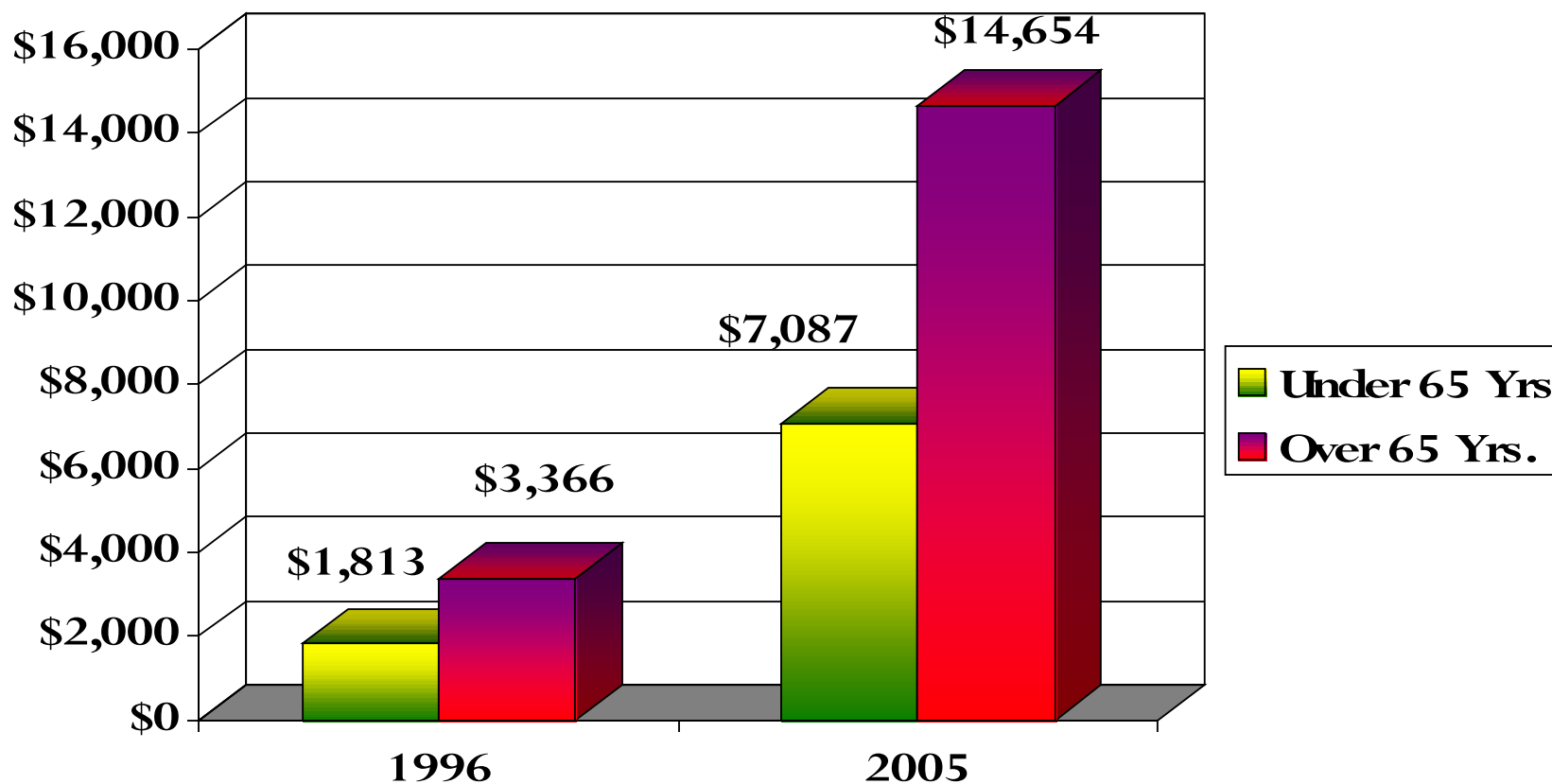
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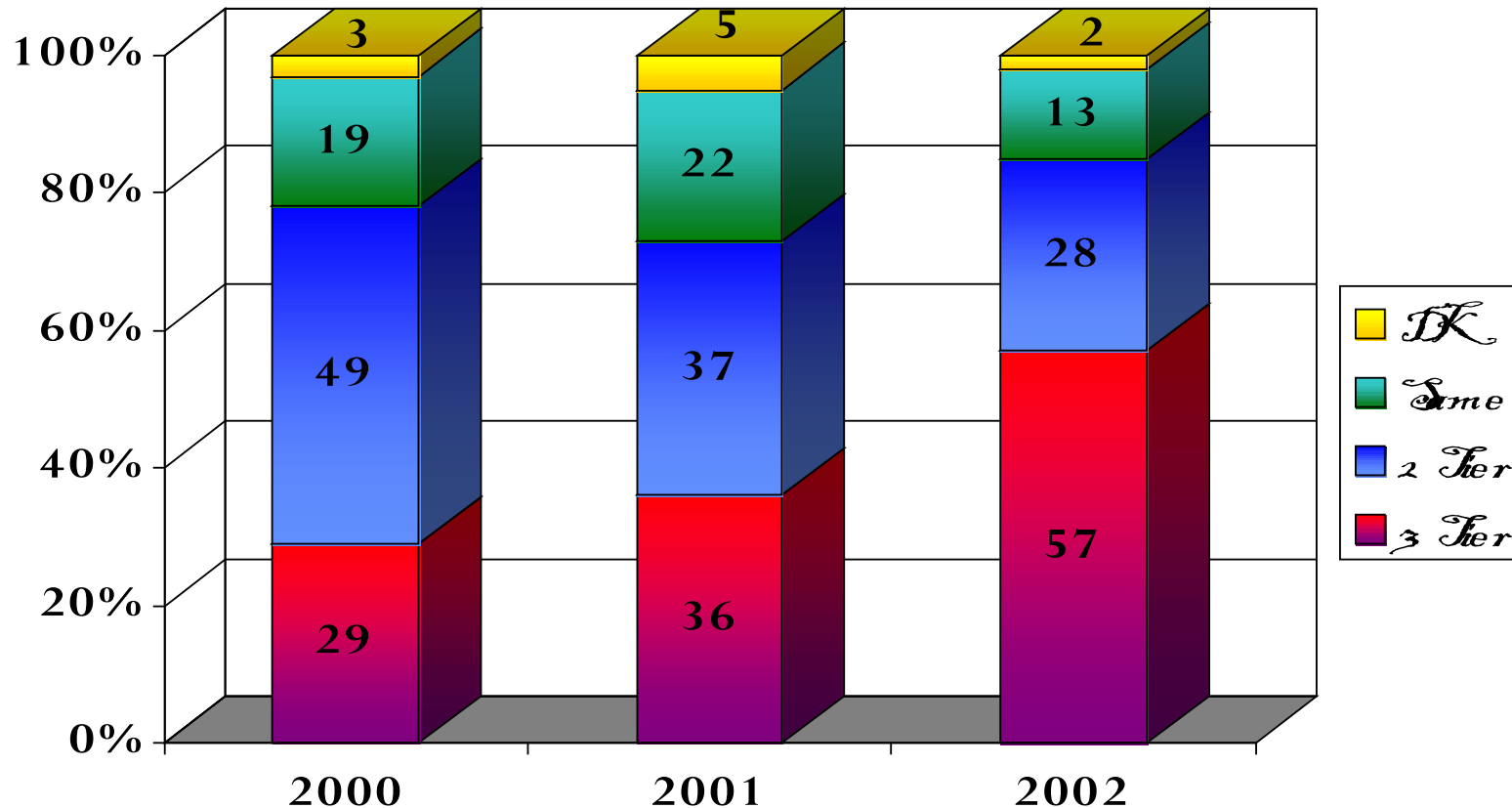
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USA Per Capita Health Care Spending 1996-2005



Workers to Pay More For Drug Plans



3 Tier: Different co-pays based on drug
2Tier: Different co-pays for generic Vs Rx
Same: Payment same for all drugs
DK: Don't know

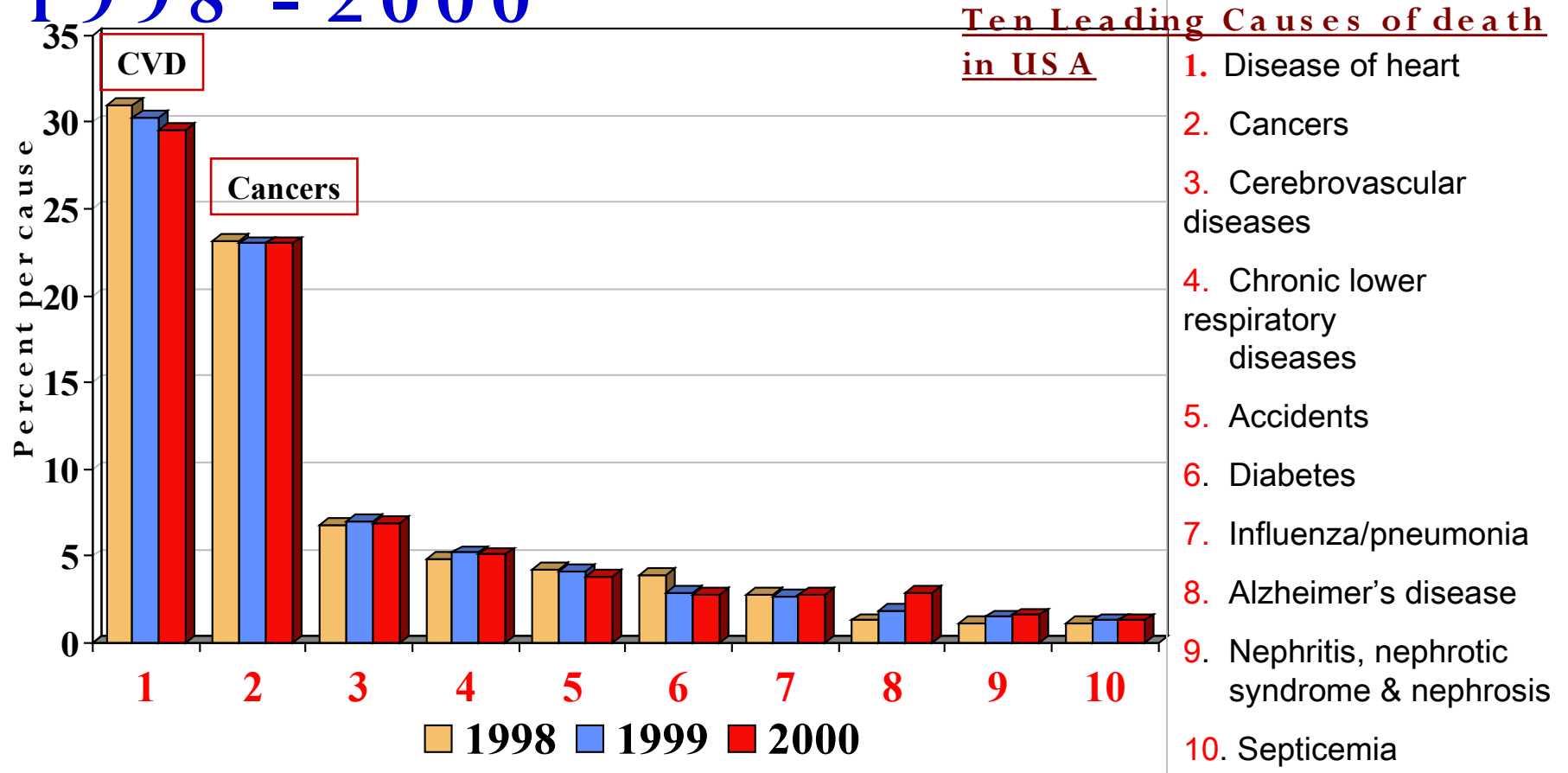
Healthcare Economics

- Nutraceu ticals consumed for wellness and future health
- Healthcare premiums increasing and coverage declining, co-payments increasing
- Physicians and HMO's more positive (PDR Herbals)
- More awareness of side effects from drugs (also herbals!)
- Economic value seen in nutraceuticals by consumers
- **POSITIVE** results needed to reinforce continued use

<u>Medication</u>	<u>Cost/Mth.</u>	<u>Co-Pay</u>	<u>Revenues</u>
Proscar	\$90	\$10-\$20	\$600 million
Saw Palmetto	\$10-15	N/A	
Statin Drugs	\$40-80	\$10-20	\$25 billion
Fish Oil	\$6.75	N/A	

Ten Leading Causes of Death

1998 - 2000

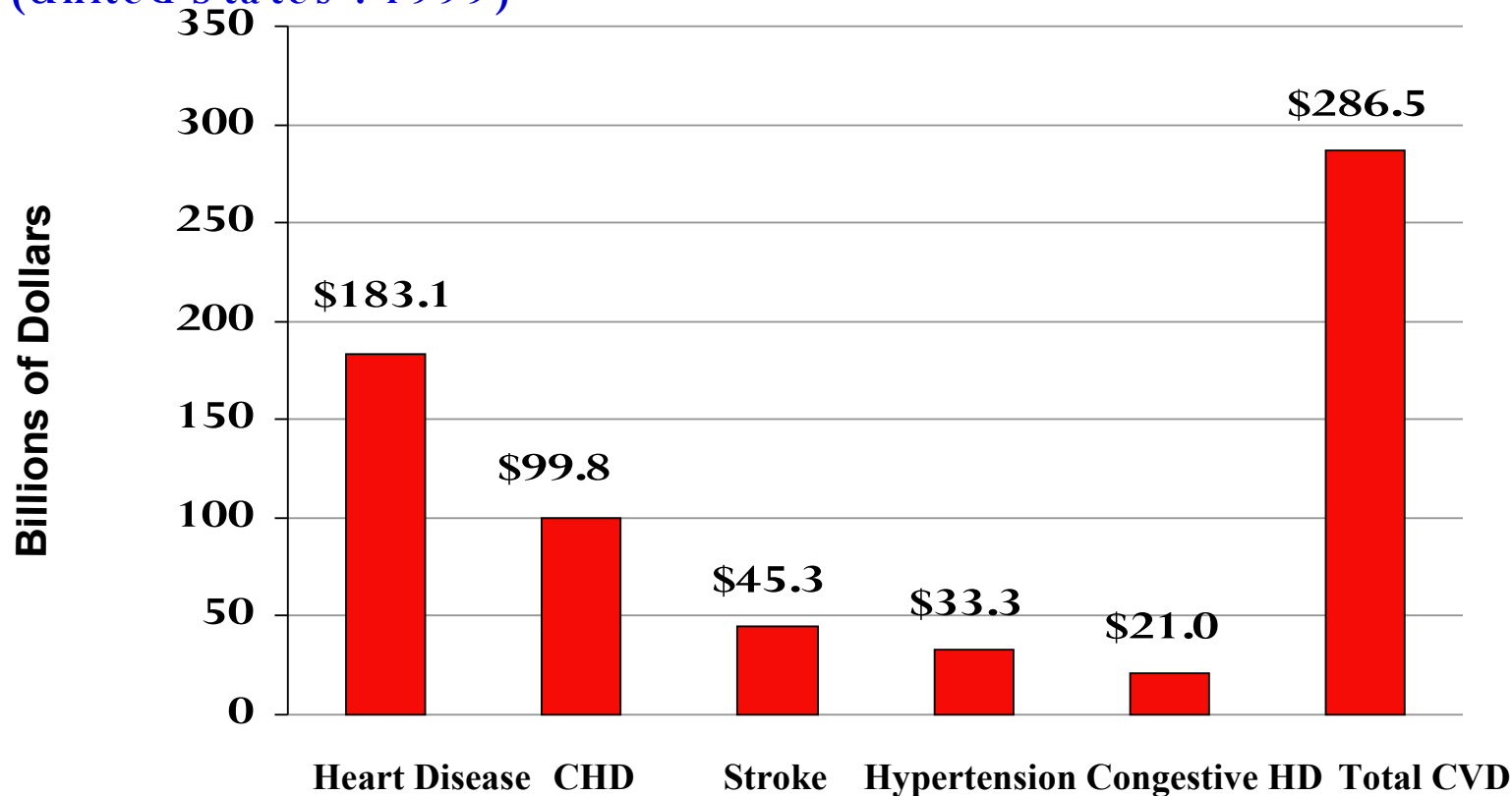


Rising Health Care Costs

- 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.

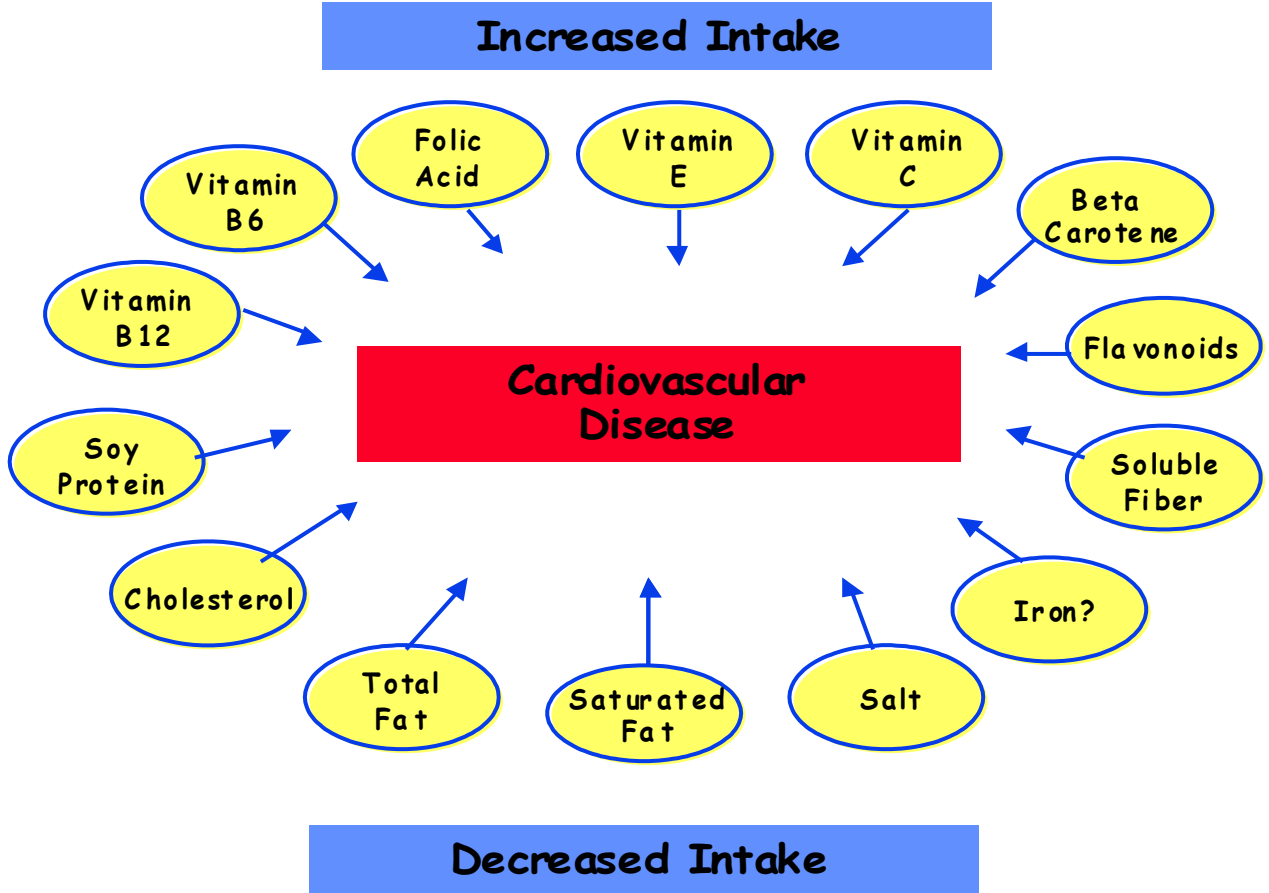
Estimated Direct and Indirect Costs of Cardiovascular Diseases and Stroke

(United States : 1999)



Am. Heart Assoc.

Convergence of Various Factors in CVD

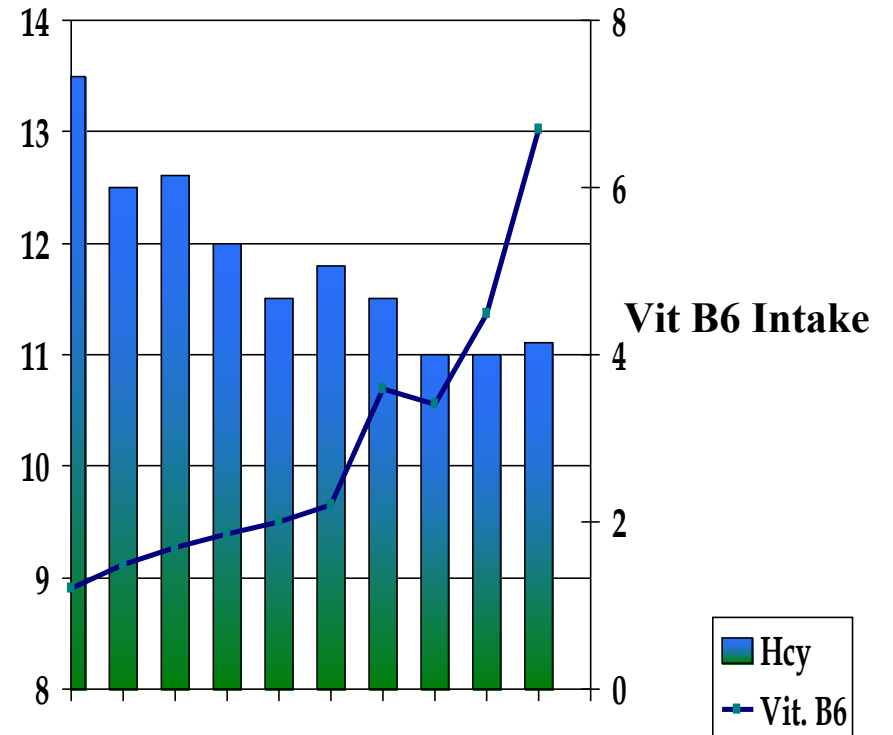
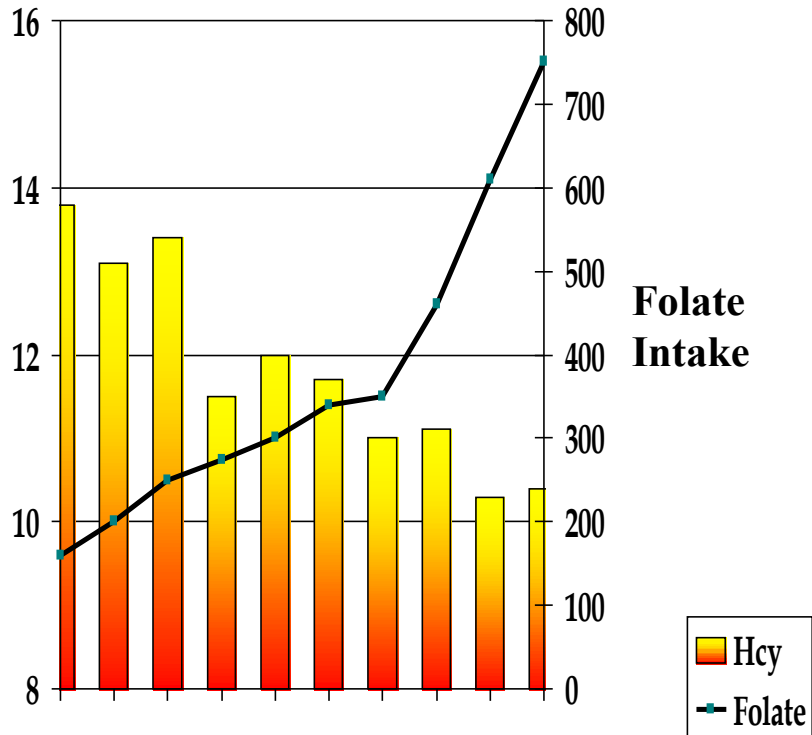


Plasma Homocysteine As A Risk Factor

- 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.

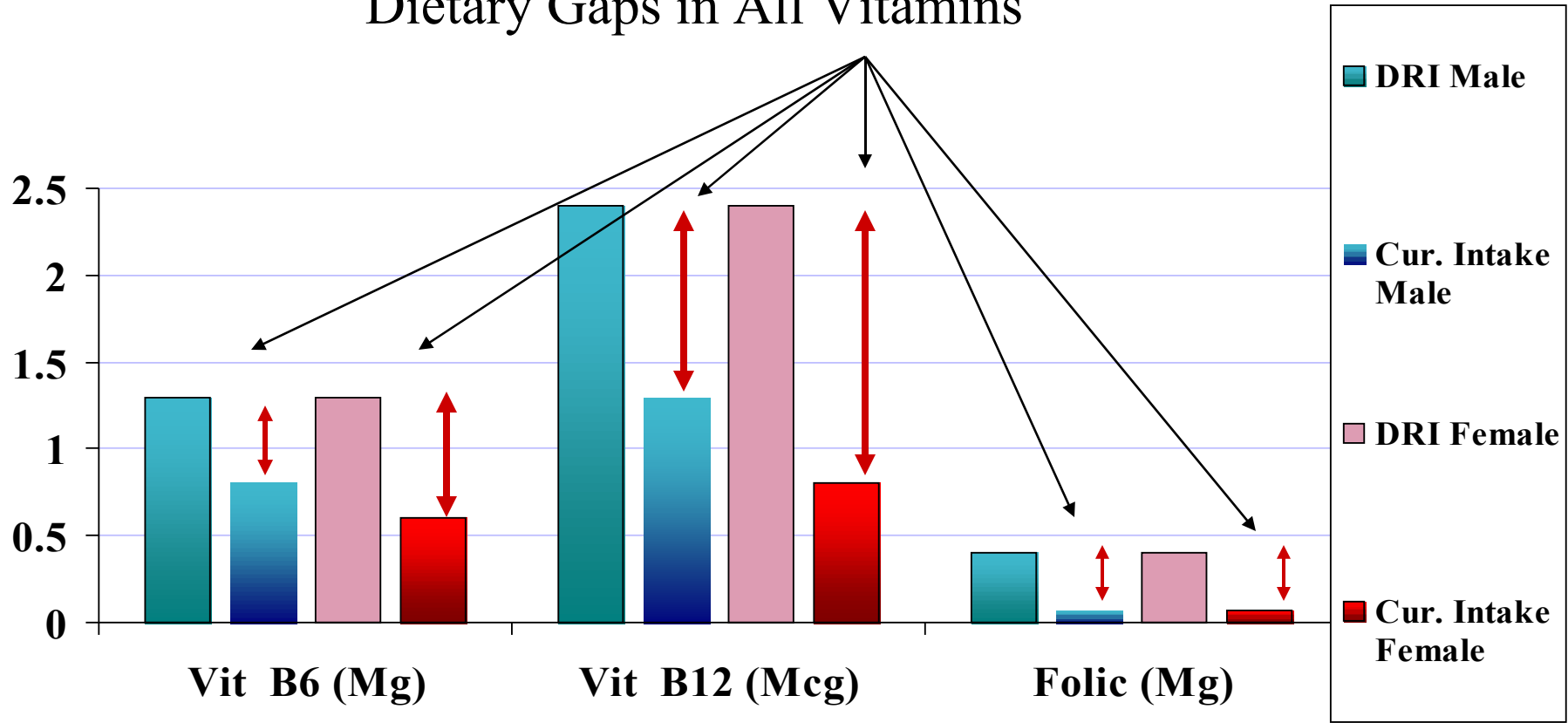
In general ~20% reduction in Homocysteine levels
lower CAD/stenosis ~30%

As Vit. B6 and Folate Intake Rise Hcy Declines



Comparison of DRI's and Intakes

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

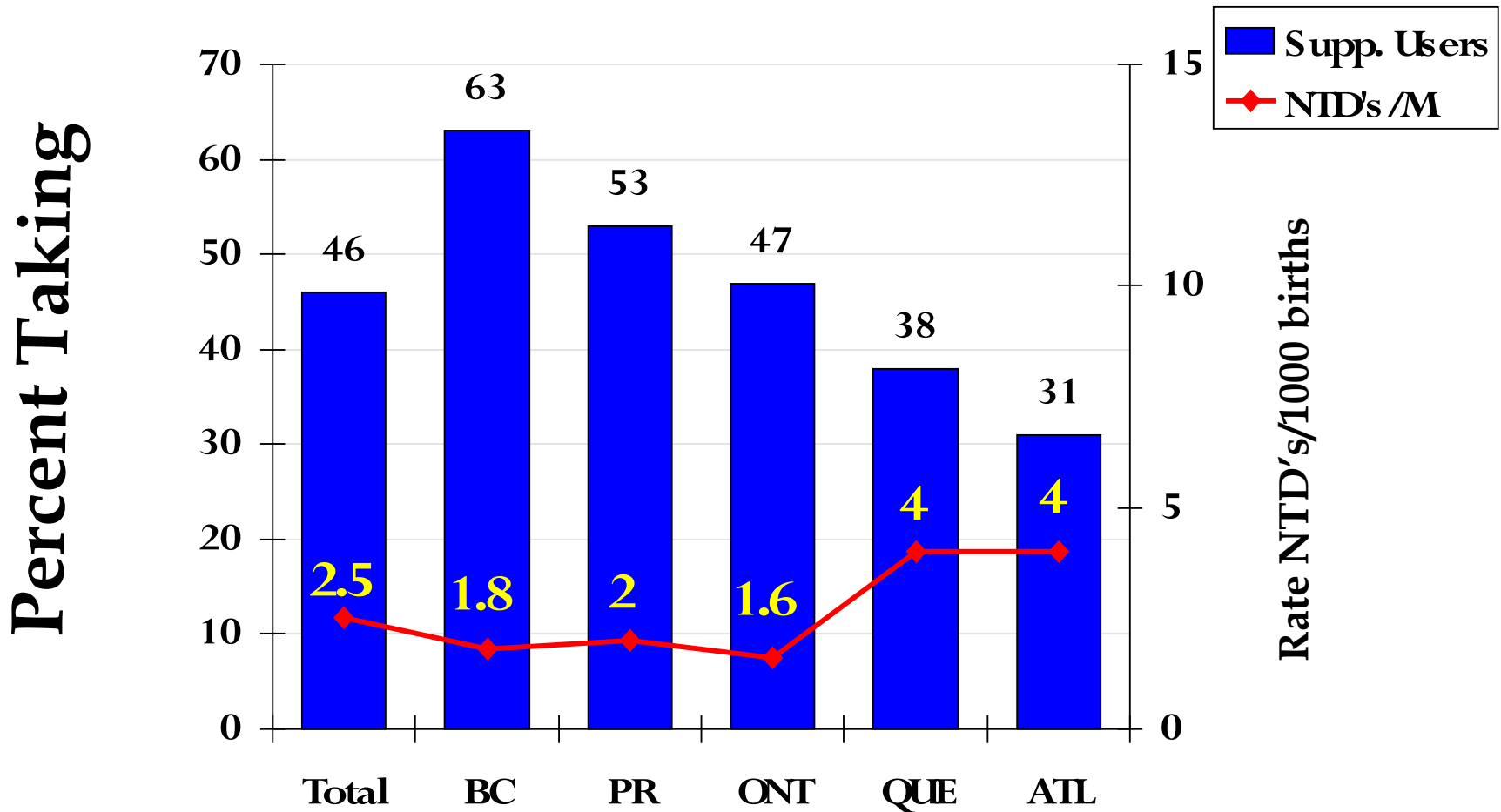
\$90 million

\$1.5 billion

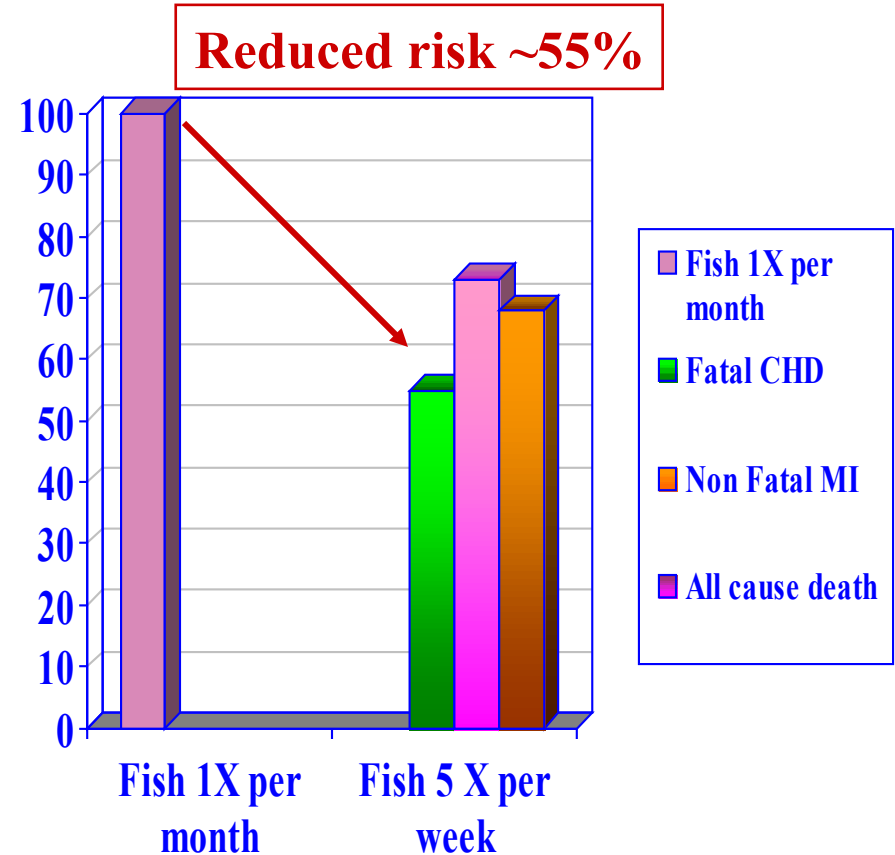
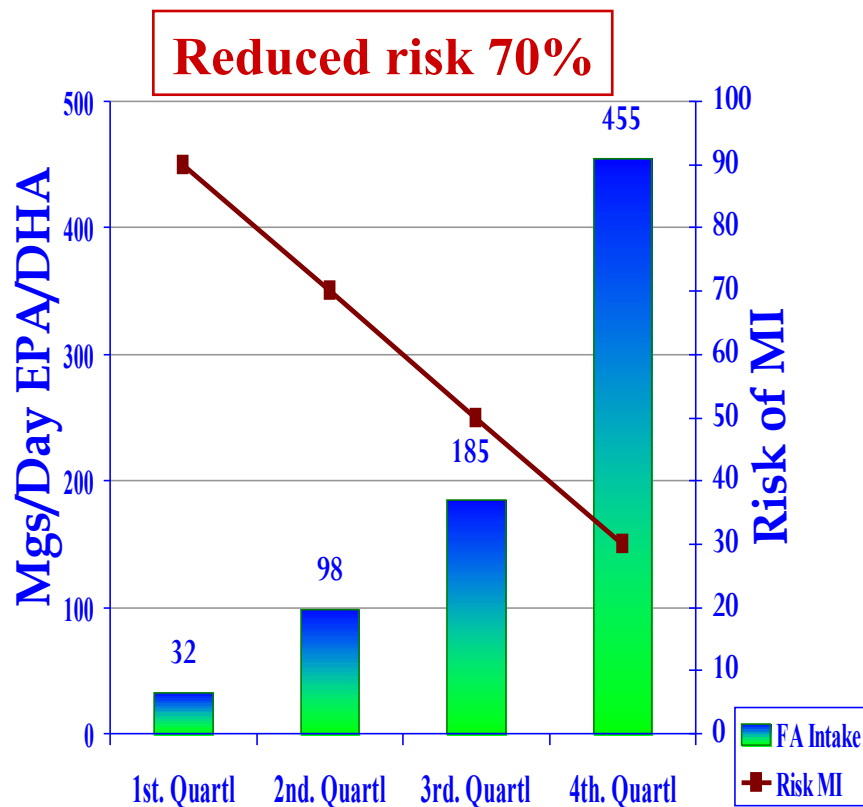
\$1.6 billion

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

VM Supplement Use and NTD's in Canada



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



Vitamin E and Heart Health

Study	Location	n=	Dose	Outcome
CHAOS	Cambridge.	2,002	400 IU	70% less non fatal MI
CLASS	Hodis, USA	156	100 IU	Reduced progression of plaque
HOPE	Canada	9,297	400 IU	No effect
GISSI	Italy	11,324	300 IU	Did not reach significance
SPACE	Italy	196	800 IU	Reduced CVD in dialysis patients
ASAP	Finland	520	270 IU	Reduced rate of intimal thickness
HPS	Oxford	20,536	600 IU	No effect
PPP	Italy	4,495	300 IU	No effect on primary end-points

Inconsistent results:

- Duration of trial
- Prevention trial in diseased group or comparison to drugs
- CVD is multi-factorial and nutrition intervention, “too little too late”
- Seems to be a synergy between vitamin E and Vit.C

Economic Benefits of Vitamin E supplementation and CHD (1992-5 data)

- Approximately 2,100,000 patients (1992)
- Estimated costs \$51.8 billion (1995 \$), 58.5% men
- Acute myocardial infarction costs of \$22 billion
- Utilized intervention and epidemiological studies with risk estimates using 2 studies
- Used hospital discharge data for codes and costs

Risk reductions

37% (Health Prof. Study)

77% (CHAOS study)

Vit. E Intake Estimated Savings

100 IU

400 IU

\$4.7-5.6 billion

if all people >age 50

\$4.4-5.0 billion

Total cost savings: ~\$5 Billion including vitamin E costs

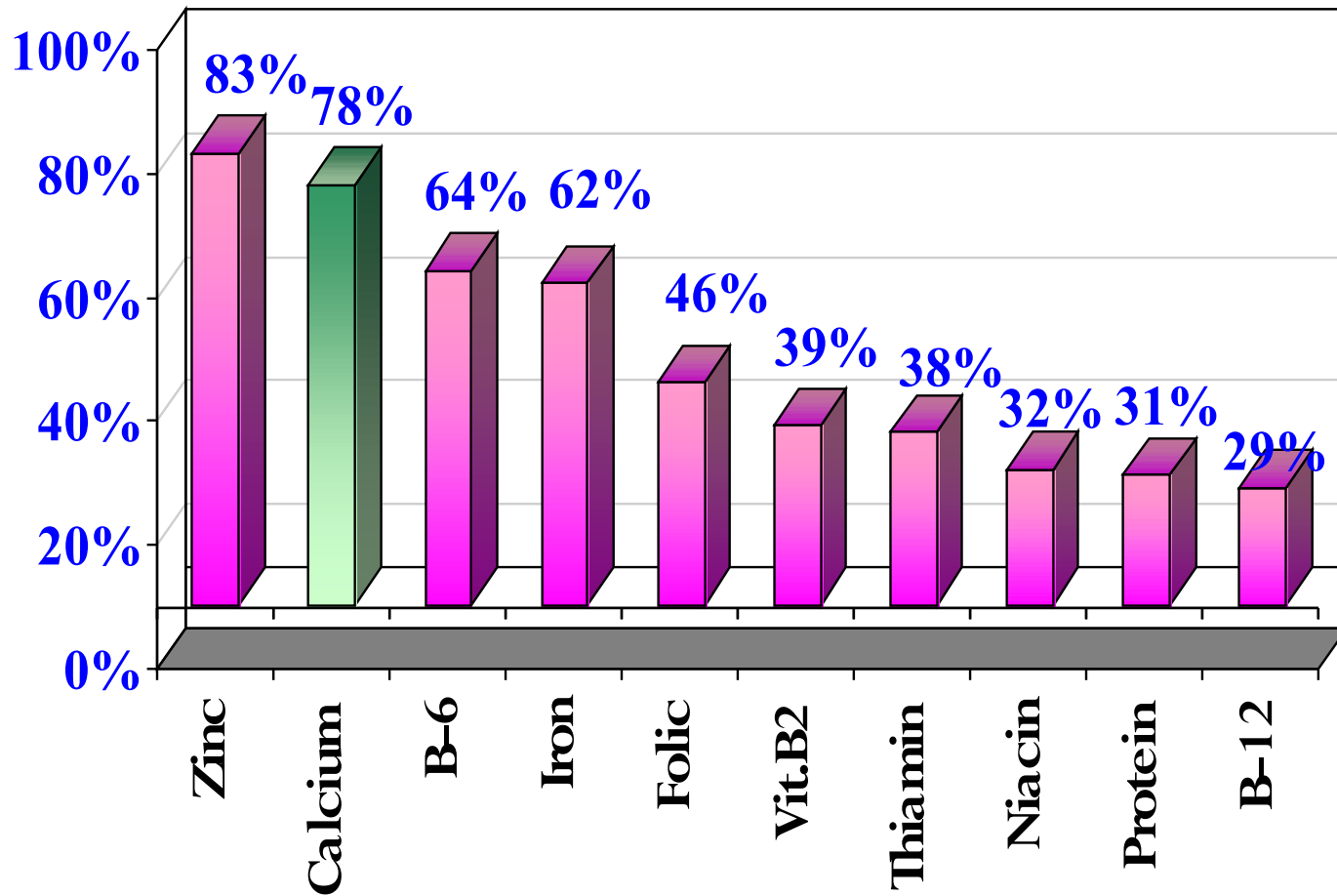
Hospital Costs Vs Nutritional Status (admissions)

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

	Nutritional Risk Gp.	Not at Risk Gp.	Other Studies
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

Percent of Women Over 20 yrs. Who Do Not Meet RDA



Calcium and Hip Fractures

- 14% women over 50 years have osteoporosis
- 30% of persons with hip fractures go into a nursing home within a year
- 20% of persons die within one year of a hip fracture
- Estimated 1,500,000 fractures and 300,000 hip fractures per year
- Estimated \$10-15 billion savings in direct costs

Calcium and Hip Fractures

- Meta-analysis of 3 DBP clinical trials, and analysis of NHANES data.
- Analysis of hospital discharge for hip fractures and costs from Gov. data
- Supplements of 1200mg Ca. used for 34 months.
- Results using 1995 data:

~50% reduction
in fractures

- 290,327 patients >50 years at a cost of \$5.6 billion
- Estimated 134,764 fractures and \$2.6 billion saved

Diabetes Facts

- One quarter of obese people have undetected diabetes, 150 million people globally, of which 90 million type II, and expected to double in next 25 years.
- Diabetes costs about \$100 billion annually in USA
- Diabetes leads to a cascade of disease such as CVD, nerve damage, cataracts, kidney disease and amputations
- 20-30% of children in USA overweight leading experts to predict a future diabetes epidemic

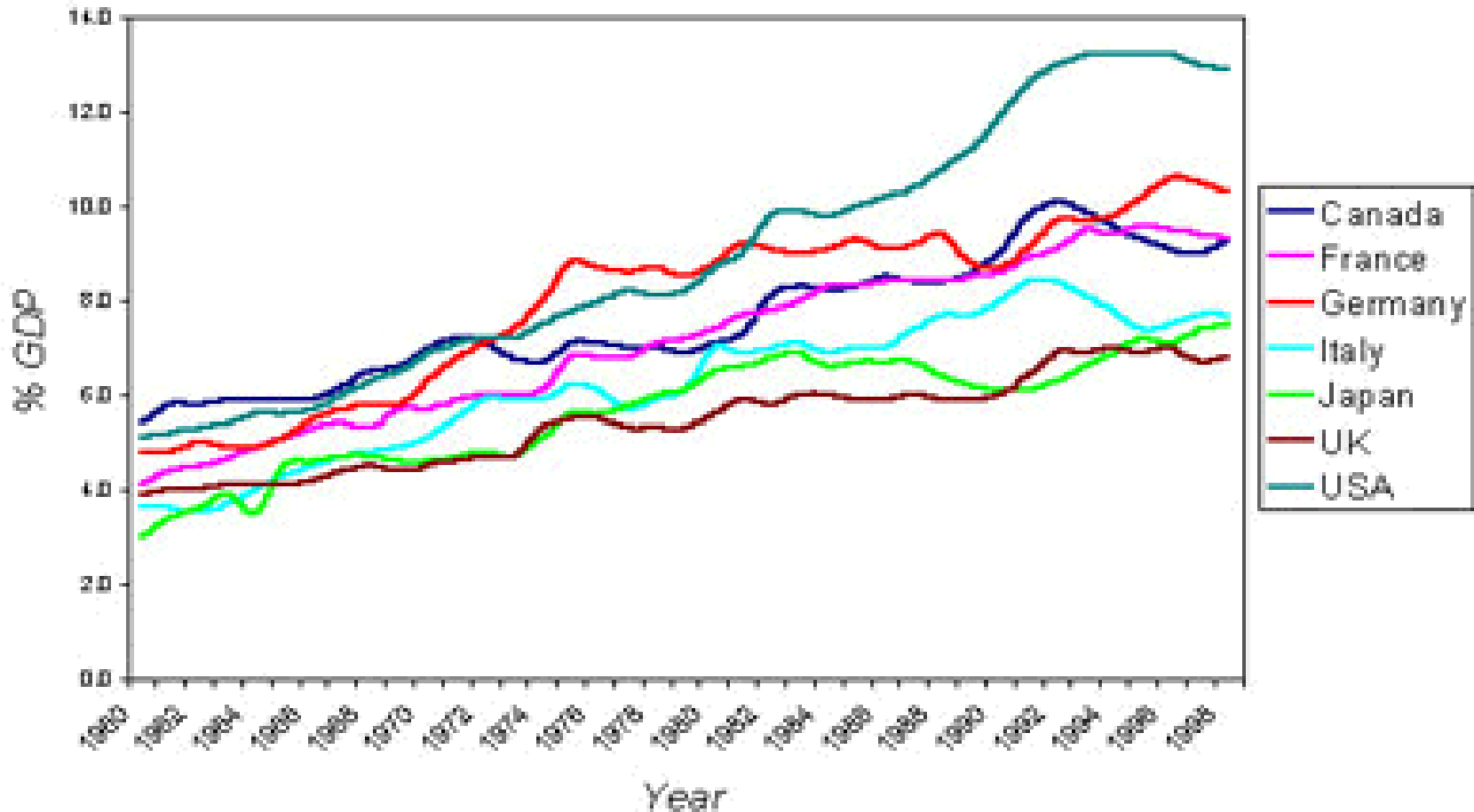
Diabetes Trial for Cost Savings

- Type II diabetes glycemic control trial in an HMO (n=4744)
- No new drugs added to regimens and lifestyle a major contributor
- 1% Improvement in glycemic control over four years lead to statistically significant savings.
- Savings were between \$685-950 per patient per year
- Based on 17 million Type II diabetics in US, this amounts to annual savings:

\$ 1 1 . 6 - \$ 1 6 . 1 5 billion savings per year.

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 (\$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)

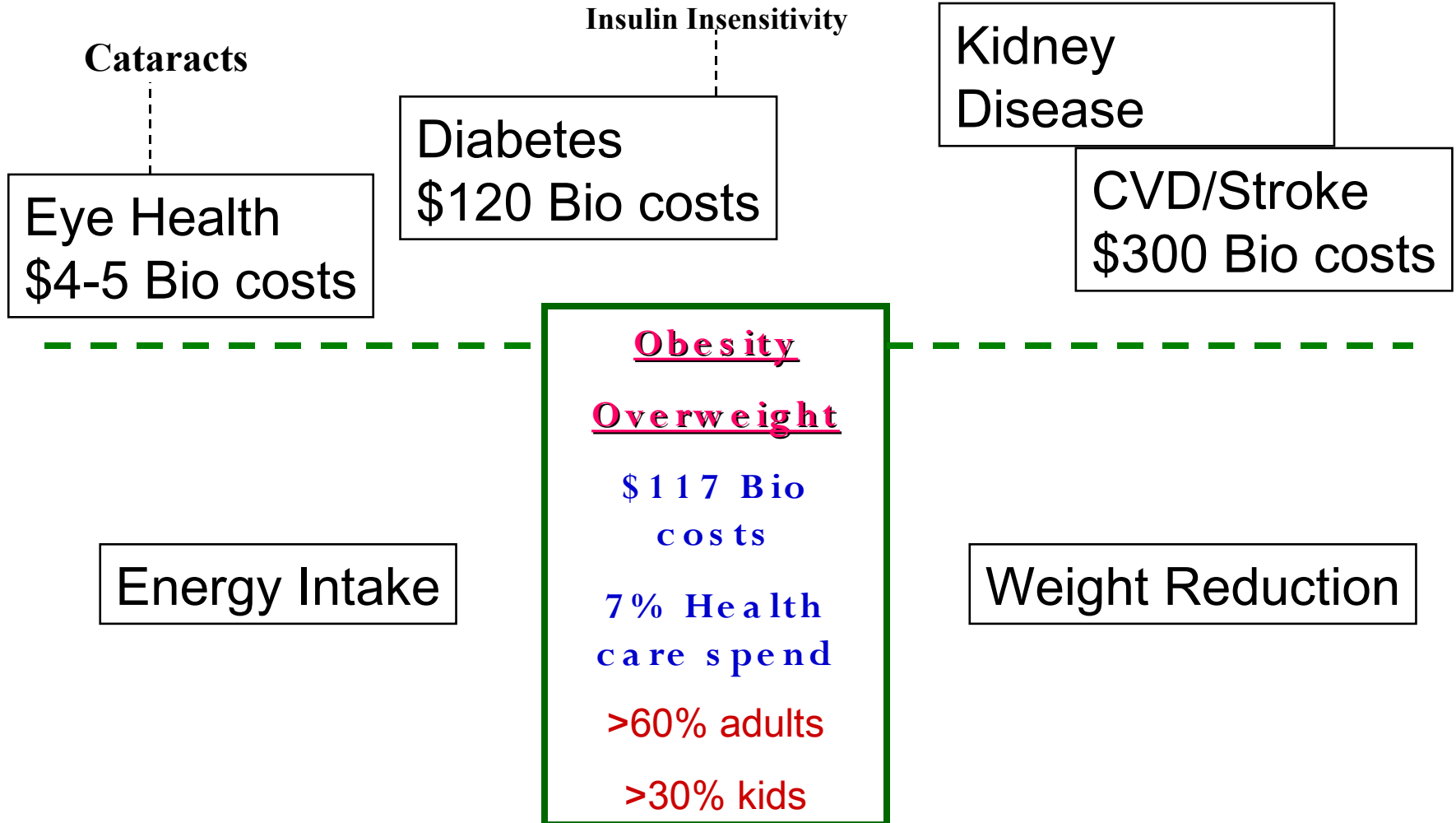
<u>Cause</u>	<u>Annual Costs</u> <u>Billions</u>	<u>% Diet Related</u>	<u>Potential Saving Bio</u>
CHD	\$13	40-50%	\$6
Cancer	\$20	80%	\$8
Diabetes	\$10	35-50%	\$1
Dementia's/Alz	\$5-6	?	n/a
Kidney	\$3	?	n/a
Arthritis	\$11	20%	\$0.5
Psychiatric	\$3	?	n/a
Other	\$44		
TOTAL	\$ 100		\$ 19 Billions

Per Capita spending; \$3,174, Seniors \$10,834

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

Obesity the Root Cause of Many Diseases.

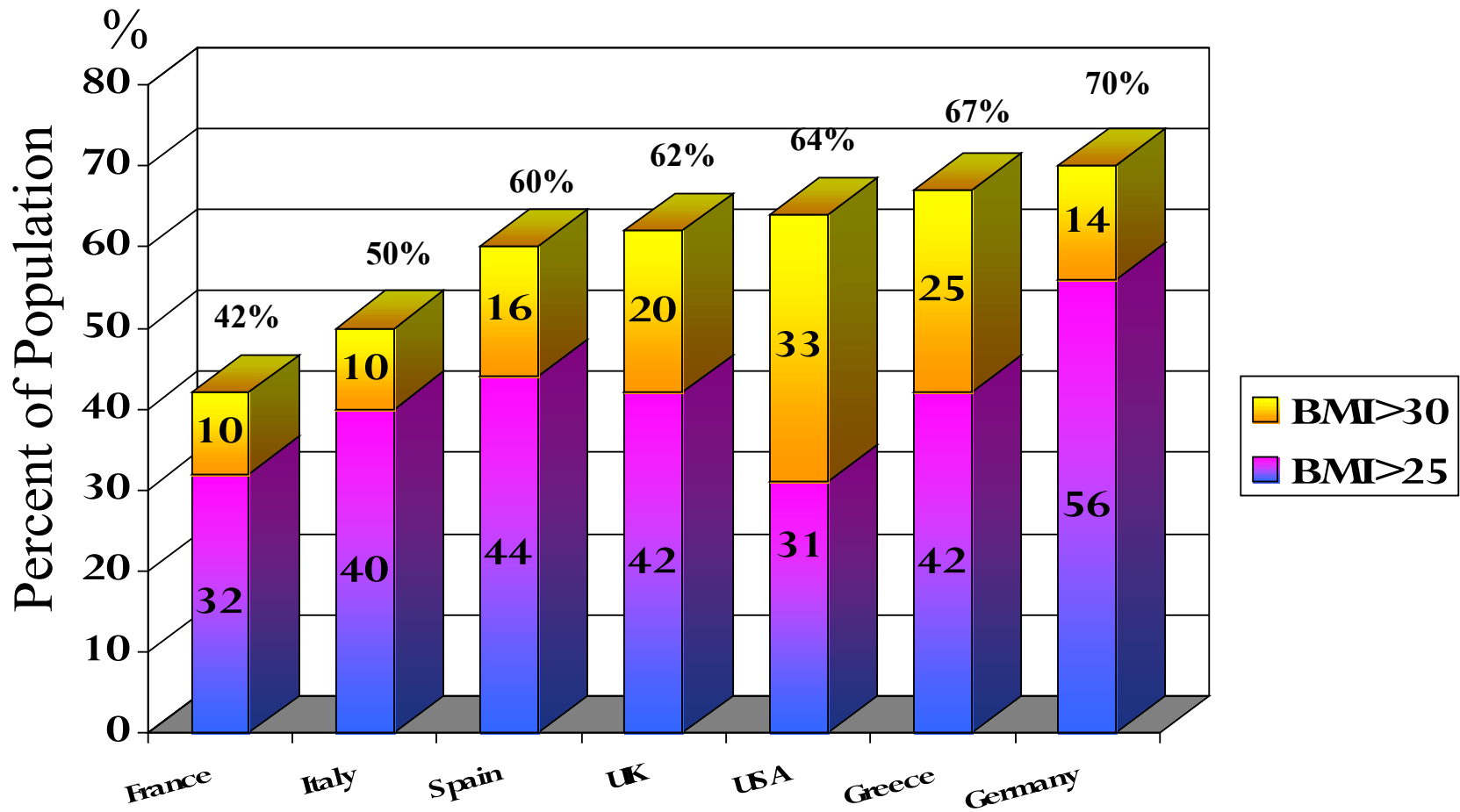


Costs Associated with Obesity and Inactivity in USA (1995)

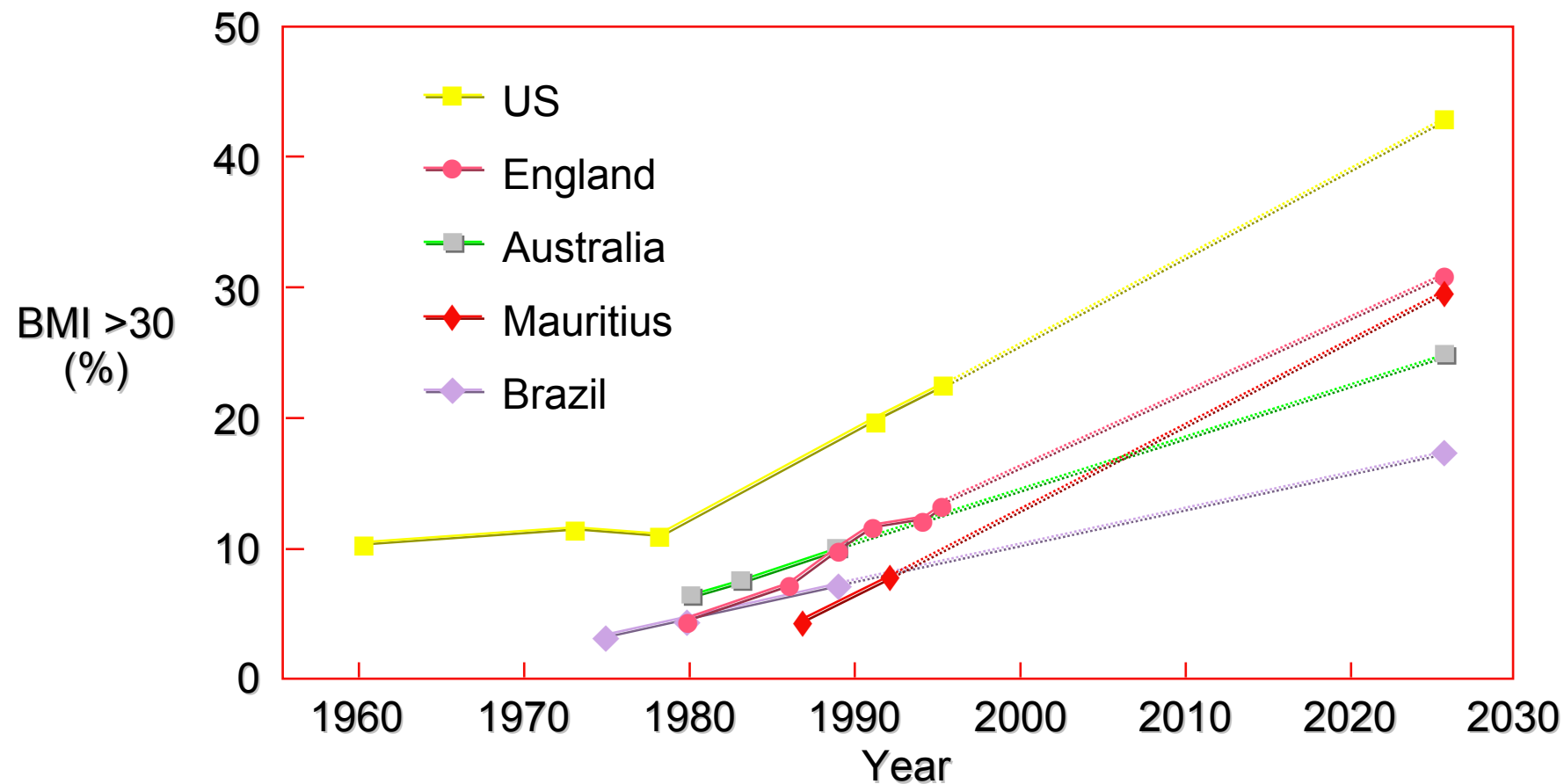
	<u>Inactivity</u>	<u>Obesity</u>
Diabetes II	\$6.4	\$36.6
CHD	\$8.9	\$16.2
Hypertension	\$2.3	\$7.6
Gall Bladder	\$1.9	\$4.3
Cancer		
Breast	\$0.38	\$0.53
Colon	\$2.0	\$0.89
Osteoporosis Fractures	\$2.4	\$3.6
<hr/>		
Total Billions	\$24.3	\$70.0 billion
% of Health Costs	2.4%	7.0%

% of Health Costs Other Sources/Countries:USA	5.0%
France	2.0%
NL	4.0%
Austral.	2.0%

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>.

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?

Reductions in Mortality of Fruit Eaters in UK

- 24% reduction in heart disease
- 32% reduction in stroke death
- 21% reduction in all cause death

Rationale: High content Vit. C for antioxidant protection; Vit. C protection of Vit. E; carotenes or other nutrients

Nutritional Trends

Understanding consumer's health needs is the key!

- Health concerns from an aging population
- Demand for healthier food and drinks
- Growing awareness of “positive health” from diet
- Increasing demands for dietary supplements
- Expectation of a longer, more active life
- Interest in self-diagnostic/feedback in illness prevention
- Growing interest in products that may reduce the symptoms of aging

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%)

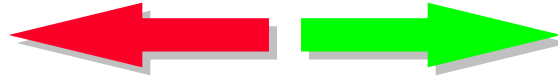
Arthritis (66%)

Alzheimers (54%)

Cataracts (50%)

Physician Comments to Patients Regarding Various Supplements

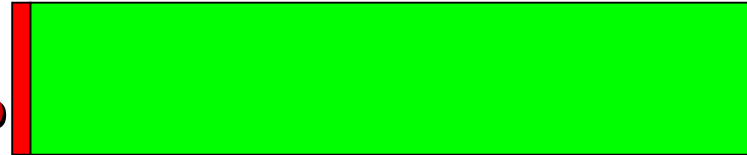
NEGATIVE



POSITIVE

Vitamins / Minerals

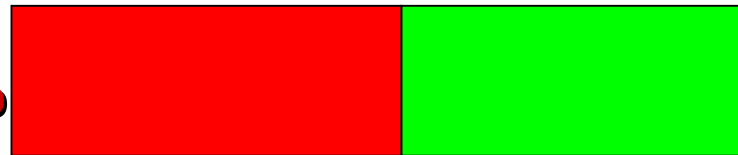
2%



83%

Herbal Supplements

31%



28%

Homeopathic Remedies

37%

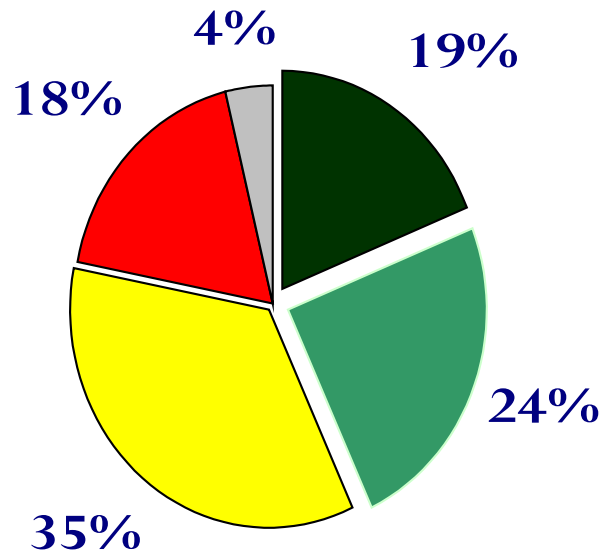


13%

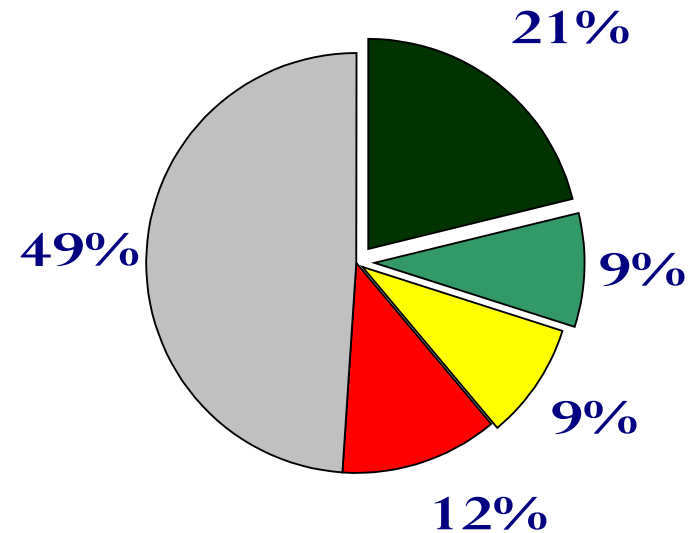
Bone Function

Consumers Attitude - Action

Osteoporosis Concern



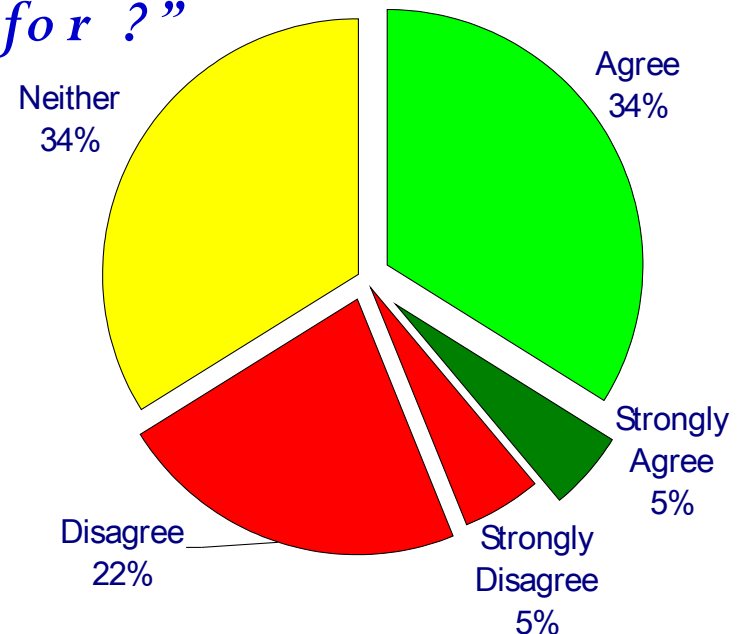
Calcium Fortified OJ



Consumer Comments on Fortification Premiums

“Are foods and beverages that are fortified with extra nutrition worth paying a slight premium for ?”

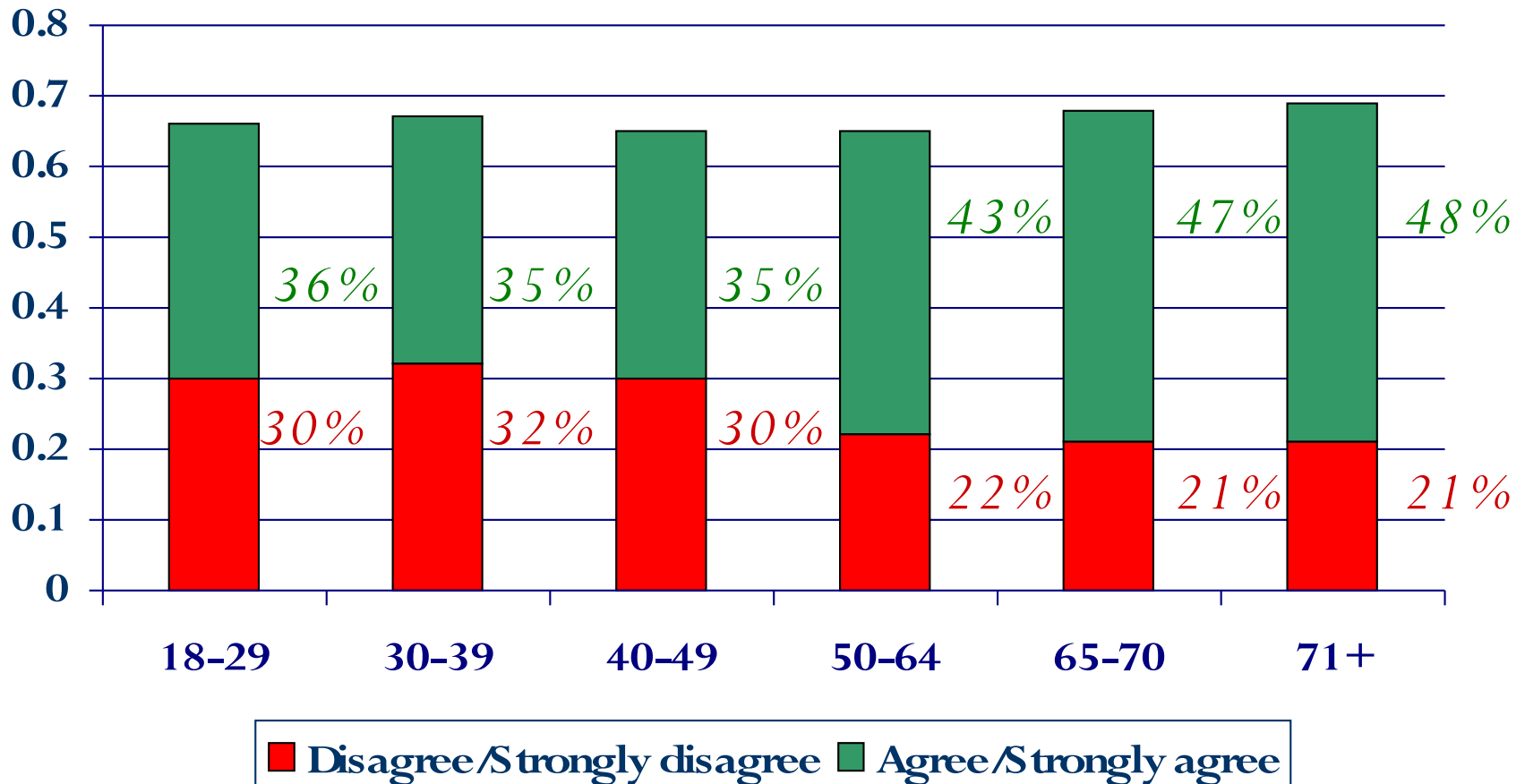
39% of shoppers agree.
25% disagree.



One RDA for ALL Vits. and Minerals costs less than ONE CENT per day !

Fortification Premium

“Are foods and beverages that are fortified with extra nutrition worth paying a slight premium for?”



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

Integrated Healthcare

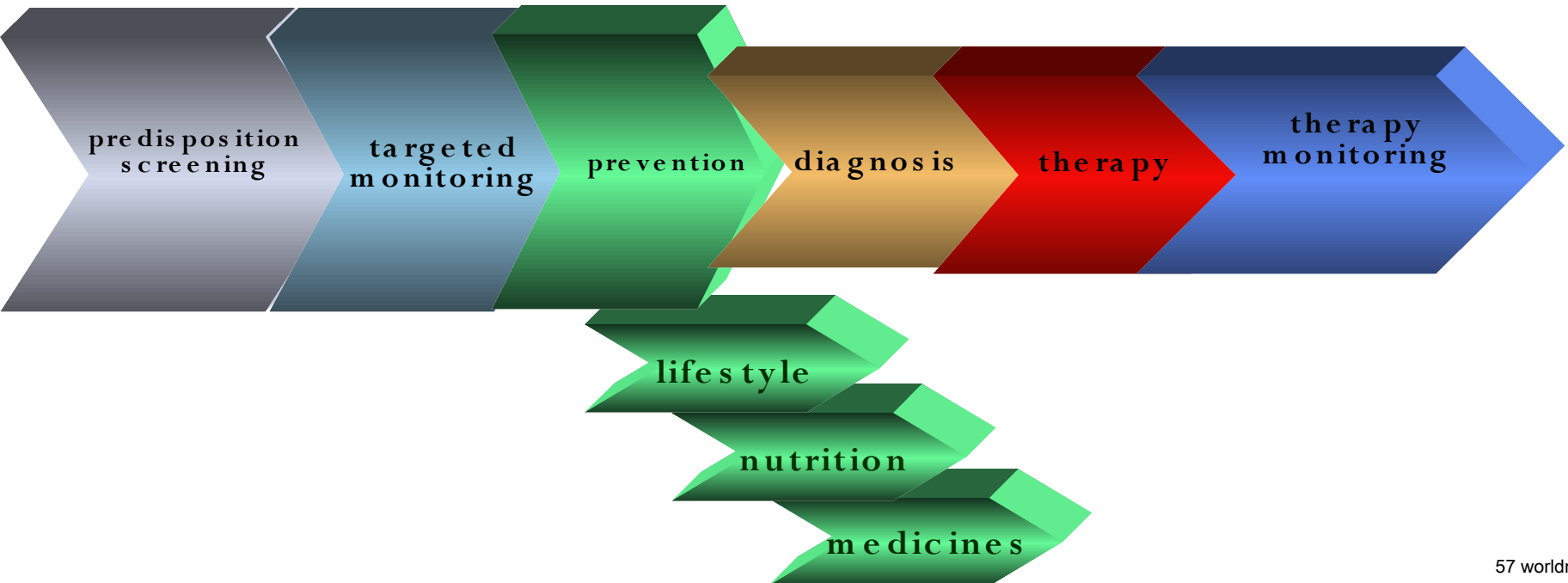
Concepts

from

today ...



...into the



Health Economics and Nutraceuticals

- 1988 6 health economists in entire pharma industry
- 1998 600, today >1000
- Governments see rising health costs but demand proven value for money. “Customers” buying outcomes, rather than treatments.

CLINICAL TRIALS DATA

Leading targets should be the chronic/expensive to treat diseases: CHD, Hypertension, asthma, diabetes, obesity, OA, GI conditions, CNS

Who will pay: Gov., Health Ins ce, GP, Patient?

More countries have treatment guidelines, formularies, HMO's same.

Health Economics and Nutraceuticals

Where do Functional Foods fit in?

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

Guidelines for Data Analysis Use

- Well controlled, large clinical trials preferably double blind placebo controlled, with statistical analysis
- Studies should be powered for analysis
- Epidemiological studies useful as supporting data
- No animal studies, except for mechanistic studies

**FDA Rule #1: “In God We Trust, Everyone else
brings data” !**

The Functional Food Industry: It All Depends on Your Point of View!

**Is this the
beginning of a
great story

OR

the end of a great
experiment?**



INDUSTRY OF WELLNESS FOODS

LEGISLATION/REGULATION

CONSUMER AWARENESS

HEALTHCARE COSTS

MEDIA COVERAGE

PROF.INTEREST/SUPPORT

SCIENCE DATA-EFFICACY/SAFETY

High cholesterol? Head for Aisle 3

PETER GORRIE
FEATURE WRITER

Picture grocery shopping on a February day in, say, 2013.

As now, you enter the supermarket, grab a cart, scan the list of specials. But you no longer head directly to the shelves.

Instead, you detour to the diagnosis kiosk. There, someone — preferably someone with a little medical training — pricks your finger to take a blood sample.

In a couple of minutes, you have the test results: "Your cholesterol is high; go directly to Aisle 3:



People prefer to get their health from..

the kitchen cabinet

rather than....

the medicine cabinet