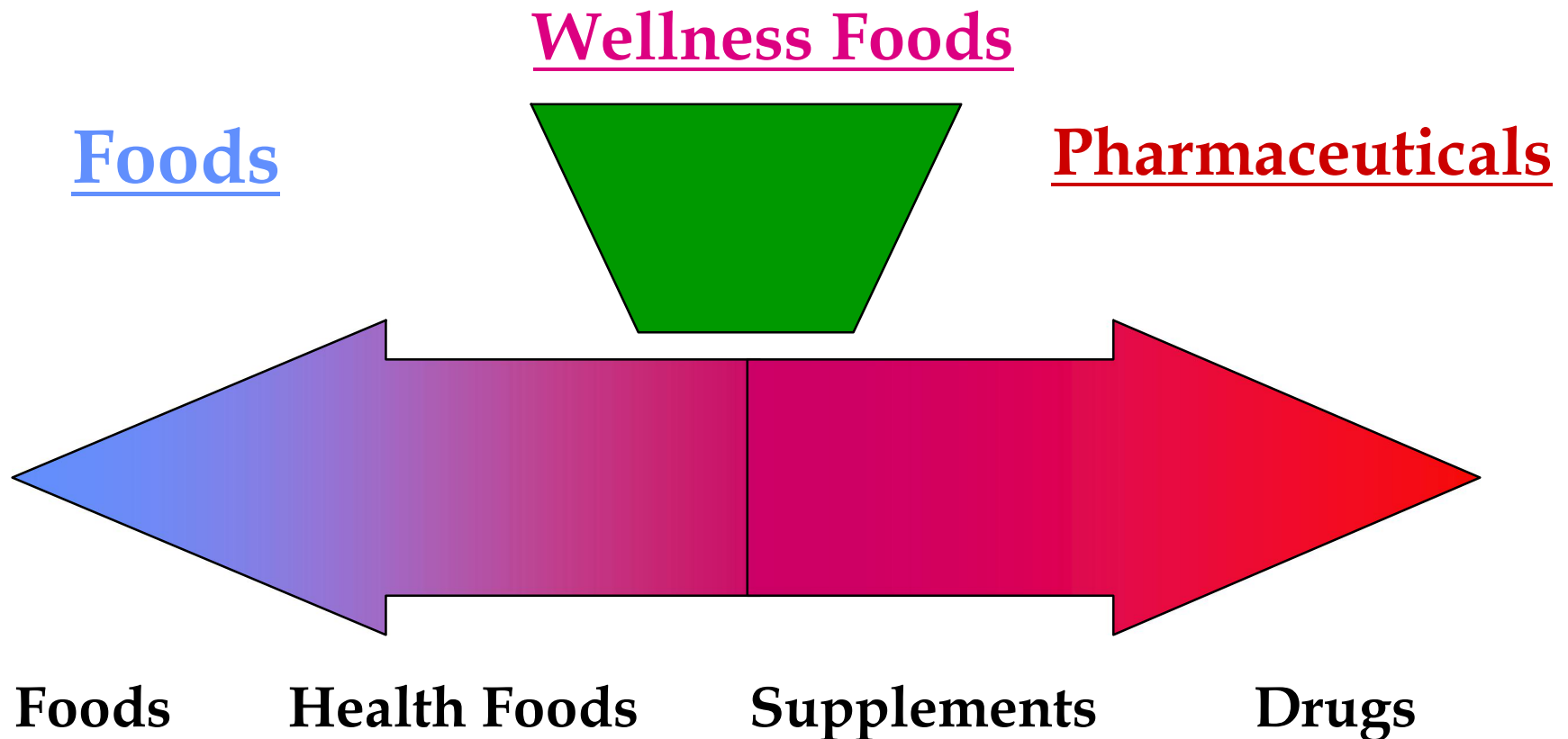


Global Trends in the Functional Food and Nutraceutical Market

Ian Newton,
Director, Business Development & Regulatory Affairs,
Roche Vitamins Inc
New Jersey, USA.

**Saskatchewan Nutraceutical Network
10/29/01**

Wellness Foods Interface



Functional Food

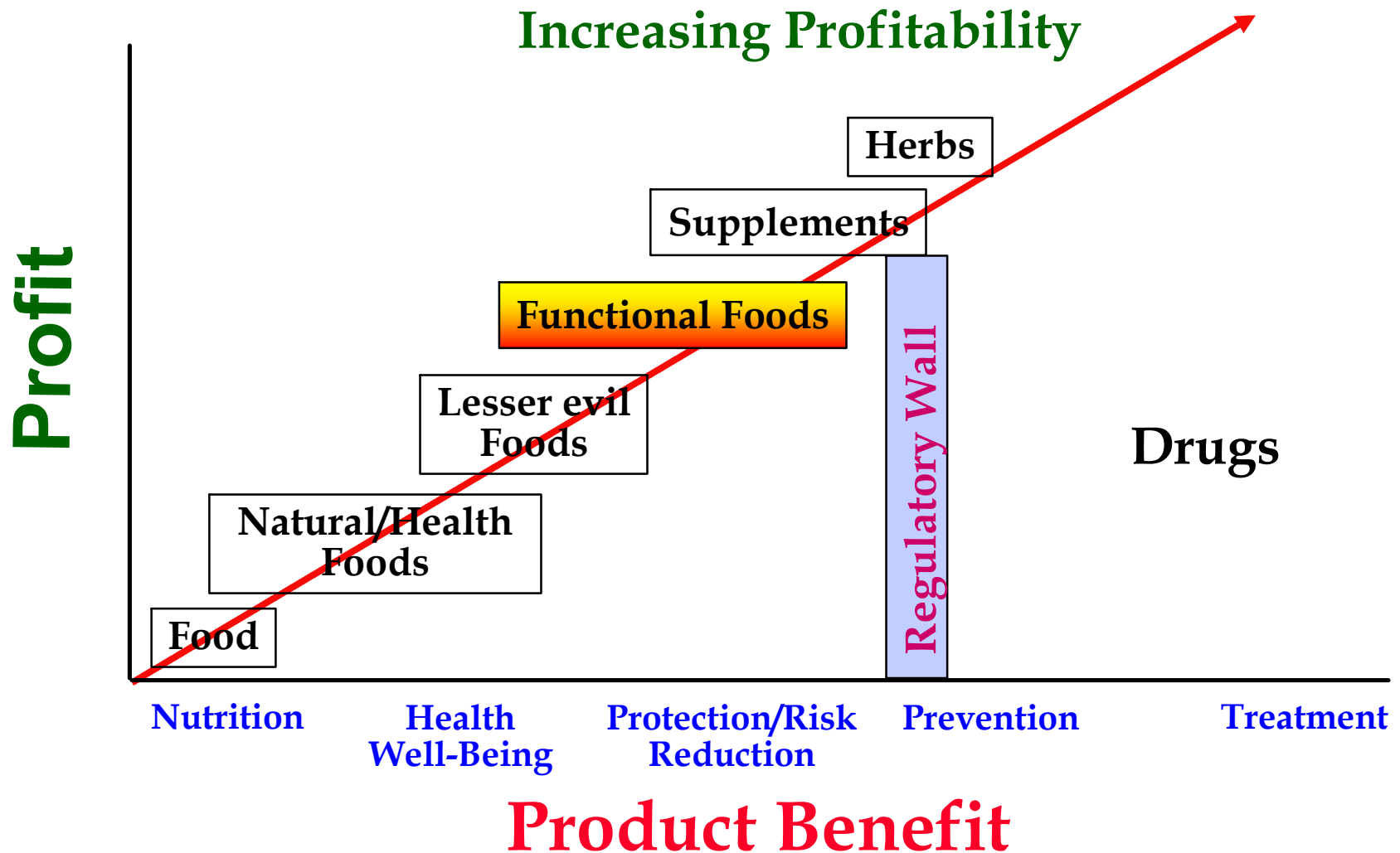
“A product consumed as part of the usual diet with demonstrated physiological benefits and/or the ability to help reduce the risk of chronic disease beyond basic nutritional functions”.

“Foods that, by virtue of physiologically active components, provide health benefits beyond basic nutrition”, or due to the addition of a healthful ingredient.

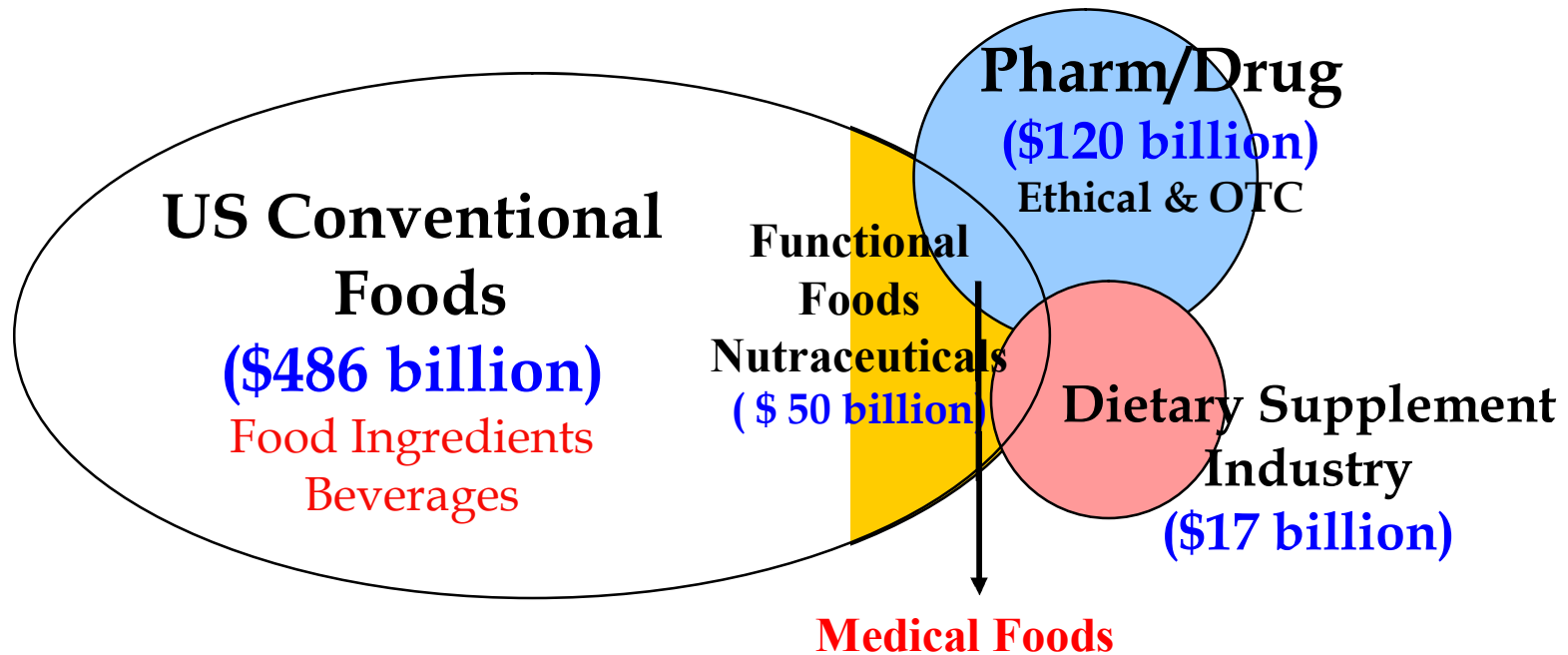
Examples:

- fiber enriched breakfast cereals and bread**
- yogurts acidophilus/bifidus in yogurts/desserts**
- fish oil enriched bread and spreads**
- calcium enriched milk**
- fat replacers in foods**

Foods to Drugs....



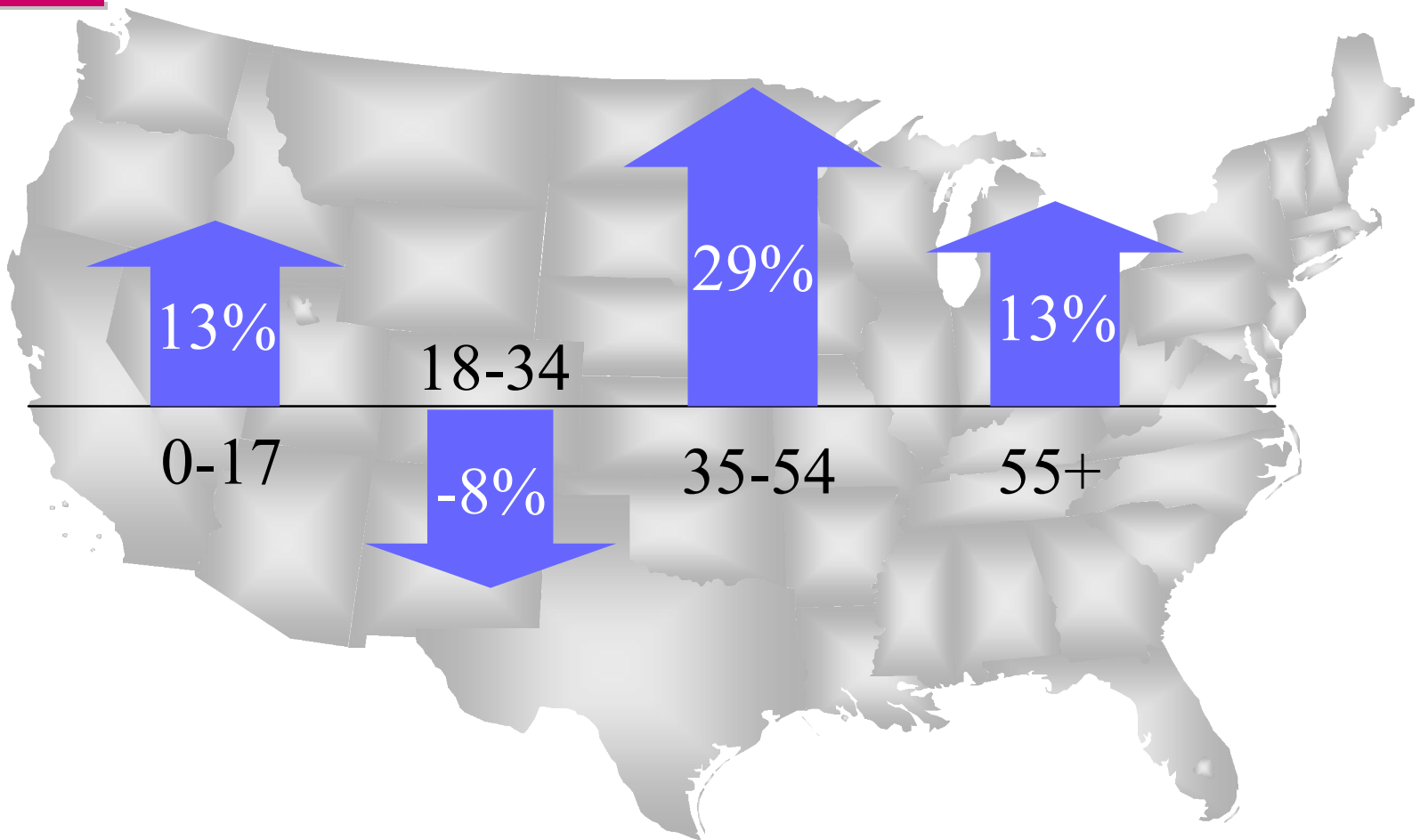
Industries with a Stake in US Dietary Supplements and Nutraceuticals



What are the Fundamental Driving Forces ?

- **Aging Demographics (76 mio Boomers and increased life expectancy)**
- **“Silent” Revolution of Alternative Medicine/Wellness**
- **Changing Attitudes About Food and Health**
95% of U.S. Population Making the “Diet Disease” connection
- **Increasing Scientific Evidence**
- **All foods fast becoming functional foods (inherently healthy ingredients)**
- **Need for growth by food companies**
- **“Life” marketing over “Death” marketing for products**
- **Regulatory framework that is fostering health messages and promotion**

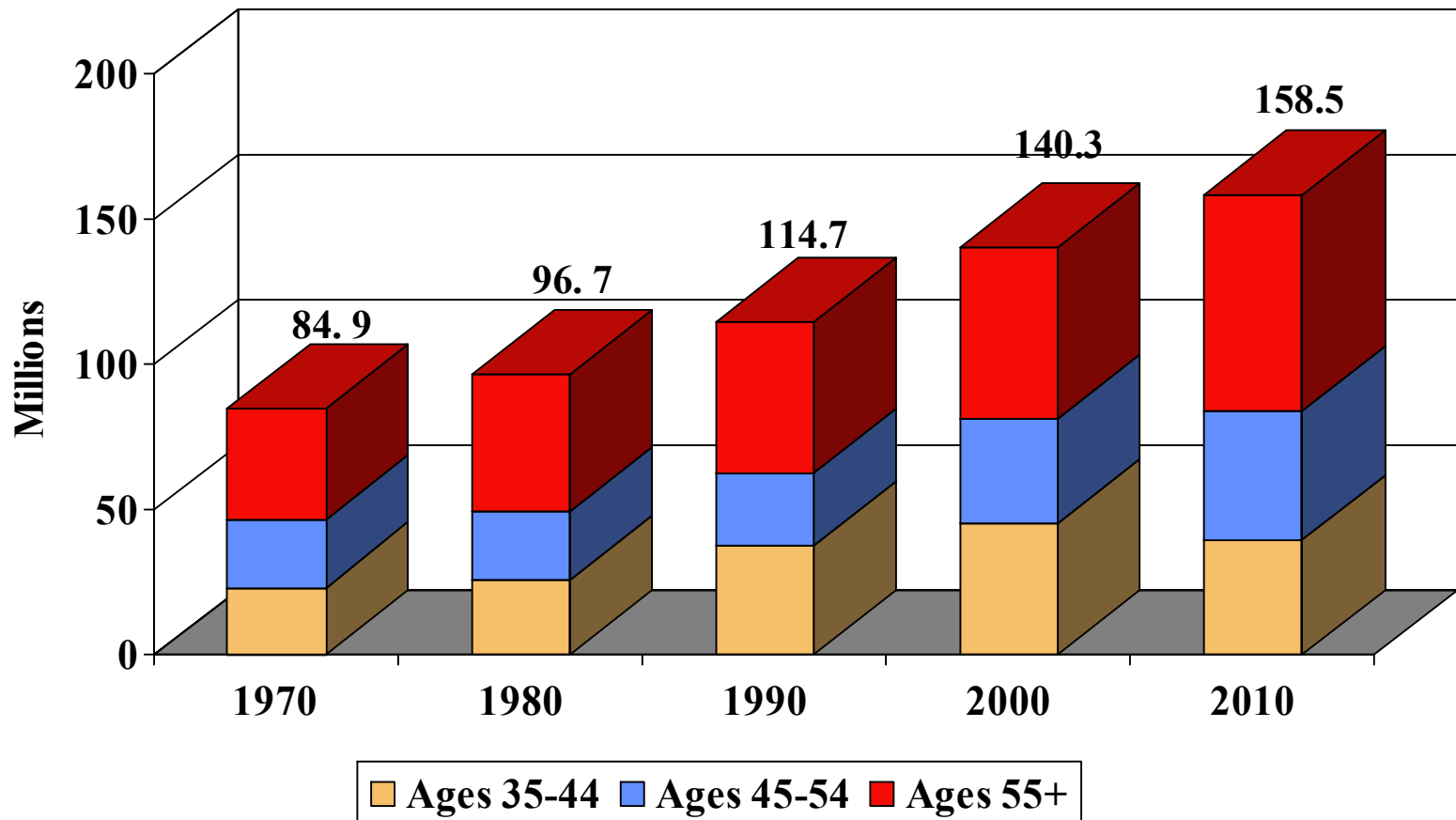
Population Growth Trends 1990 - 2000



Favorable Demographics

An Aging Population

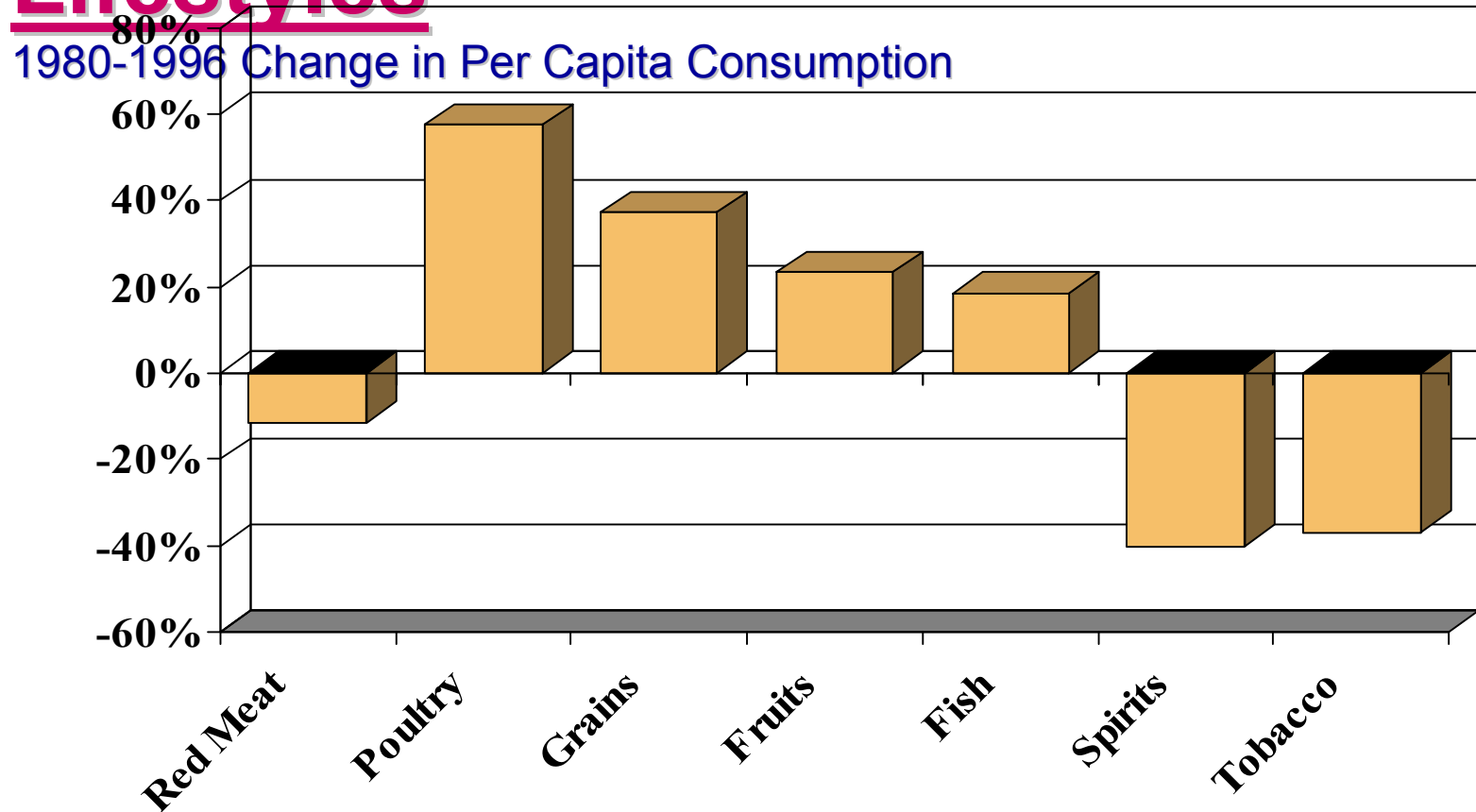
U.S. Population - Ages 35+



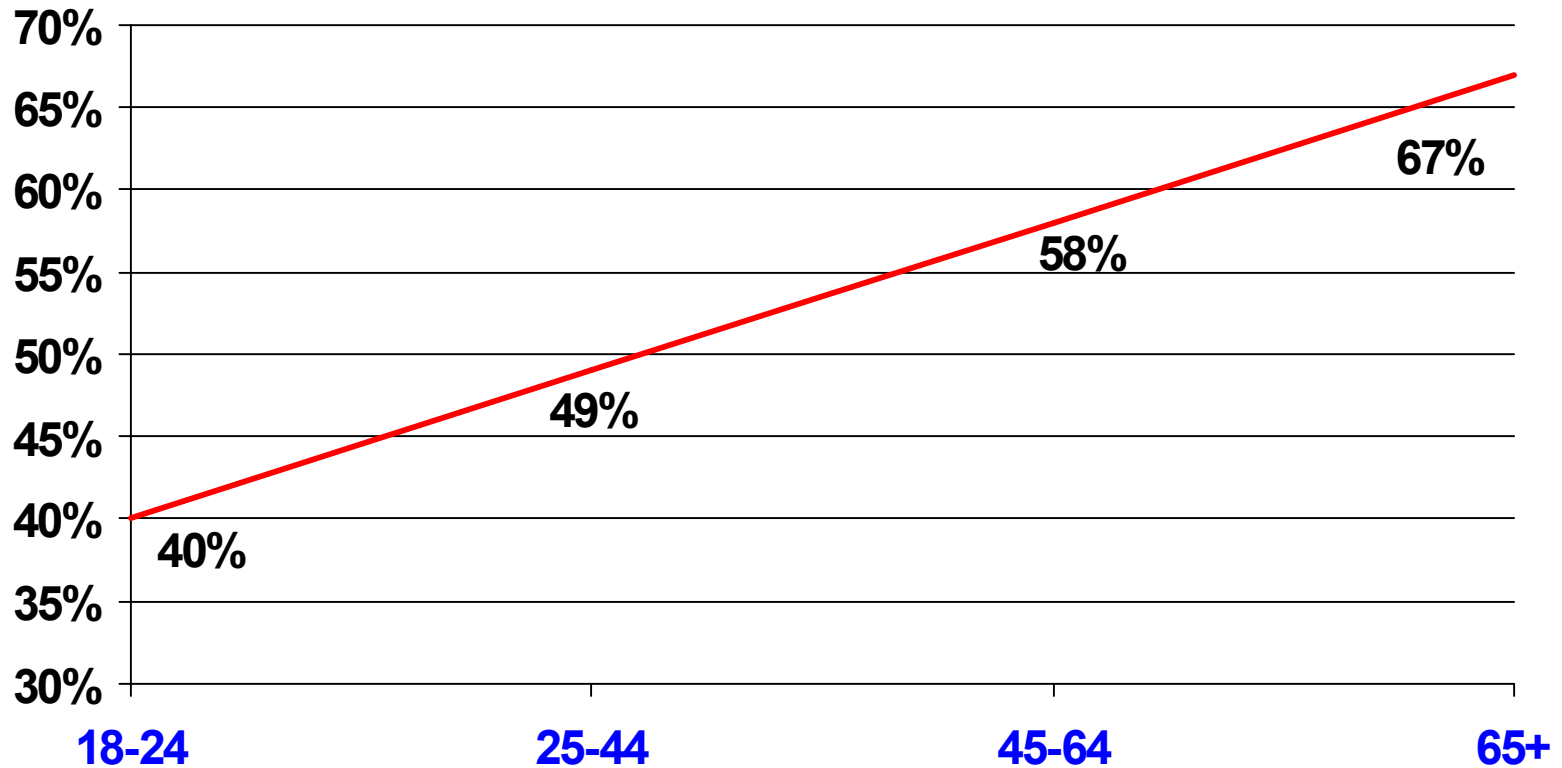
Consumption Patterns

Point to Healthier

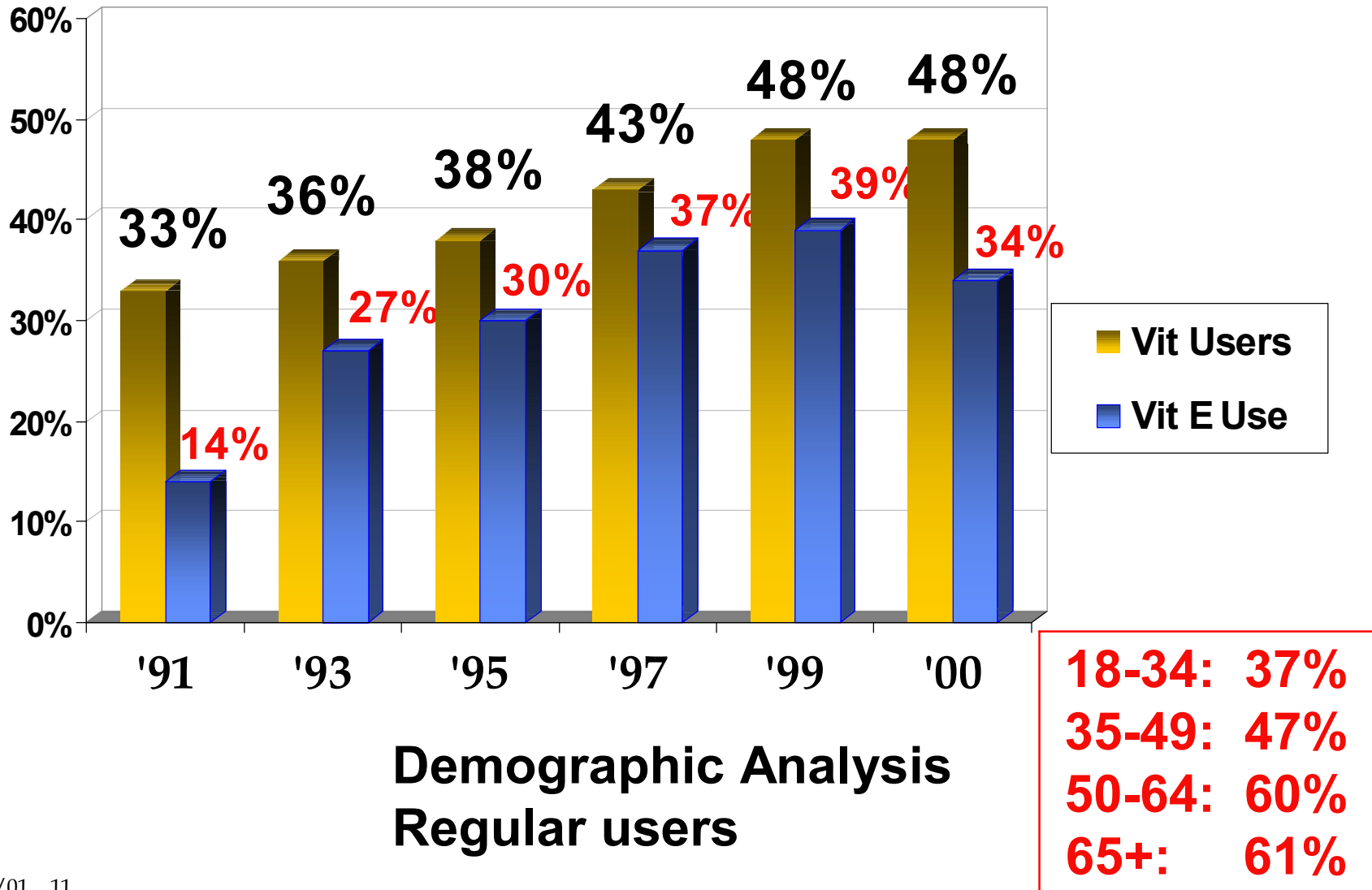
Lifestyles



Nutritional Supplement Usage Increases With Age



Trend in Current Vitamin Use



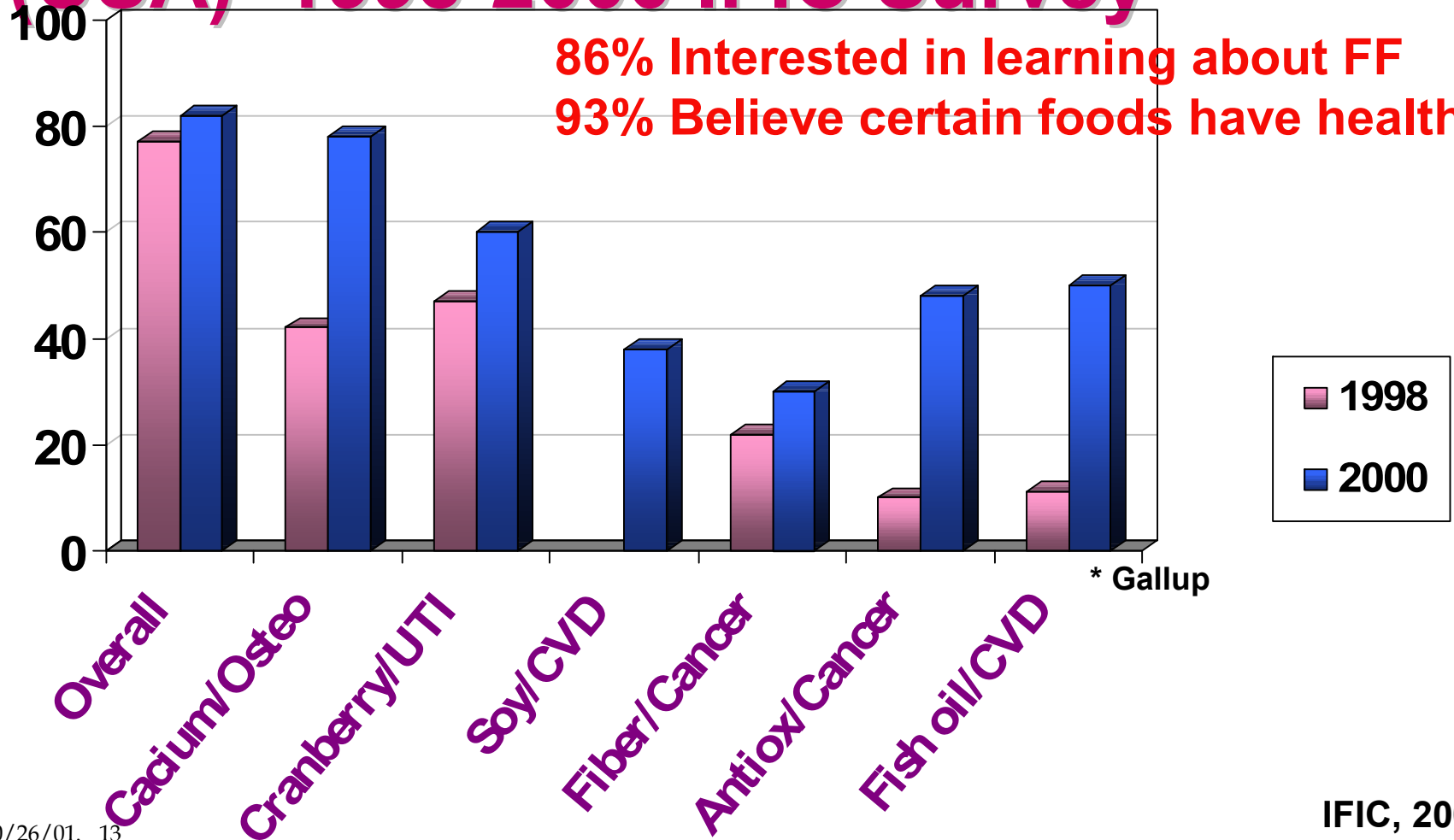
Overall Consumer Health Concerns

- Healthy eyesight 85%
- Cancer 81%
- Fatigue/energy 75%
- Heart disease 75%
- Joint pain/arthritis 73%
- High cholesterol 73%
- Blood pressure 69%
- Stress 68%
- Mental acuity 65%
- Blood triglycerides 65%
- Diabetes 59%
- Emotional stress 56%
- Stomach ulcers 41%
- Migraines 38%
- Psoriasis 29%
- Menstrual cramps 24%

Food/Health Benefit Connection

(USA) 1998-2000 IFIC Survey

86% Interested in learning about FF
93% Believe certain foods have health benefits

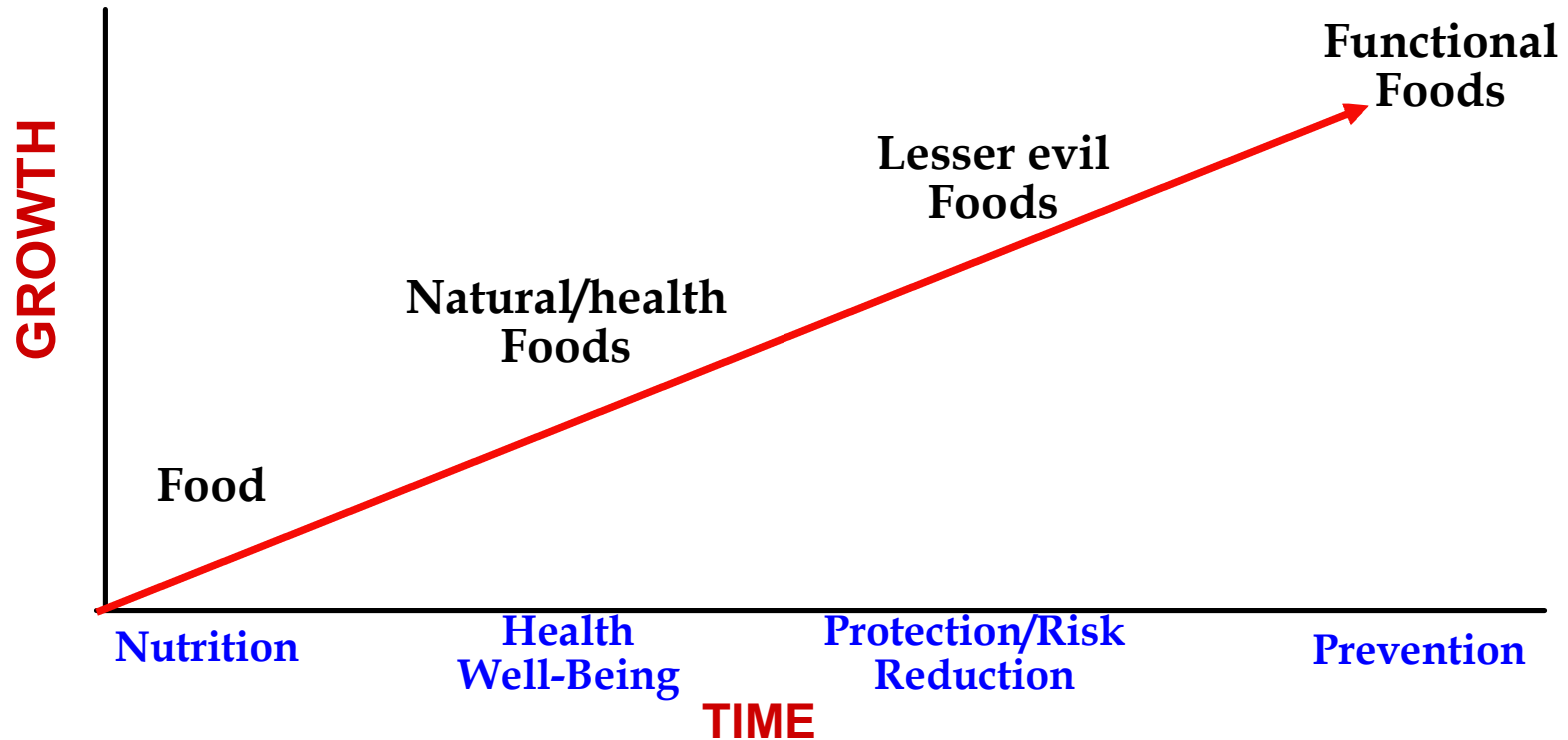


* Gallup

Transformation/Evolution of Foods

Eating Traditional Food → Healthy Eating / Functional Food

Developing Nutrition Science

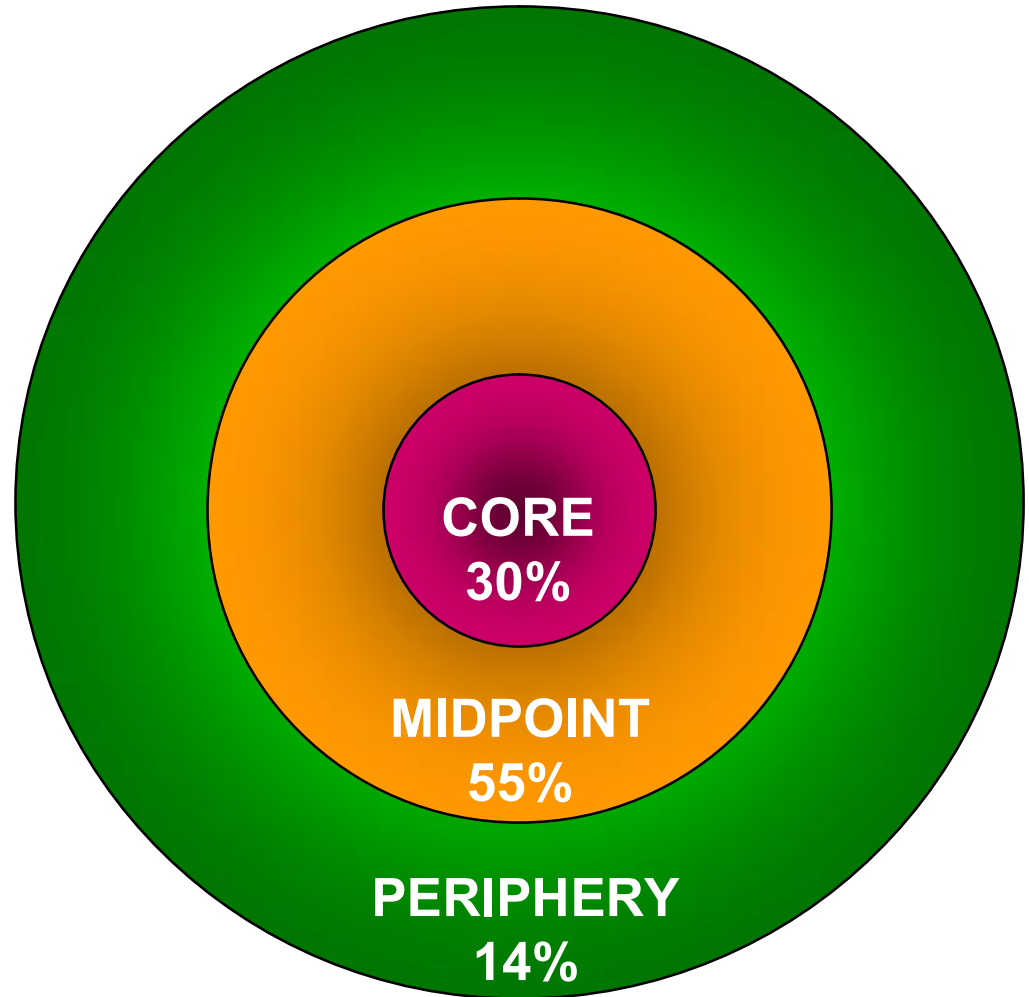


Examples of Food/Eating Evolution

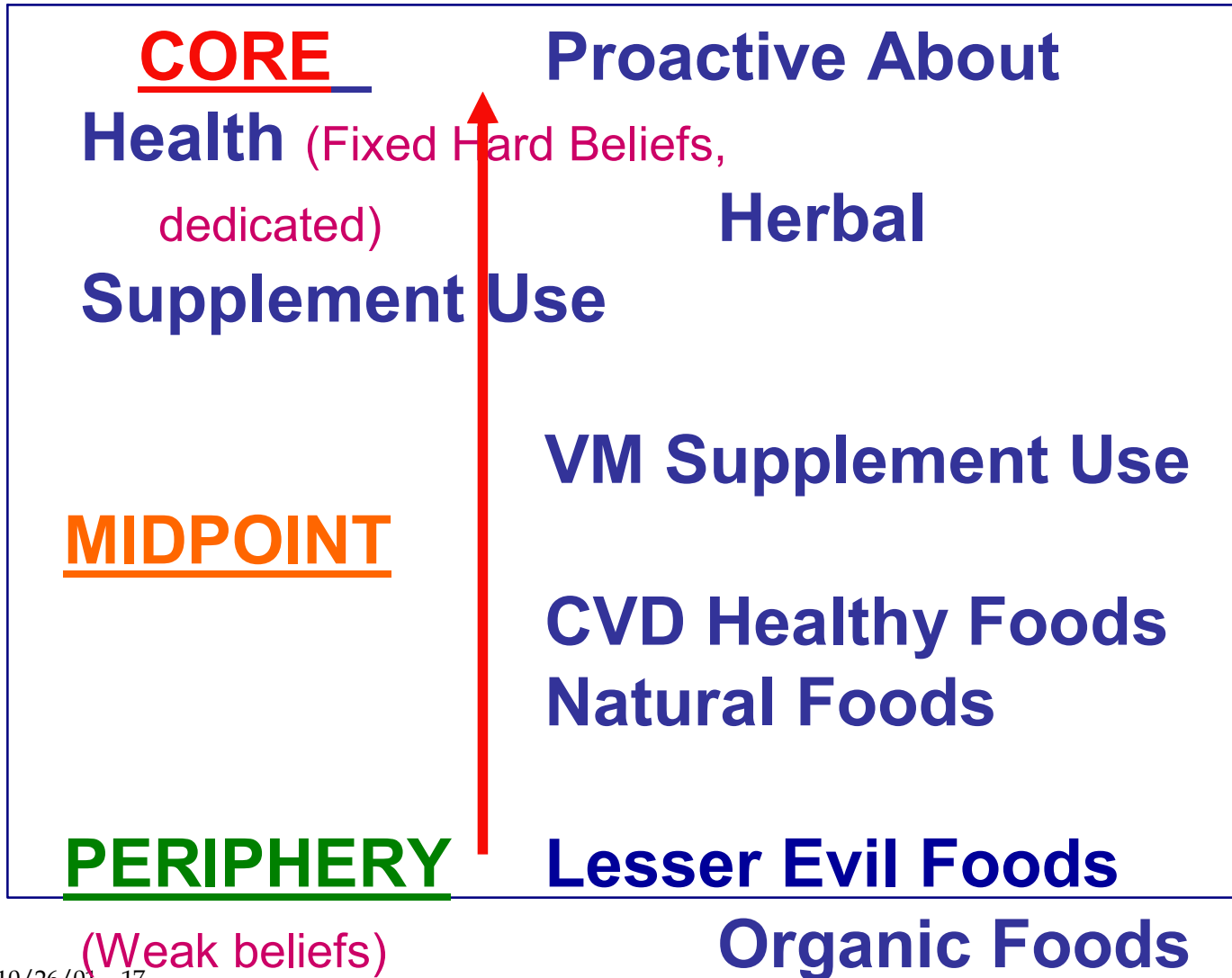
- Orange Juice (vitamins) → Health Drink (Ca, vitamins)
- Energy Bars (Sports persons) → Health Bars (All consumers)
- Calcium Supplements → Viactive Chews
- Dairy products/yoghurt → Health Drinks (Yakult, Actimel, LC-1)
- Spreads → Health Food (Benecol et al)
- RTE Cereals → Health Muesli (Plus fortified)

A Wellness Destination...

- Trend driving individual consumers towards **INDIVIDUAL** wellness regimes
- Factors are: Aging, Time, Information access, Transforming event, Empowerment, Picking own brand
- Movement from Periphery to Core

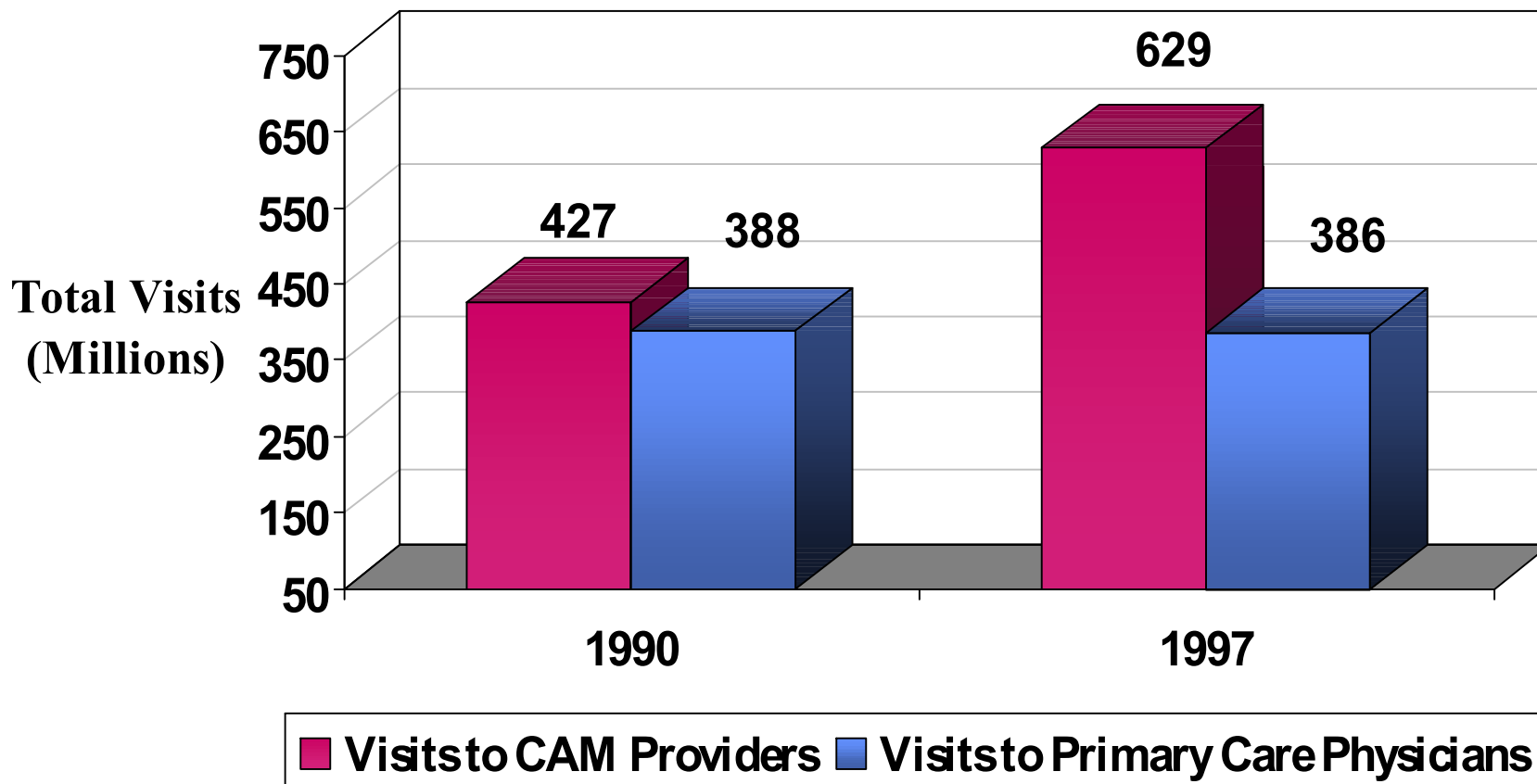


A Wellness Destination...



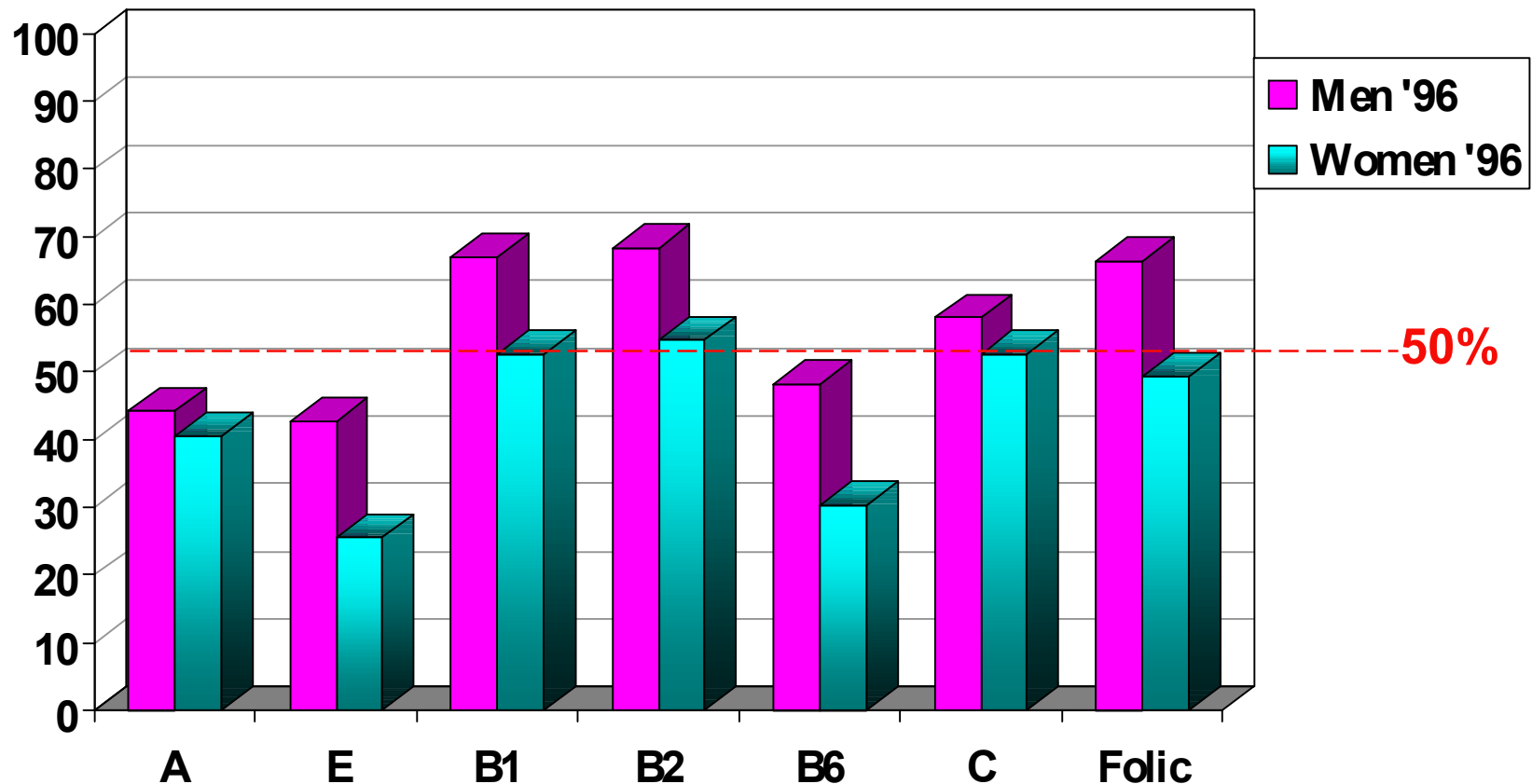
Idea is to move people to the CORE through price, branding, convenience, experience, knowledge

Trends in Visits to CAM* Providers

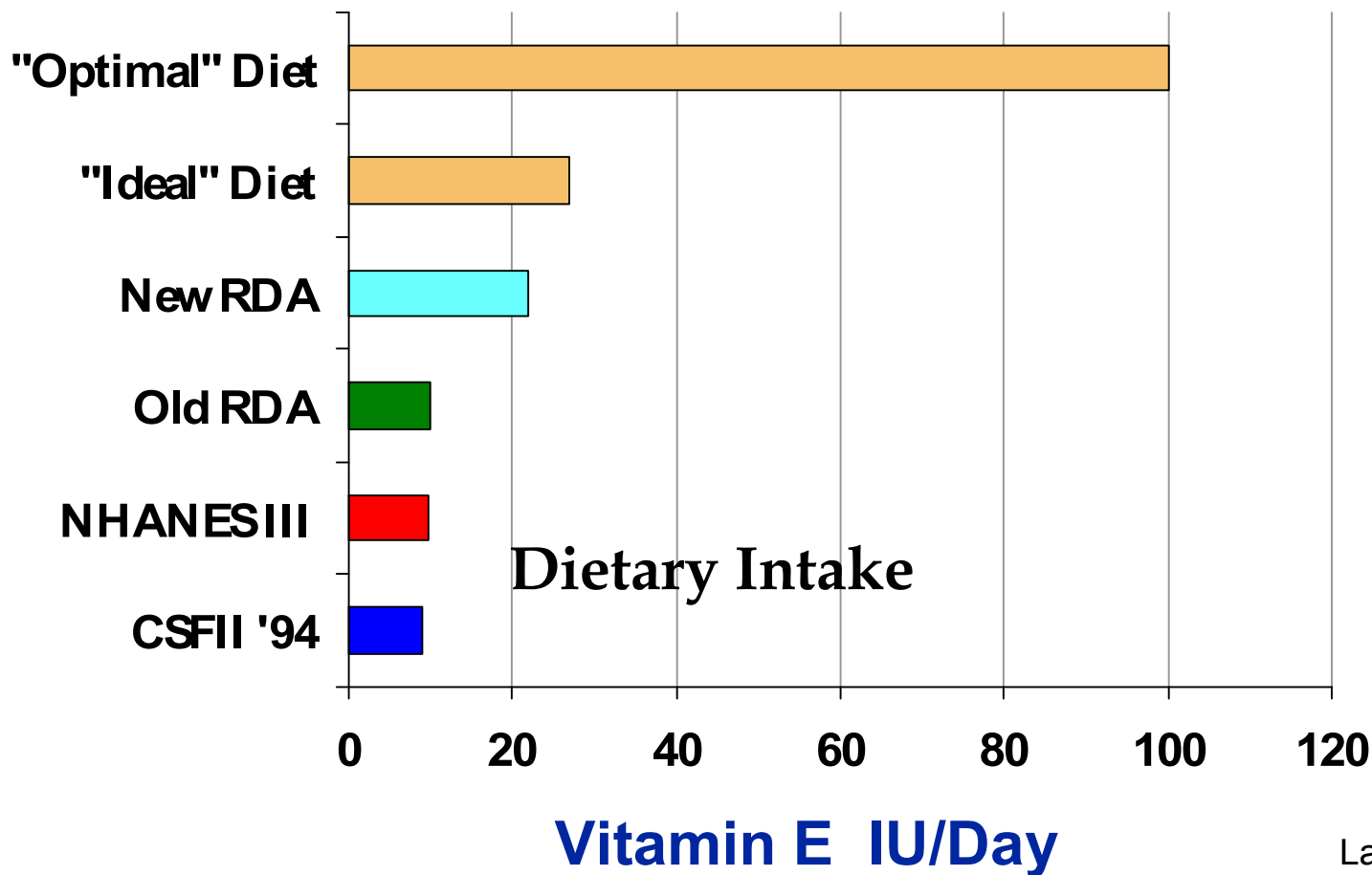


*Complimentary Alternative Medicine

Percentage of Men & Woman in USA Receiving 1 RDA



Comparison of Current Vit. E Intake vs NCI Guidelines ('94/00)

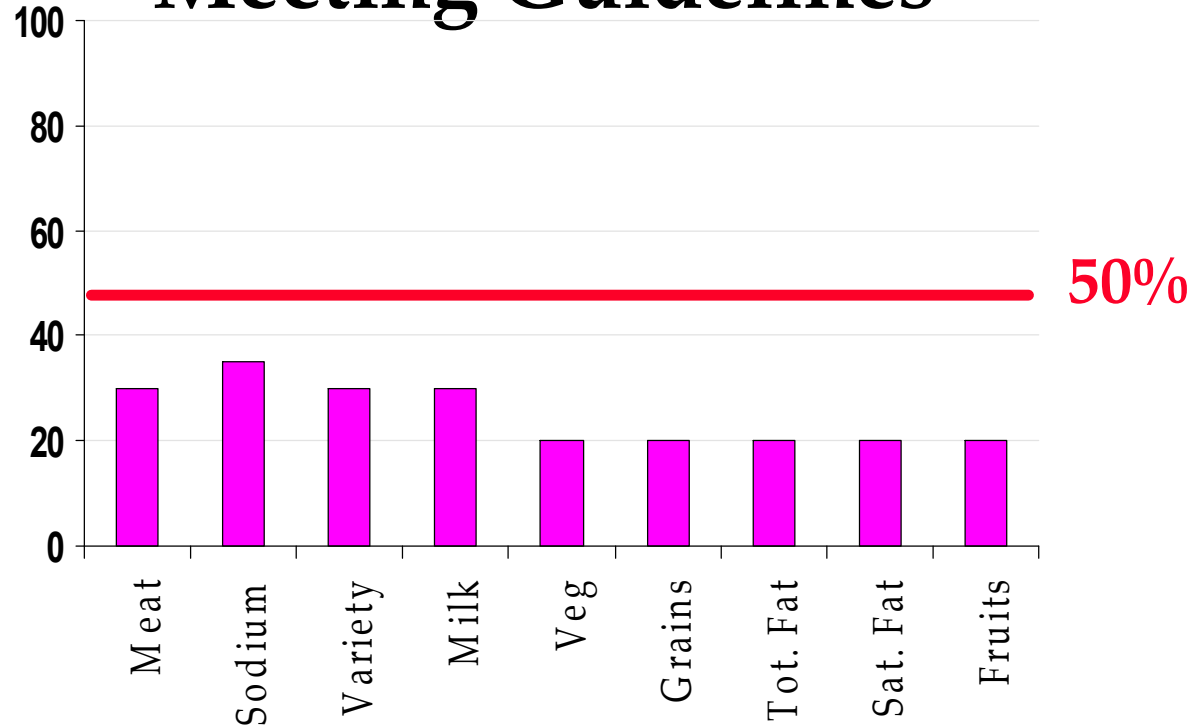


Lachance P. 1994
Block G. Langseth L. 1994
Alaimo et al 1994

Healthy Eating Index (USA)

- <20% met , grains, vegs and fruits guide
- <20% met guide for fat and sat. fat
- <30% met milk and meat guides
- <30% achieved variety guide

Percent of Population Meeting Guidelines



Current Health Claims (15)

<u>Claim</u>	<u>Food</u>	<u>DS</u>
- Calcium and Osteoporosis	X	X
- Saturated Fat and cholesterol and CHD		X
- Fat and cancer		X
- Fiber containing fruit,vegetables,grains and cancer		X
- Fiber containing fruits,vegetables,grains and CHD		X
- Fruits and vegetables and cancer		X
- Sodium and hypertension	X	
- Potassium and blood pressure and stroke		X
- Soluble fiber from psyllium husk or whole oats and CHD		X
X		
- Sugar alcohol and dental decay		X
X		
- Folate and neural tube defects		X
X		

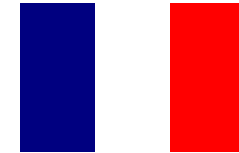
Most Health Desirable Claims by Country

UK



- Gives energy
- Promotes healthy bones
- Promotes healthy teeth
- Reduces risk of breast cancer
- Lowers cholesterol

France



- Gives energy
- Lowers cholesterol
- Increases disease resistance
- Boosts immune system
- Prevents constipation

Germany



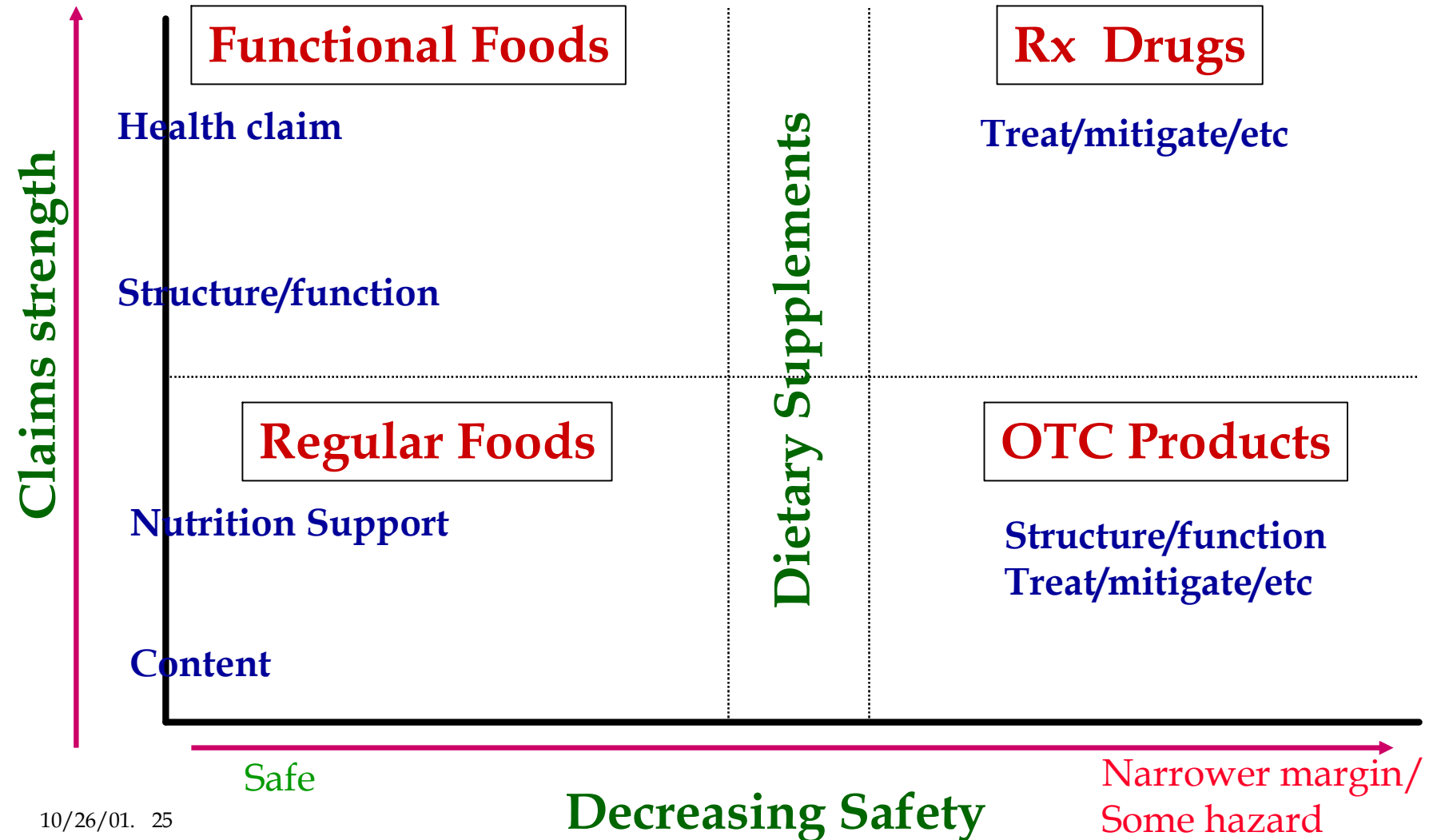
- Boosts immune system
- Promotes healthy bones
- Promotes healthy teeth
- Gives energy
- Promotes healthy gut

Food Regulatory Trends

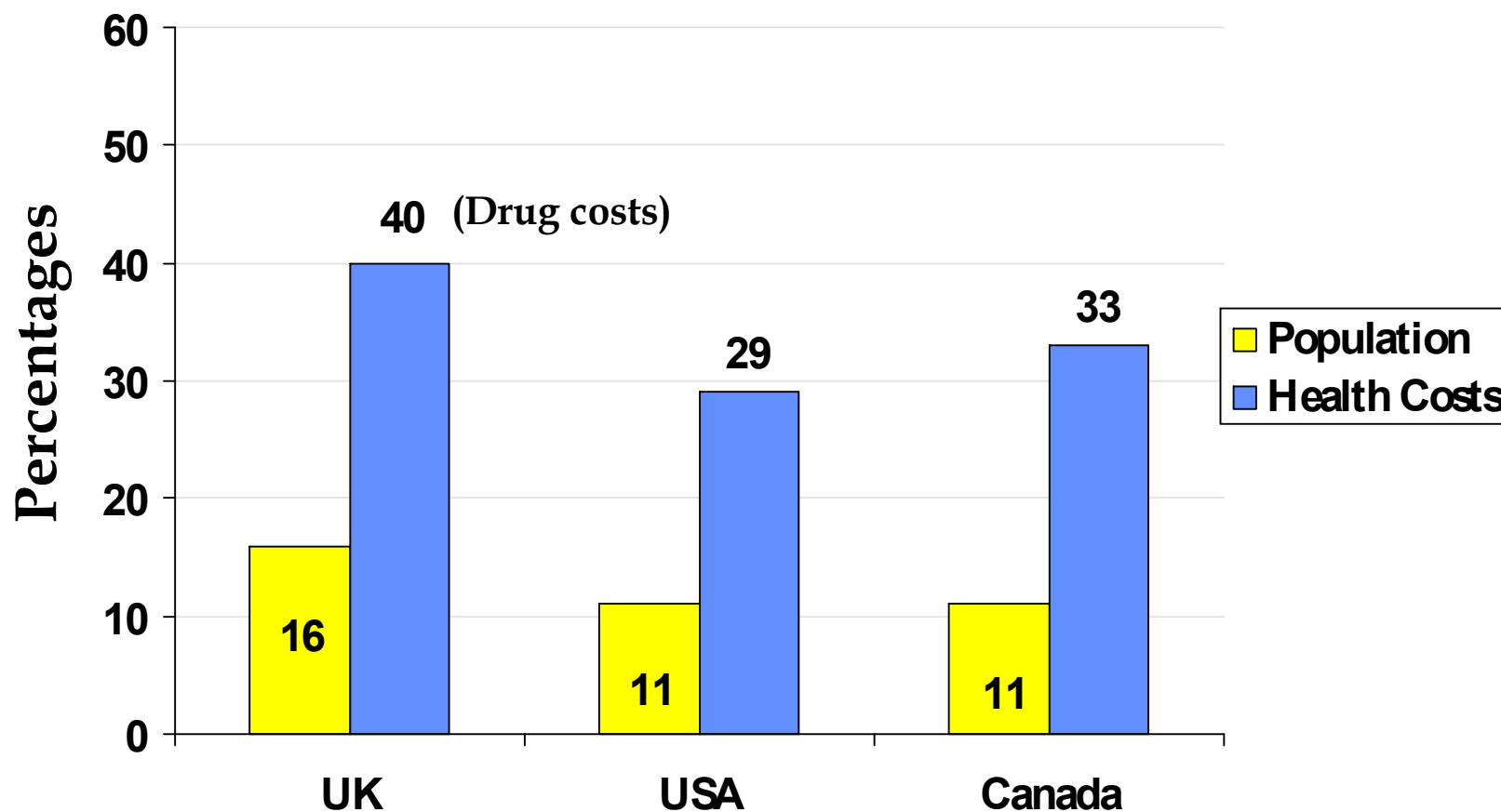


- FDA Modernization Act of 1997 includes other government agencies, e.g. NIH, CDC, etc in promulgation of future health claims
- FDA encouraged to add (approve) health claims for “good foods/ingredients” e.g. Soy/ chol. lowering, Omega 3/CVD
- Health claims will find wider awareness and understanding by consumers. **Health claims are a “license” to communicate**
- DRI (RDA) process and outcomes will have far-reaching impact on future food regulations/public policy
- Developing European and Japanese, UK, CODEX, Functional Foods regulations (and others)

Wellness Foods Continuum



Nutrition and Health Care Costs of the Elderly (mid 90's)



Elderly defined as over 65 years.

Nutrition and the Elderly

- **40% of elderly living independently in affluent countries consume insufficient amounts of one or more essential nutrients .**
- **Nutrient deficiencies increase with age.**
80% of independent elderly over 79 yrs.consume inadequate amounts of 4 or more nutrients
 - ◀ **75% too little folate**
 - ◀ **63 % too little calcium**
 - ◀ **Deficiencies also found for vitamin E, vitamin B-6, vitamin C, Zn and Mg.**

Hospital Costs vs Nutritional Status (admissions)

	At Risk Gp.	Not at Risk Gp.	Other
Studies			
Malnutrition %	46%	-	40-50%
LOS Costs *	\$6200 (+35%)	\$4600	2X
LOS	6D	4D	
Readmission	NS	NS	
Home services	31%	12%	

More Post Op complications, morbidity, mortality

Higher complications

*Length of Stay

Nutrition and the Elderly

- **Vitamin/mineral supplements of ~ one RDA of 18 vitamins, minerals and trace elements improve cognitive function of elderly over 65.**

Measures of improved health:

- **Immune function shows improvement with supplementation.**
- **Infectious-related illness occurred an average of 23 days per year vs. 48 days with placebo.**

Economic benefit :

- **\$28 could be saved in health care costs for every dollar spent.**
- **Increased natural killer cells, T4 cells and IL2.**
- **May prevent harmful brain deposits associated with neuronal damage and other disorders.**

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

Trends driving FF market

Consumers

- More health conscious
- 'Natural' self-medication
- Ageing population

Health Care

Professionals(HCP)

- New discoveries in FF
- Promote healthy eating



**Rapid development
of functional food**

Government

- Rising healthcare costs
- Regulatory framework

Retailer/Marketers

- Search for growth opportunities

Nutraceutical Preventive sub-markets

(millions persons USA)

Risks

Obesity

143

Chol

93

Plaque

50-75

High BP

Treatment

50

Immunity

Stress

104

Digestion

70

Sleep

70

Disease

CVD

60

Arthritis

43

Diabetes

16

Lifestyle

Joint Pain

80

Mental

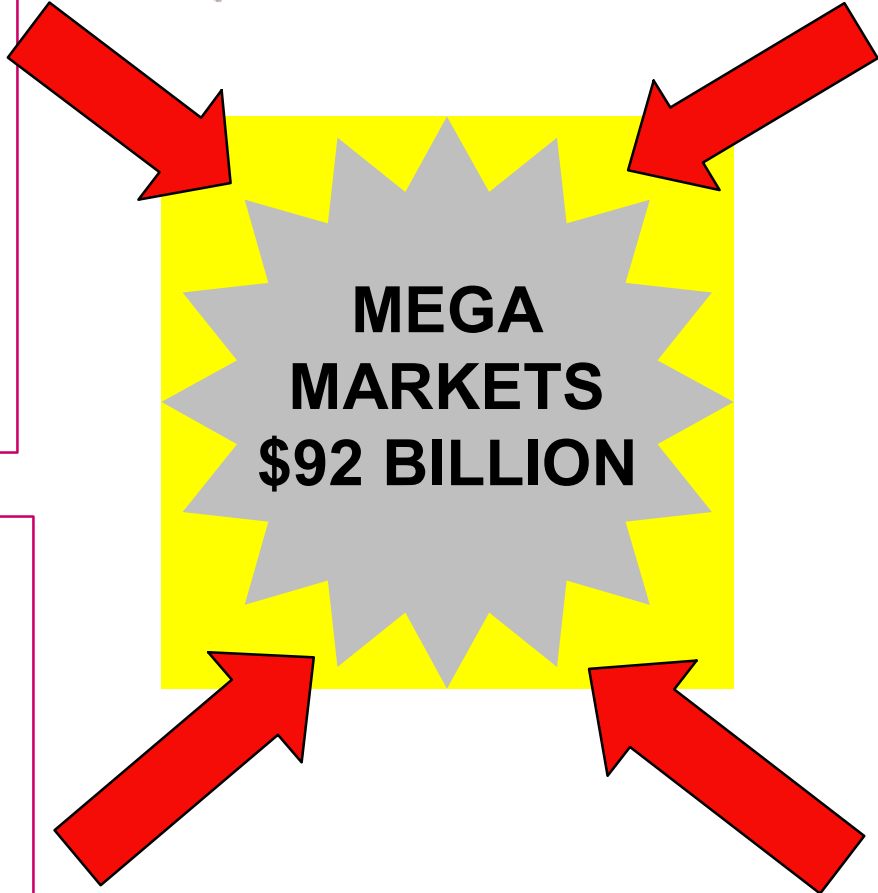
61

Ageing

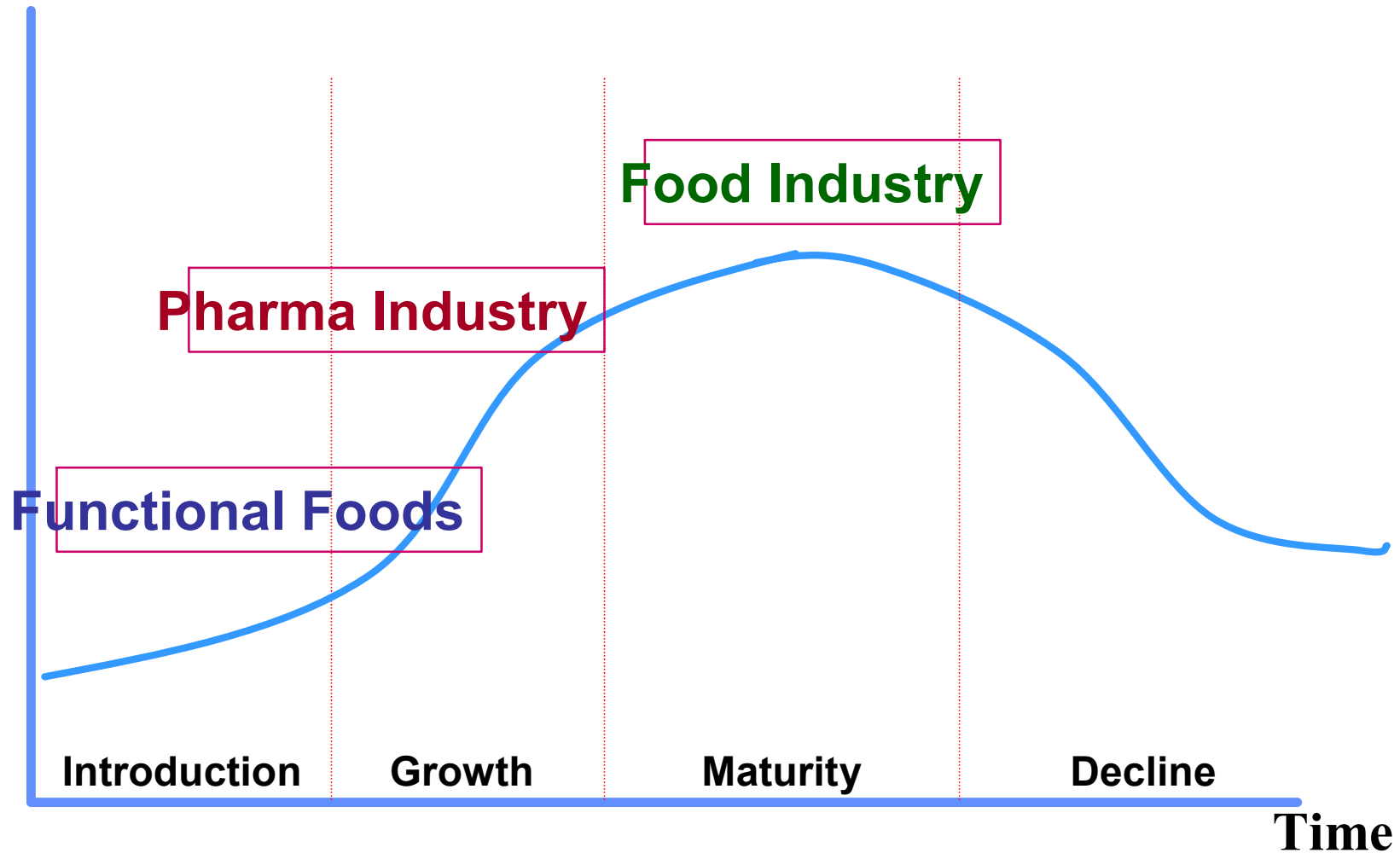
49

Energy

**MEGA
MARKETS
\$92 BILLION**



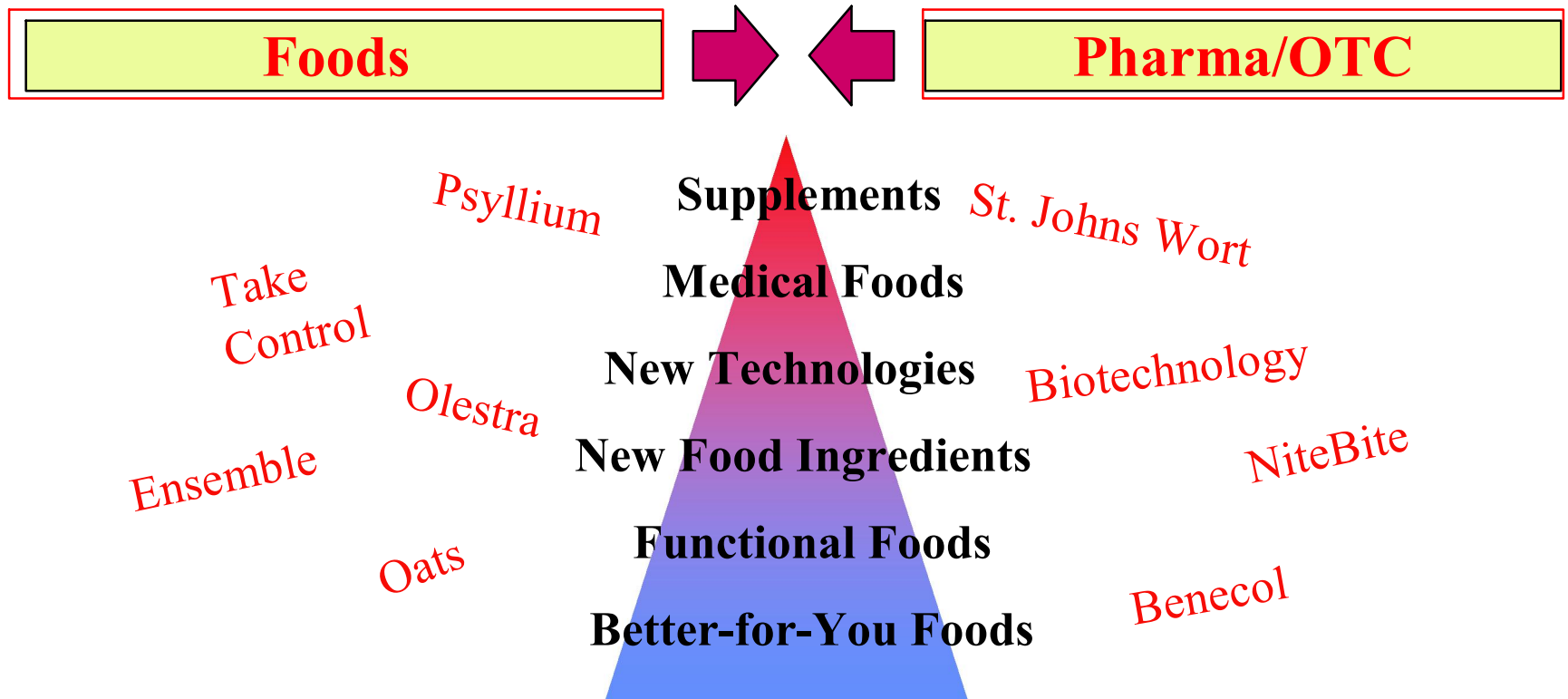
Mature Food and Pharma Industries Looking at Functional Foods



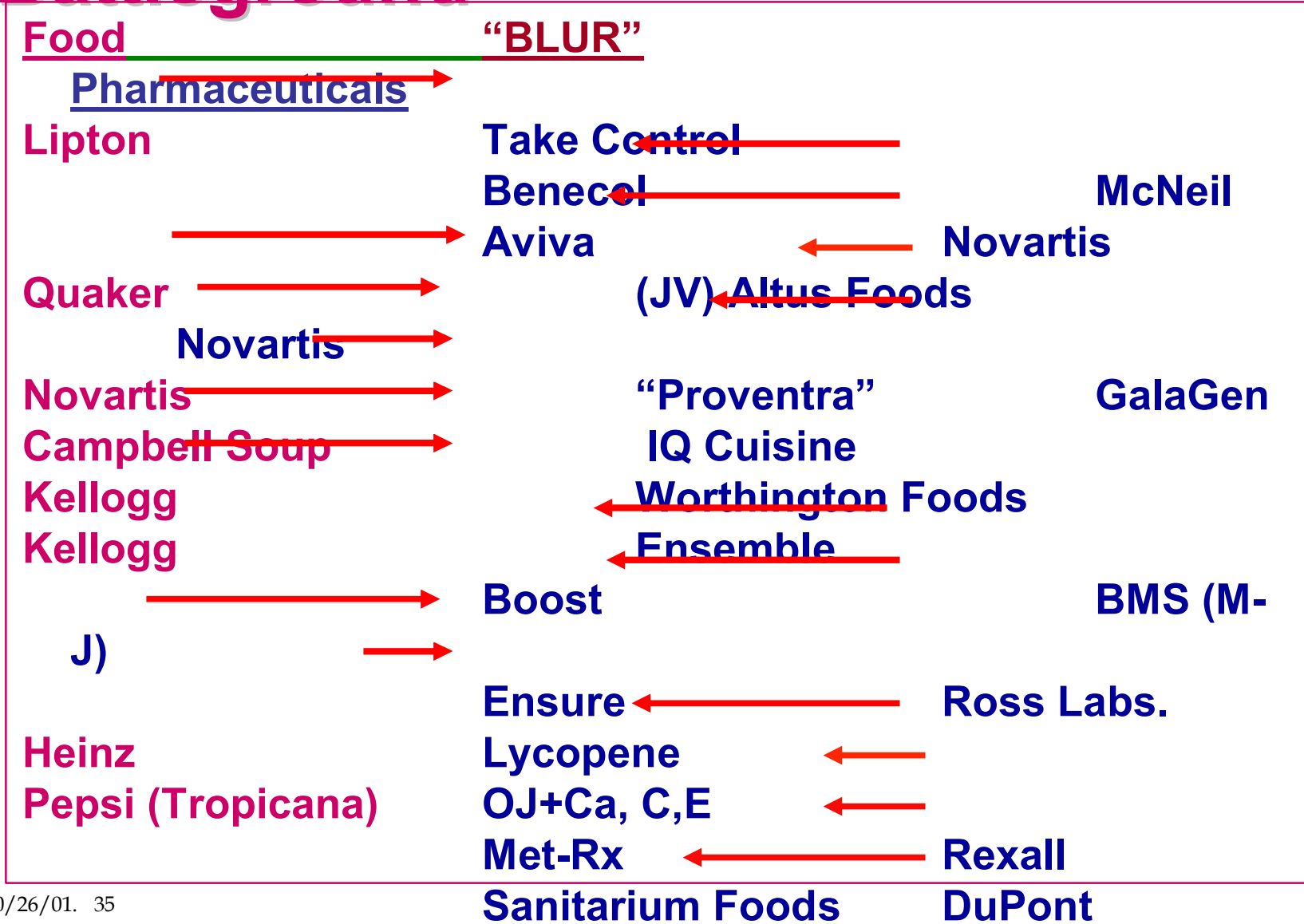
.....as a Way to Broaden their horizons

The Future “Blur” of Nutrition

- Perceptual gap is a hurdle/opportunity and needs to be understood



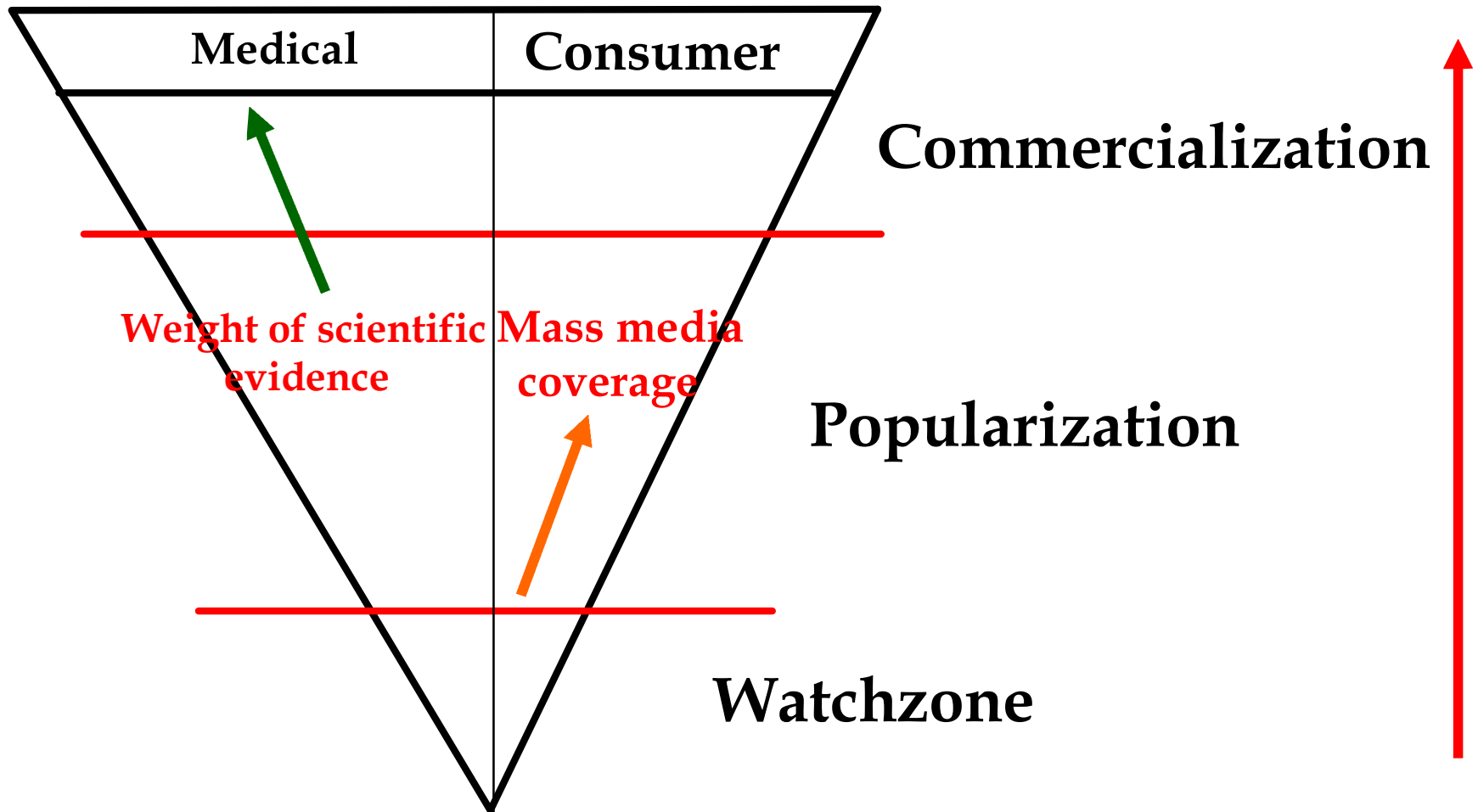
Functional Foods Battleground



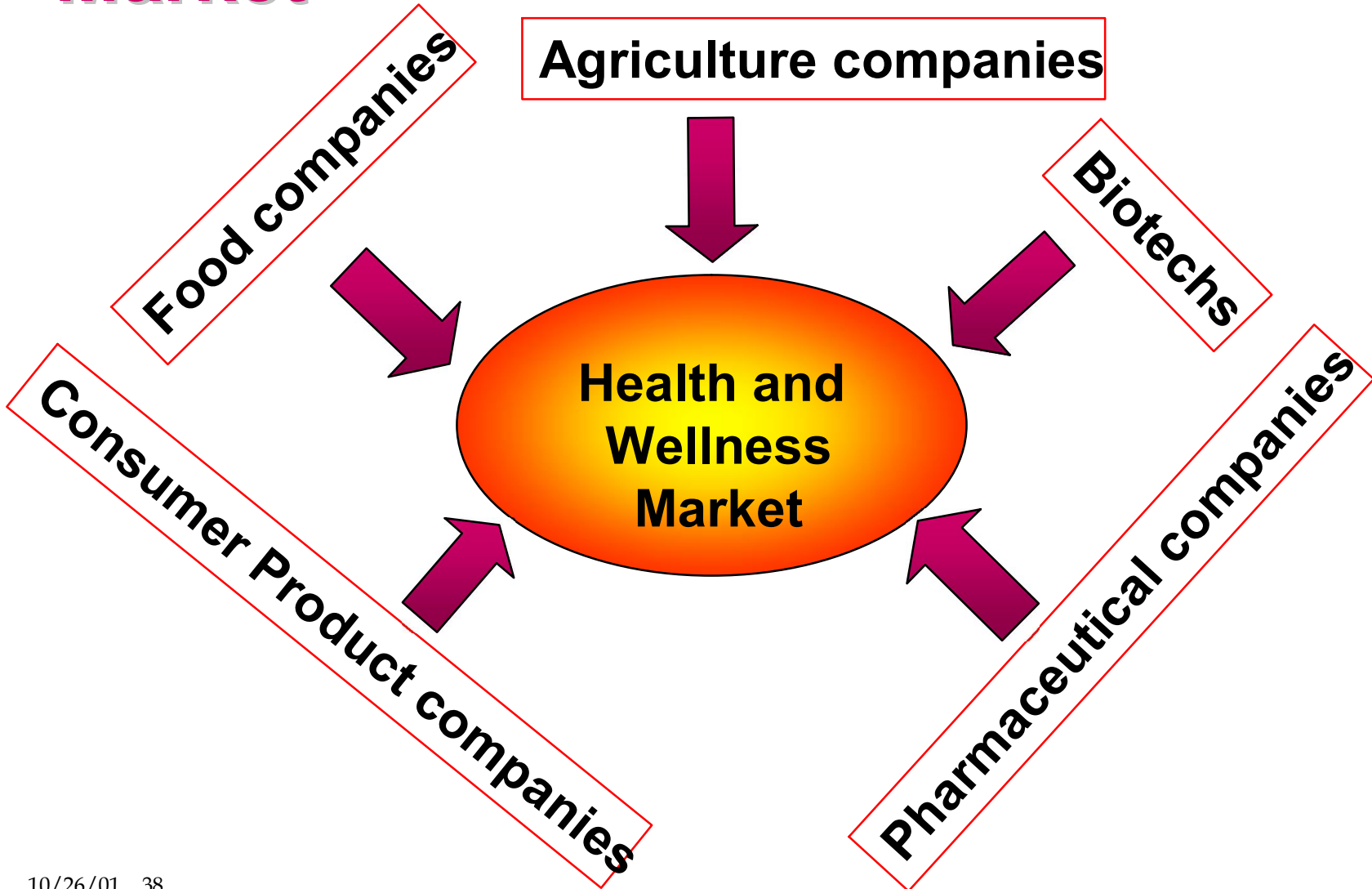
Shifting Product Form

- **Nutritionally fortified foods and beverages continue to see strong growth**
 - this data is not easy to collect at retail
- **Mainstream food, beverage, consumer products and pharmaceutical companies are entering/launching products in the “nutraceutical” market**
 - Kraft with Balance Bar acquisition
 - Nestle with Power Bar acquisition
 - BM (M-J) launch of Viactiv
 - tremendous activity in Soy

Trends in Functional Foods



Many Players in an Emerging Market



Many Players are Entering

Big Players

- ADM
- AHP
- Aventis
- DuPont
- McNeil Consumer Health
- Merck
- Monsanto
- Mead Johnson
- Novartis
- P&G

Food Companies

- Campbell
- ConAgra
- General Mills
- Kraft
- Kellogg
- Nabisco
- Nestle
- Numico
- PepsiCo
- Unilever/Best

New Players Entering/Looking

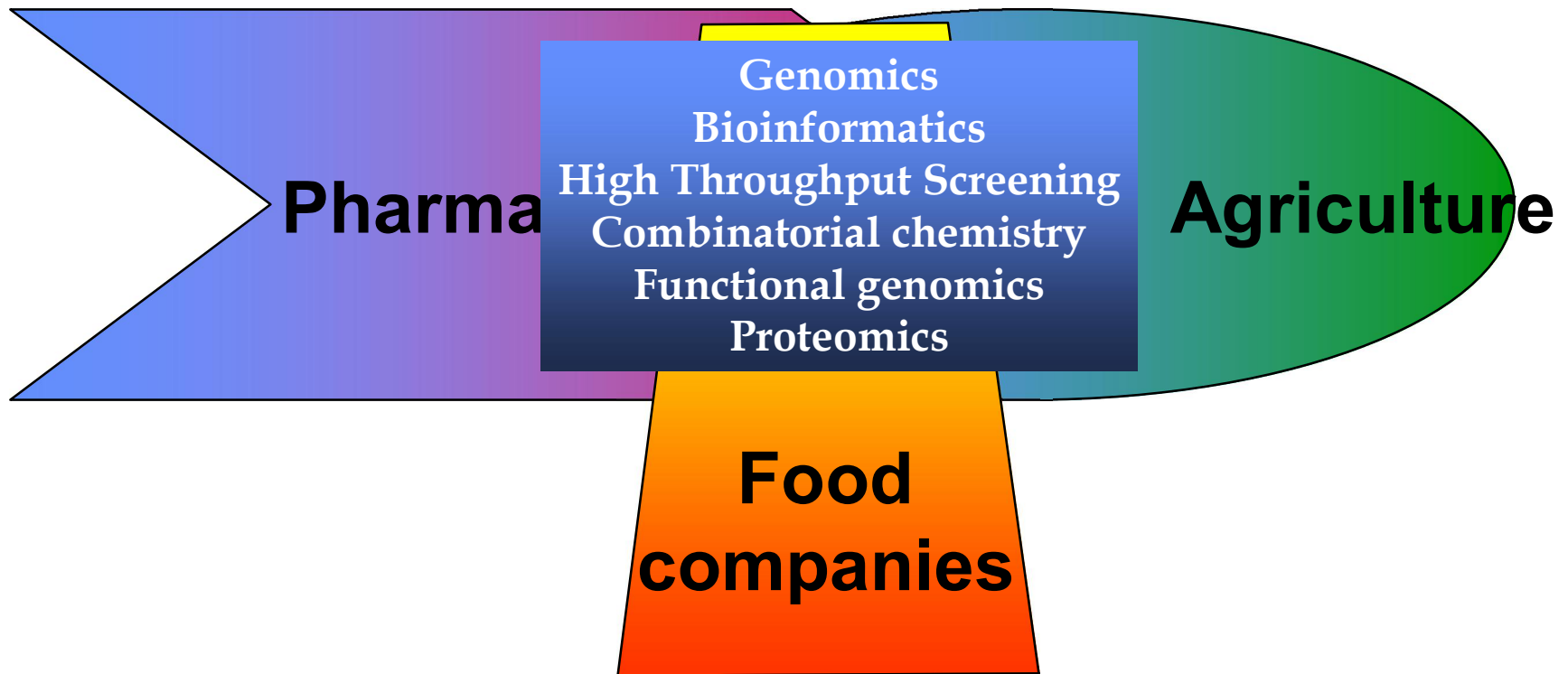
AgBio/Genomics

- Paradigm Genetics
- Maxygen
- Prodigene
- Mendel
- Nektar
- Origen
- Avigenics
- Ceres

Nutraceuticals

- Cooke Pharma
- AMBI
- Ancille Pharma
- Next
- Phytomedics
- Galileo
- Larex
- etc.

Enablement Knowledge based opportunity

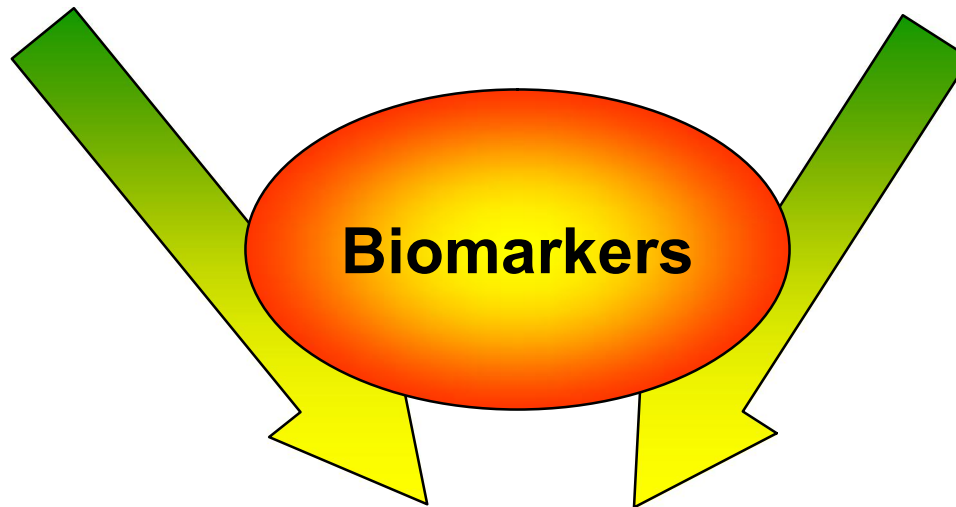


A common tool box in Pharma, Ag and Food....

The Future is Preventive Medicine

Food Genomes

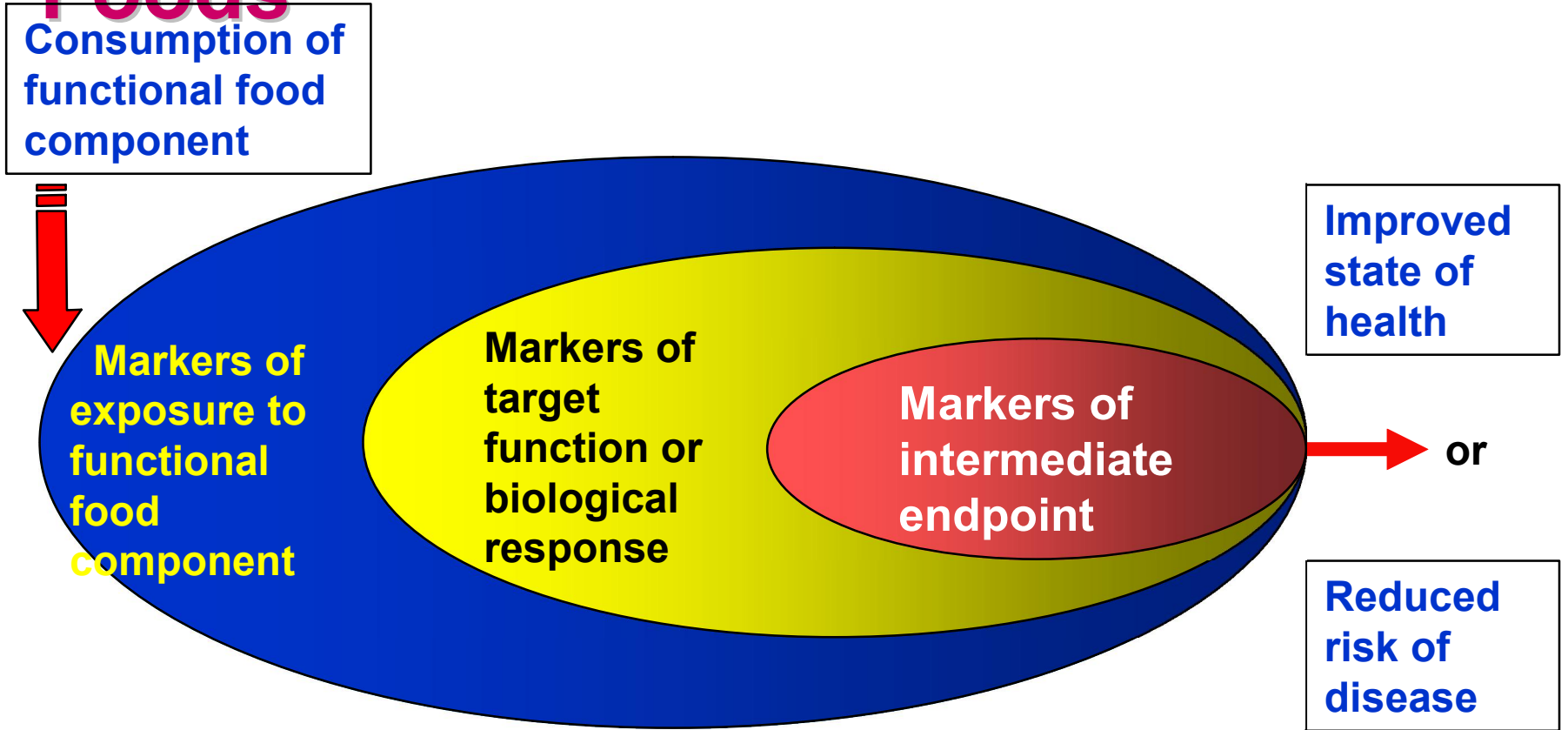
Human Genome



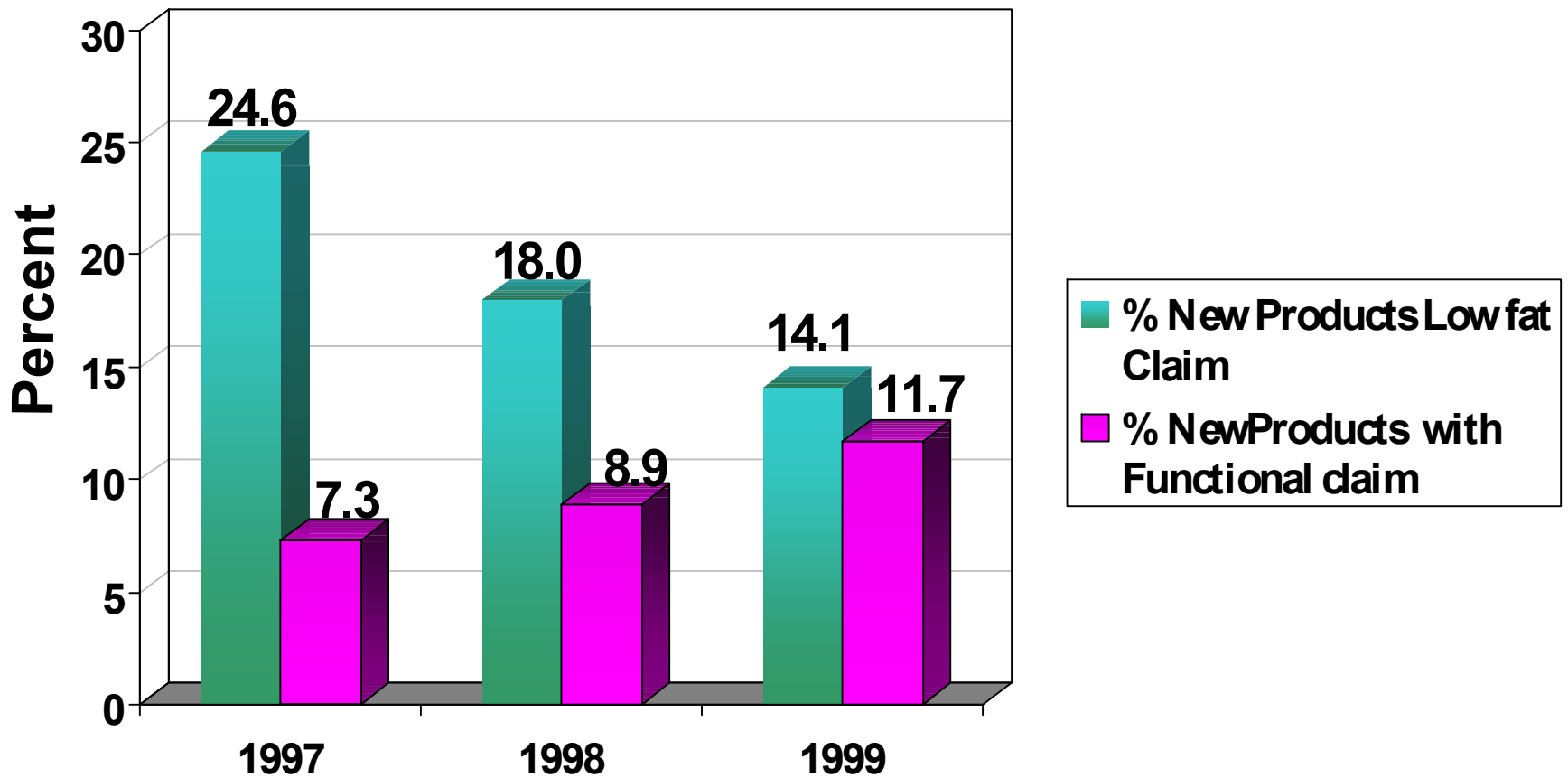
Nutraceuticals

- Supplements
- Functional Foods
- Medical foods

Biomarkers and Functional Foods

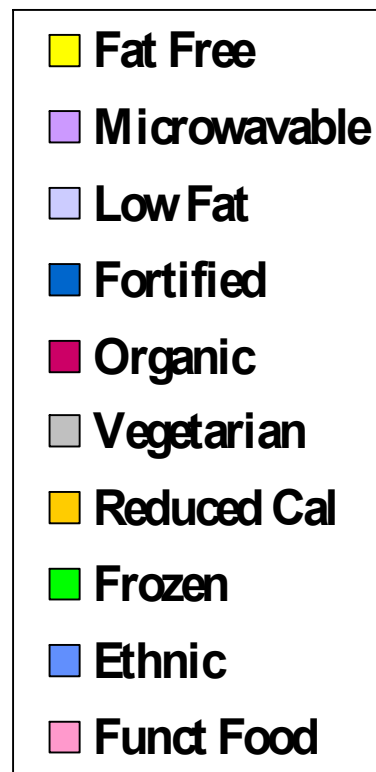
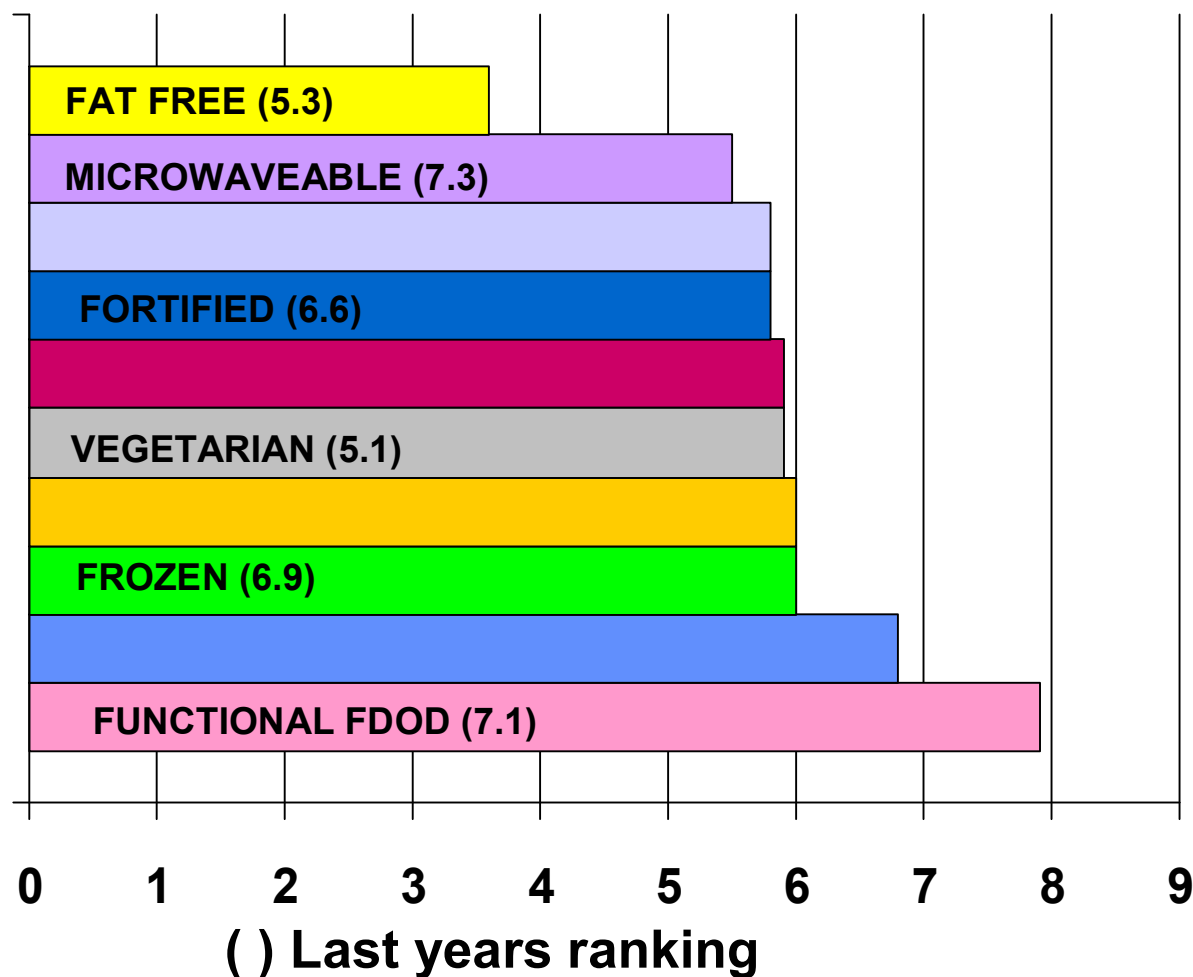


Food Companies Search for “Next big Thing”

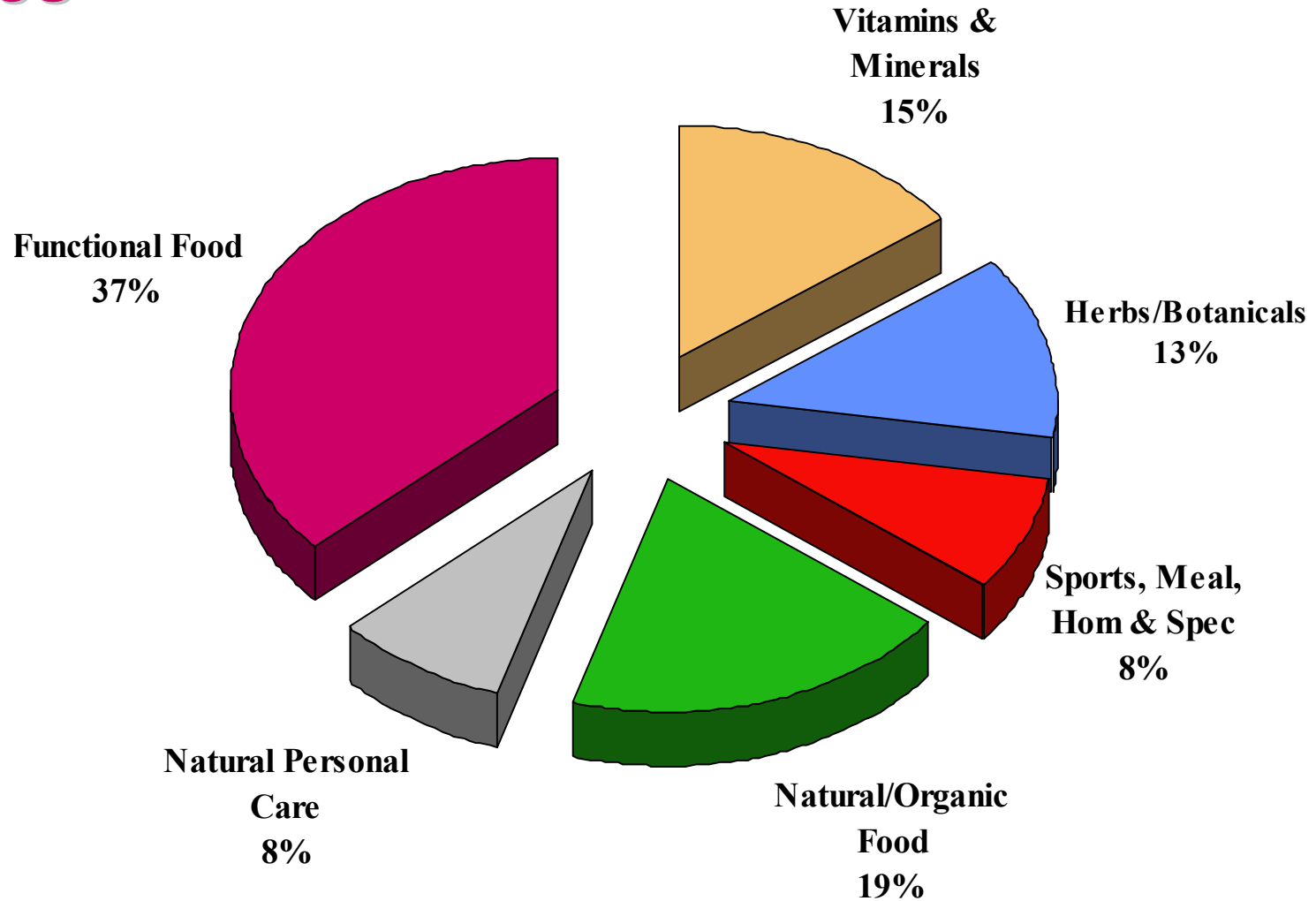


Research Directions for US Food Manufacturers 2000

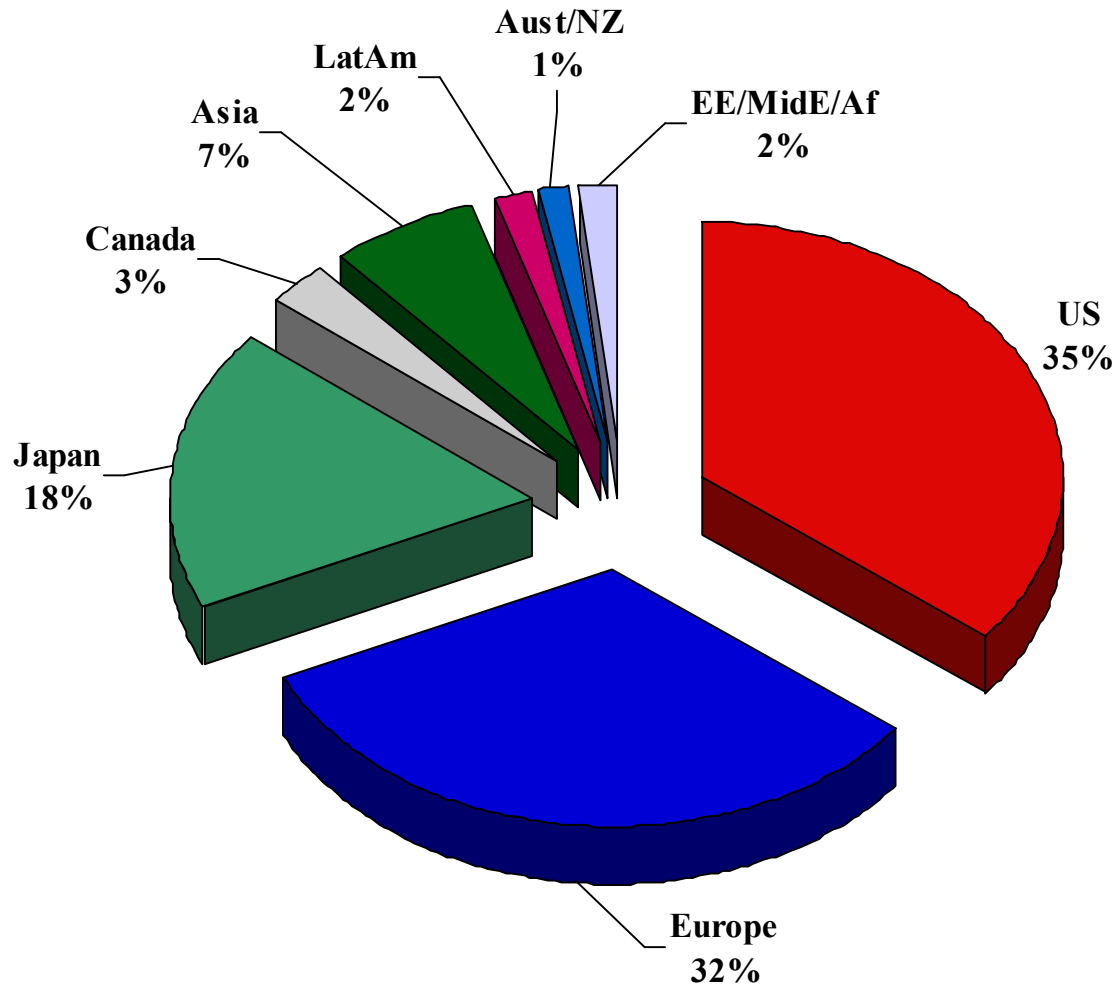
What's Hot!



\$140 billion 2000 Global Consumer Sales



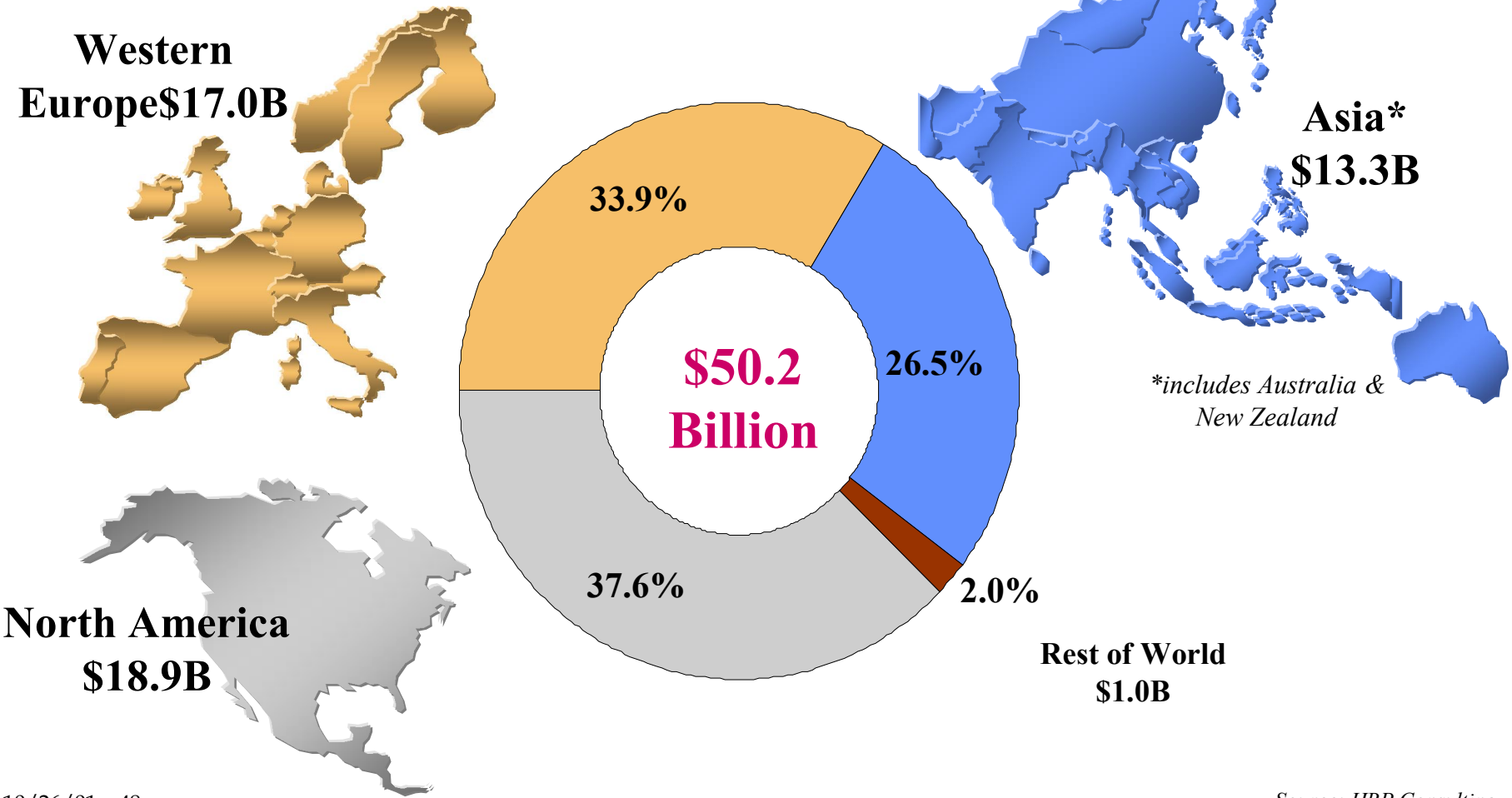
\$140 billion 2000 Global Sales by Region



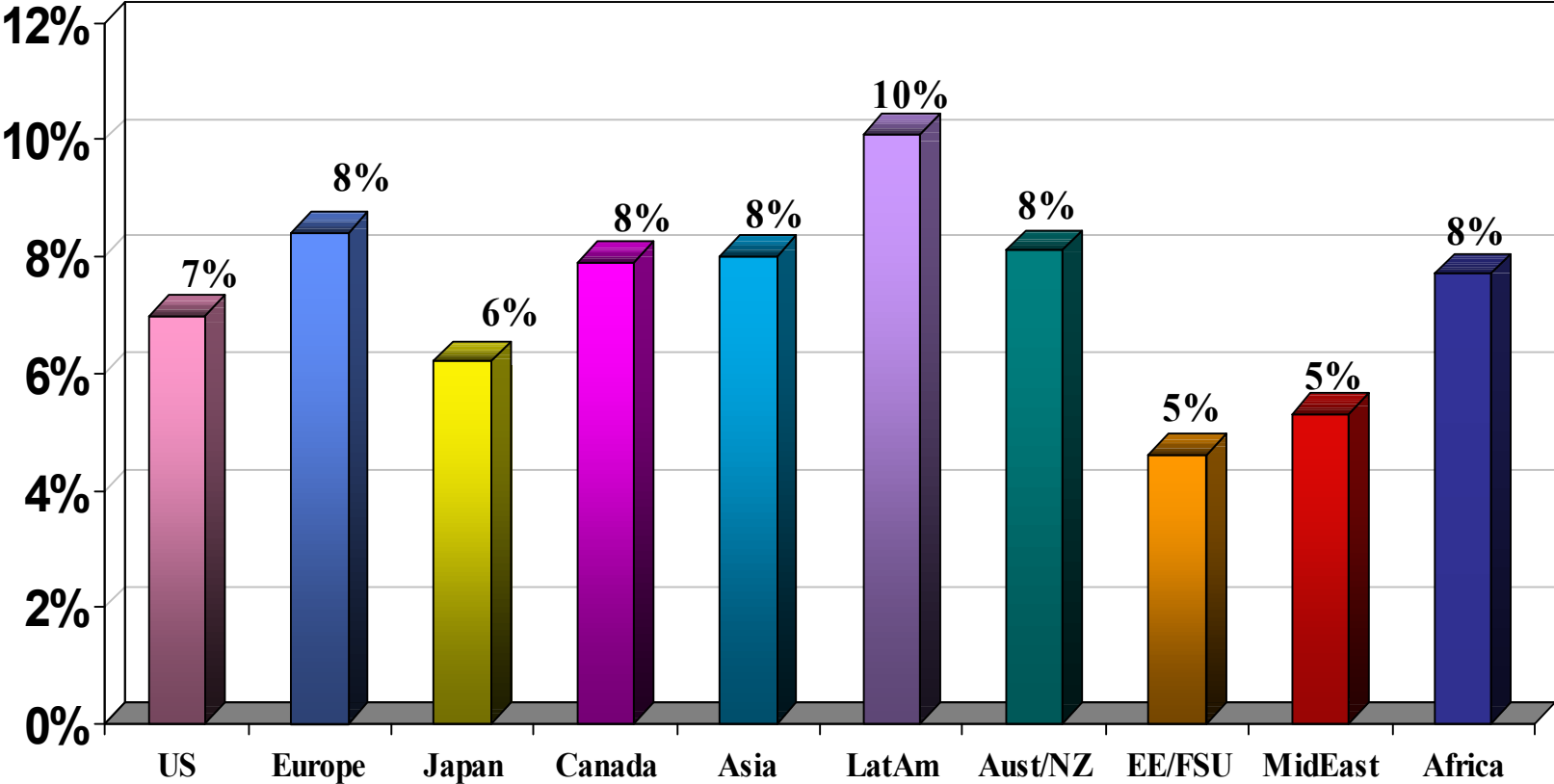
\$50.2 Billion Global Functional Foods Industry

Led by the North American Market

GLOBAL MARKET OF FUNCTIONAL FOODS
(% of 2000 Retail Sales by Region)

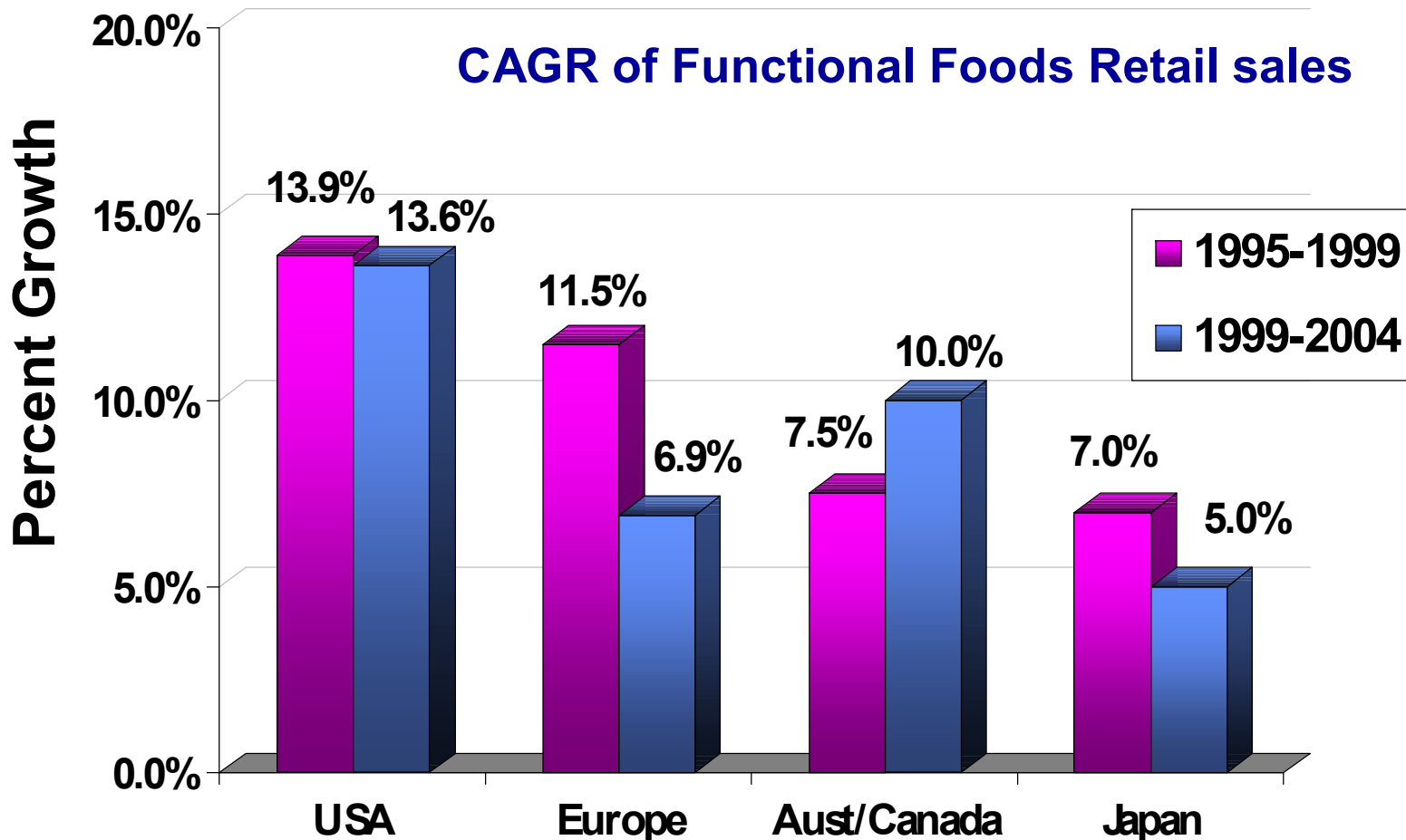


2000 Global Growth by Region



Growth in Functional Foods

US tends to dominate mainly due to lighter regulatory burden?



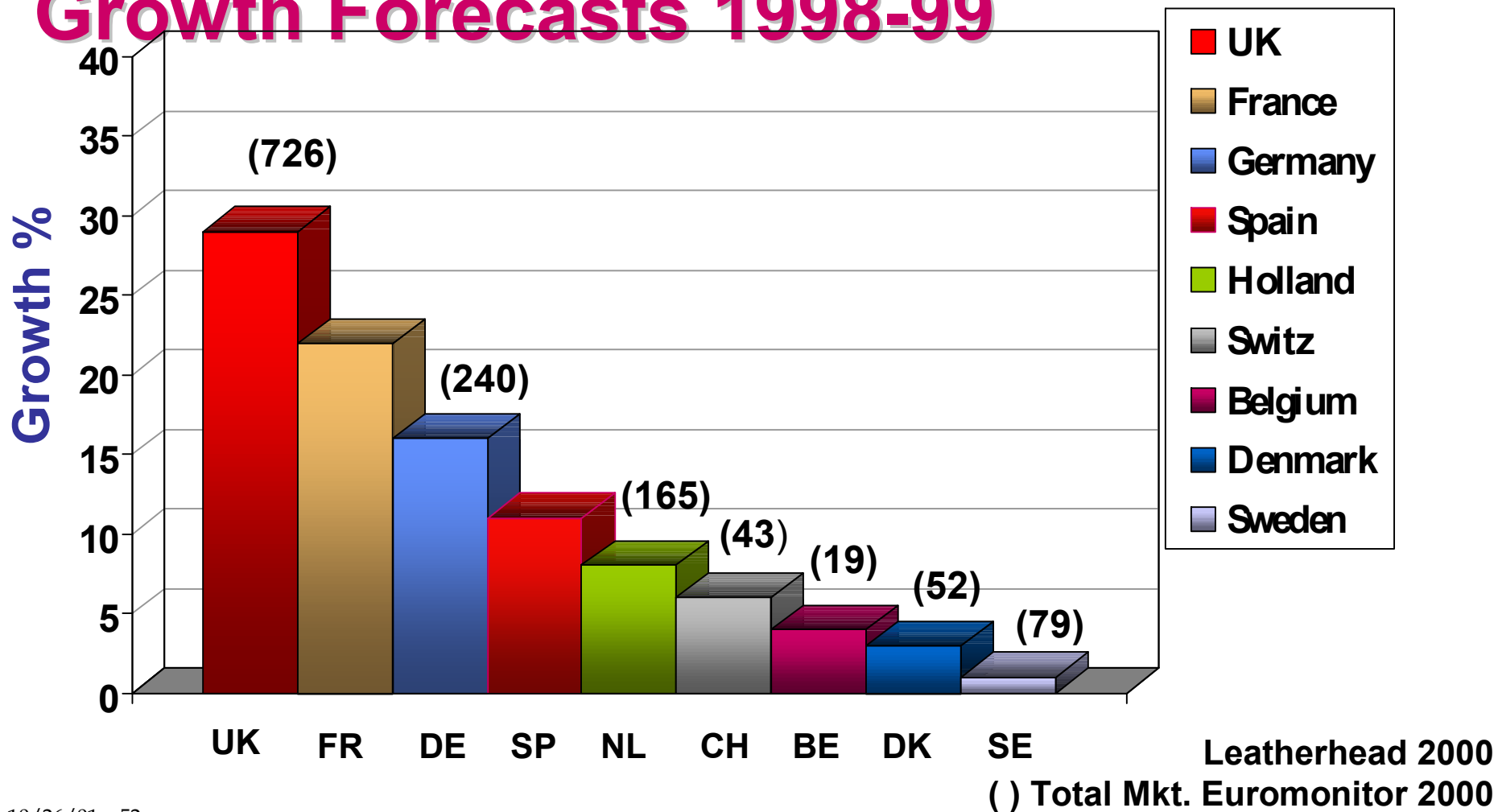
Functional Food Markets Around the World. (US \$millions)

1995/1999

COUNTRY	LEADING SECTOR	1995	1999
USA	Bakery and cereals	6,552	9,754
UK	RTE cereals	598.9	726
CANADA	Bakery and cereals	501.7	561.2
AUST.	RTE cereals	386.8	331.1
FINLAND	Probiotic dairy	332.6	274
GERMANY	Functional drinks	229.6	240
HOLLAND	Dairy	87.6	165.1
SWEDEN	Dairy	47	78.7
DENMARK	Dairy	22.4	52.3
JAPAN	Probiotic dairy	22.1	823.3
BELGIUM	Functional dairy	21.1	19.4
AUSTRIA	Functional dairy	7.3	47.4
SWITZ	Probiotic dairy	6.8	43.1
NORWAY	Dairy	3.6	15.7

European Functional Food Market

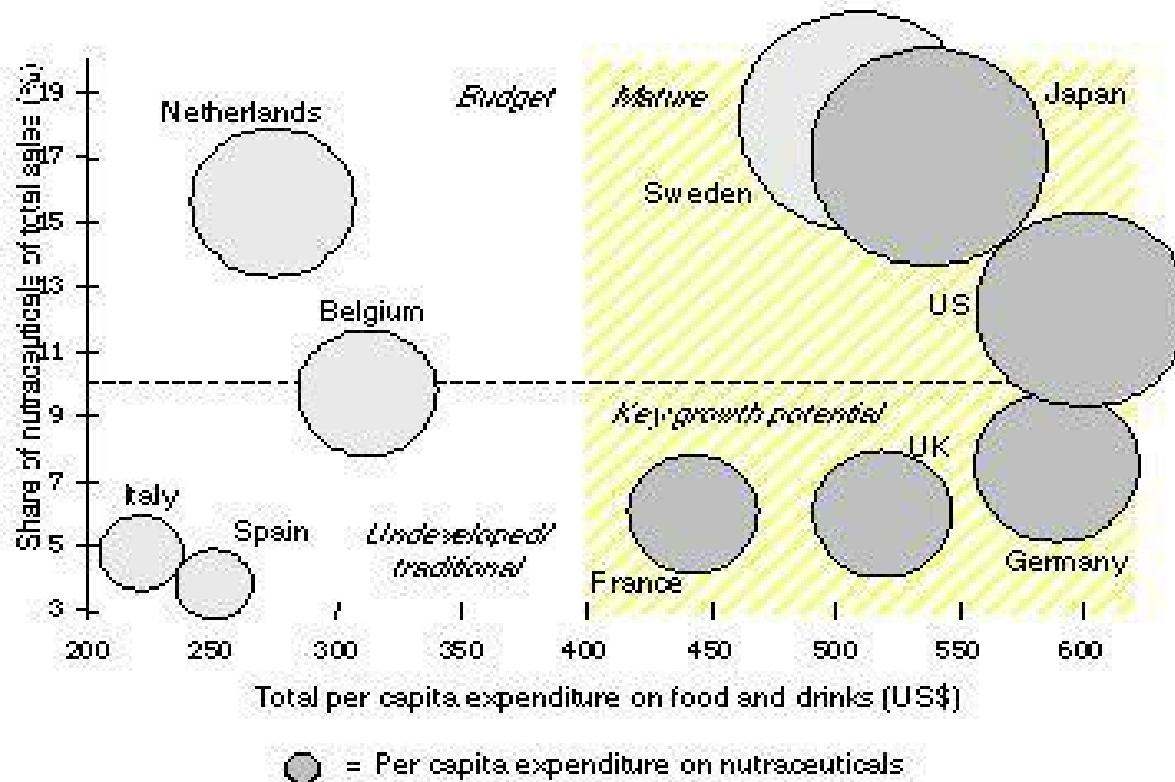
Growth Forecasts 1998-99



European Nutraceutical

Ma

The UK is set to be the most dynamic nutraceuticals market



NB: covers only soft drinks, dairy, breakfast cereals and sugar confectionery

Source: Datamonitor analysis

Forecasts of Functional Food Markets 1999 and Beyond (\$ billions)

Organization	1998	1999	2000	2004	2010
MarketReach		-	15.8	-	20.2
Freedonia (world)		-	-	-	-
162.0					
NBJ (USA)	14.7	19.6	20.0	35.0	48.0
IFIS (world)	41.0	-	55.0	-	-
Euromonitor	27.9	31.7	-	51.3	-
Novartis		10.0	23.0		
Leatherhead (world)			30.0		
Leatherhead (Japan)			14.0		
Leatherhead (USA)		15.0			

Rough World Averages

~25

~30

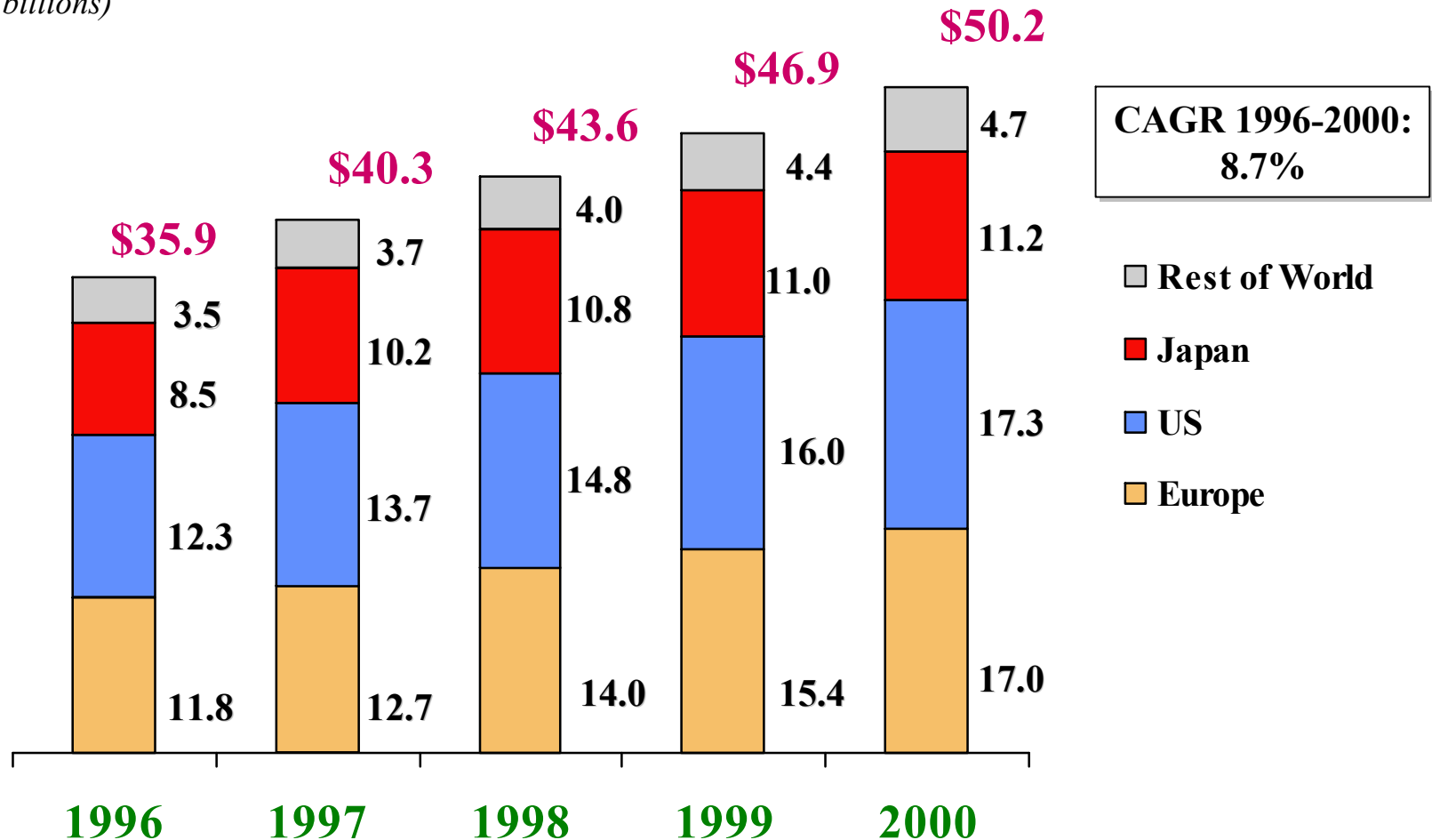
~50

CAGR 15%

Strong Historical Growth of Global Functional Foods Market...

GLOBAL RETAIL SALES OF FUNCTIONAL FOODS

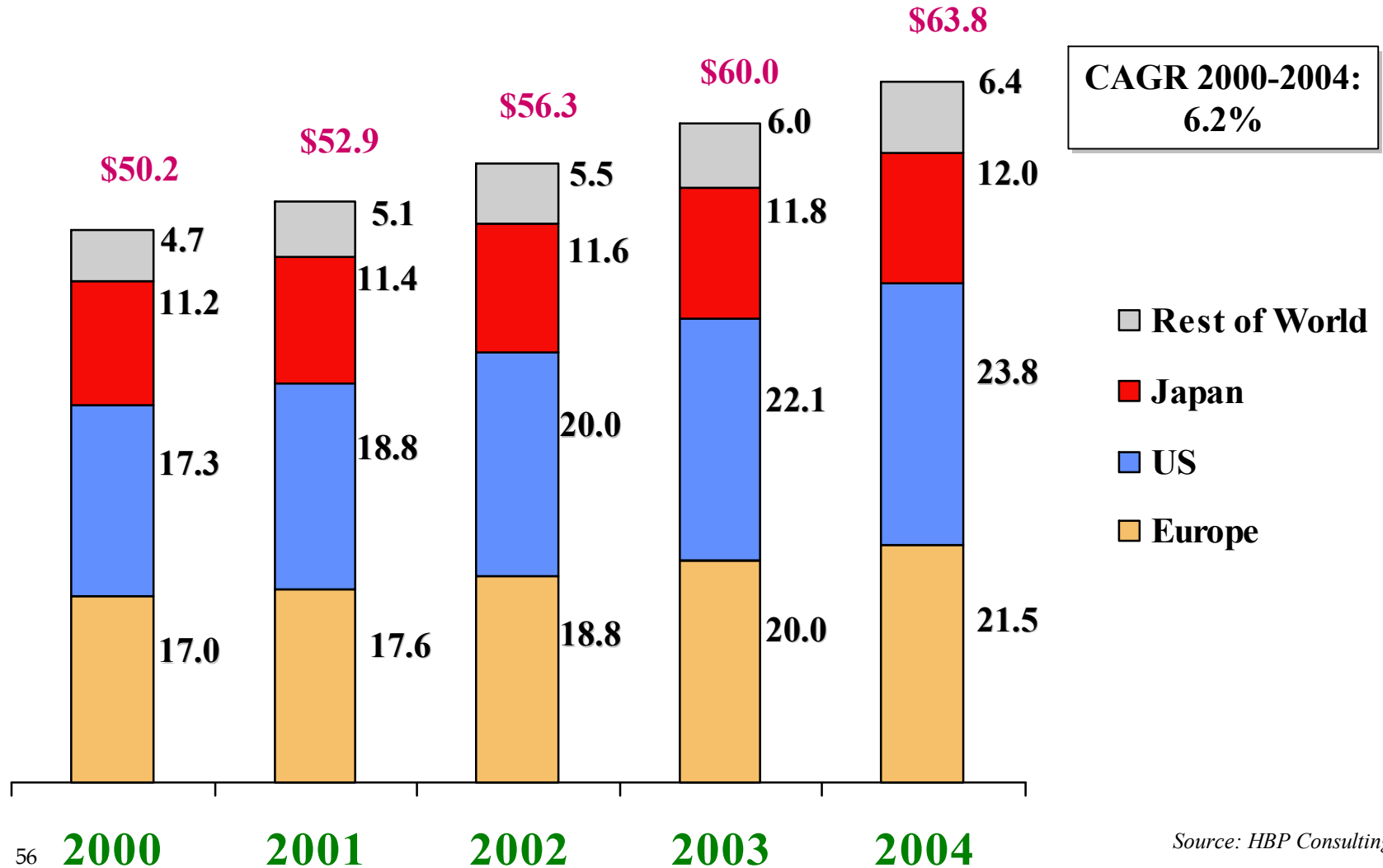
(in U.S. \$ billions)



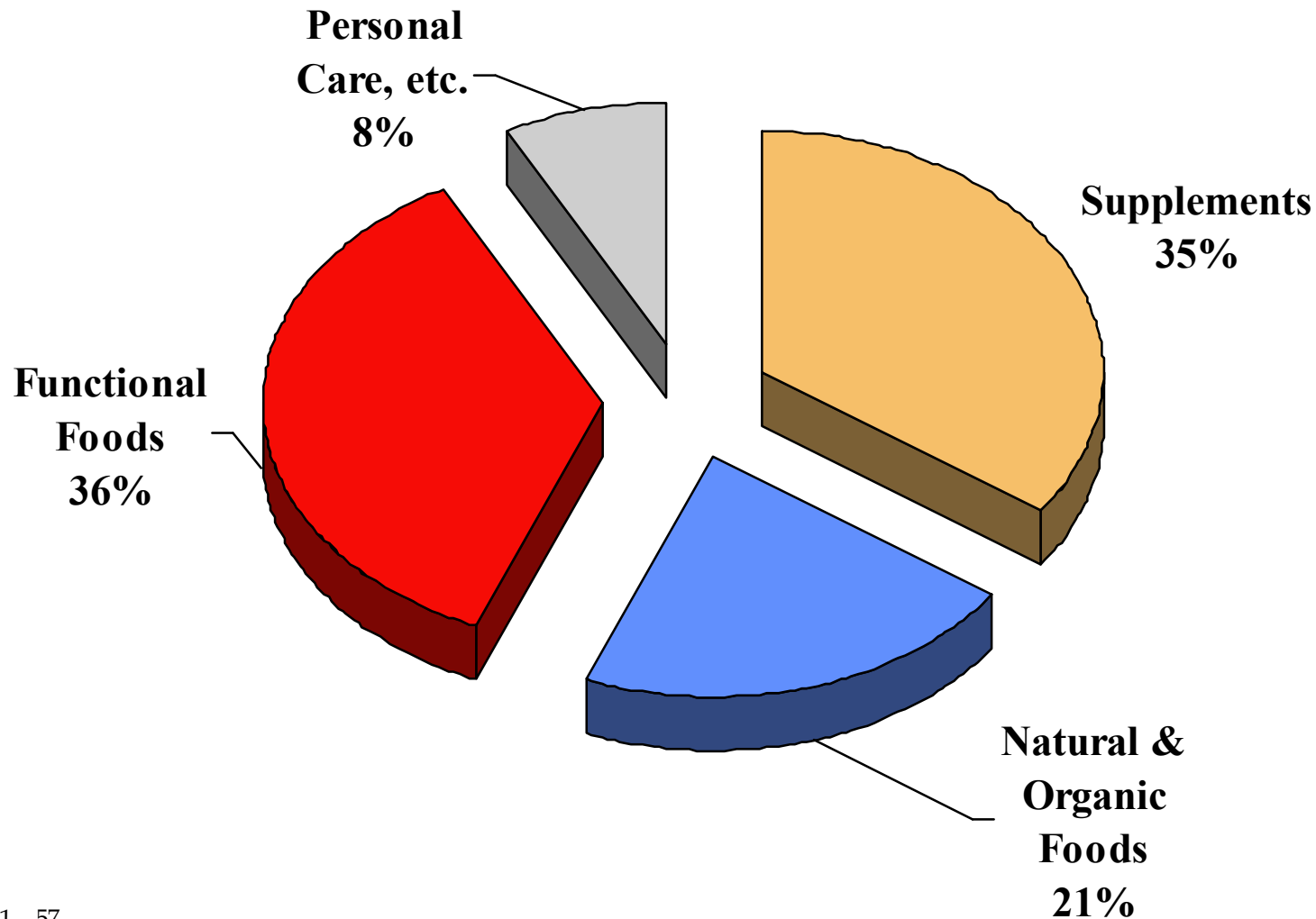
...Is Expected to Continue

GLOBAL RETAIL SALES OF FUNCTIONAL FOODS

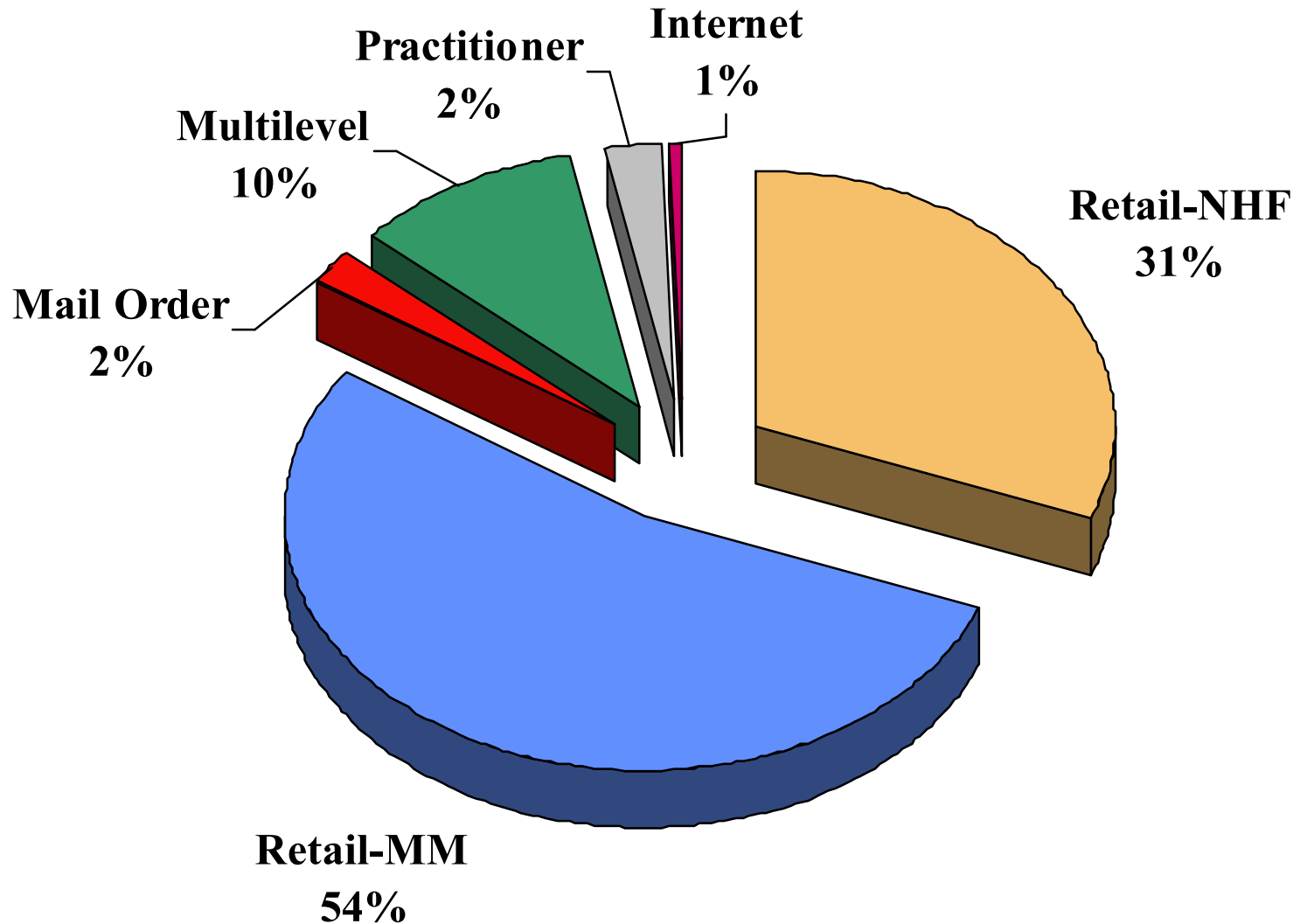
(in U.S. \$ billions)



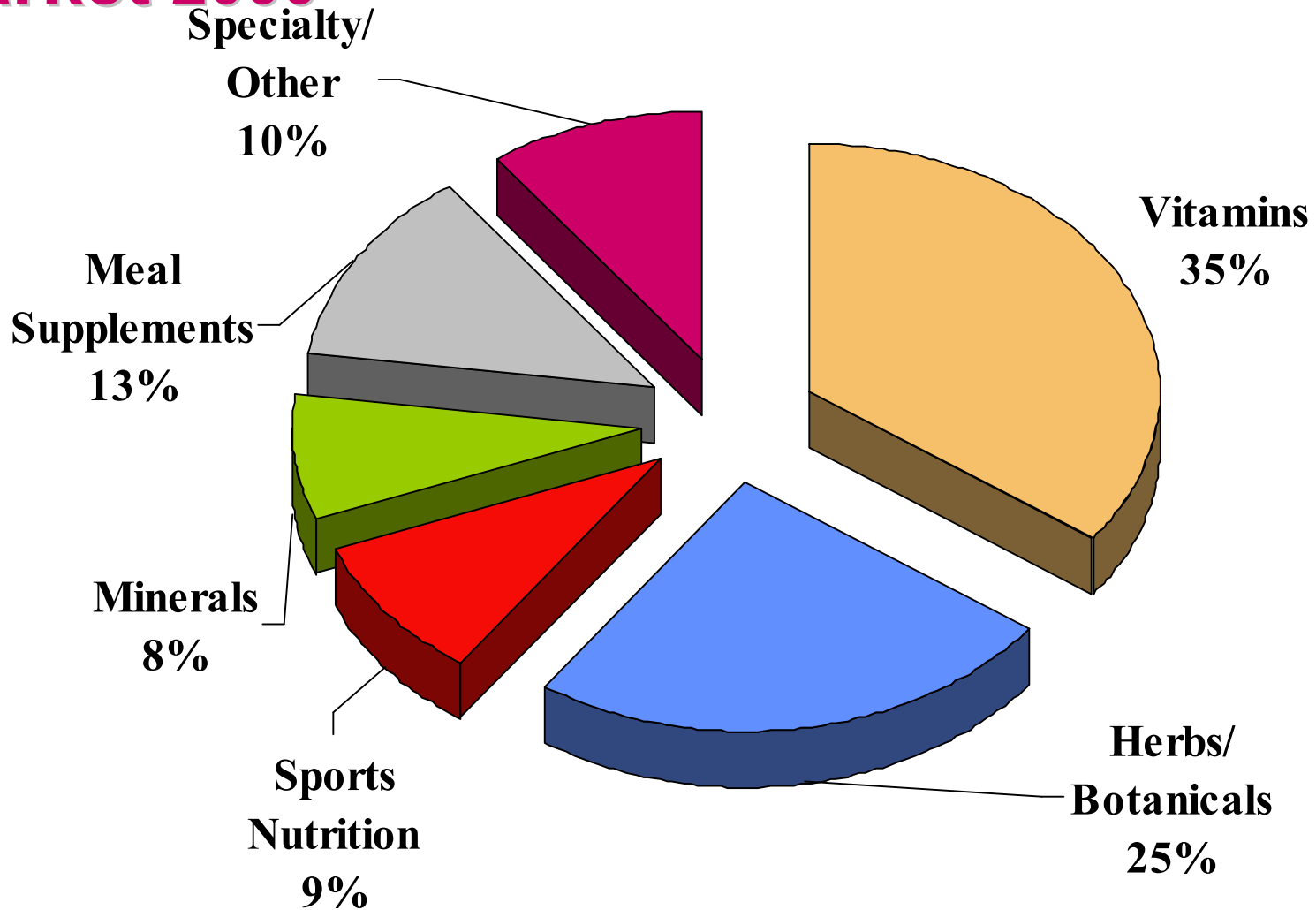
\$50 billion USA 2000 Consumer Sales



\$50 billion USA Consumer Market 2000



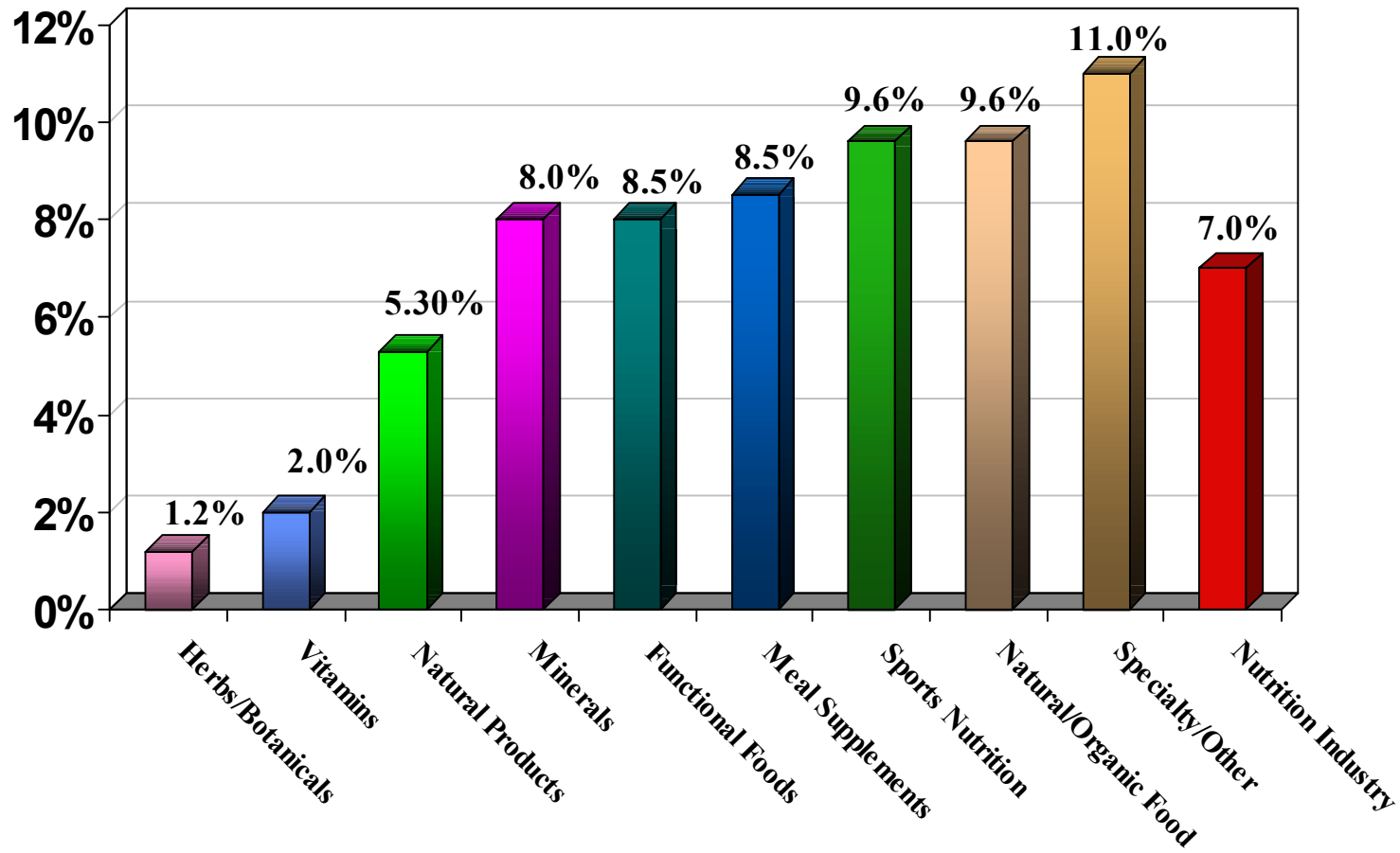
\$17.3 Billion US Supplement Market 2000



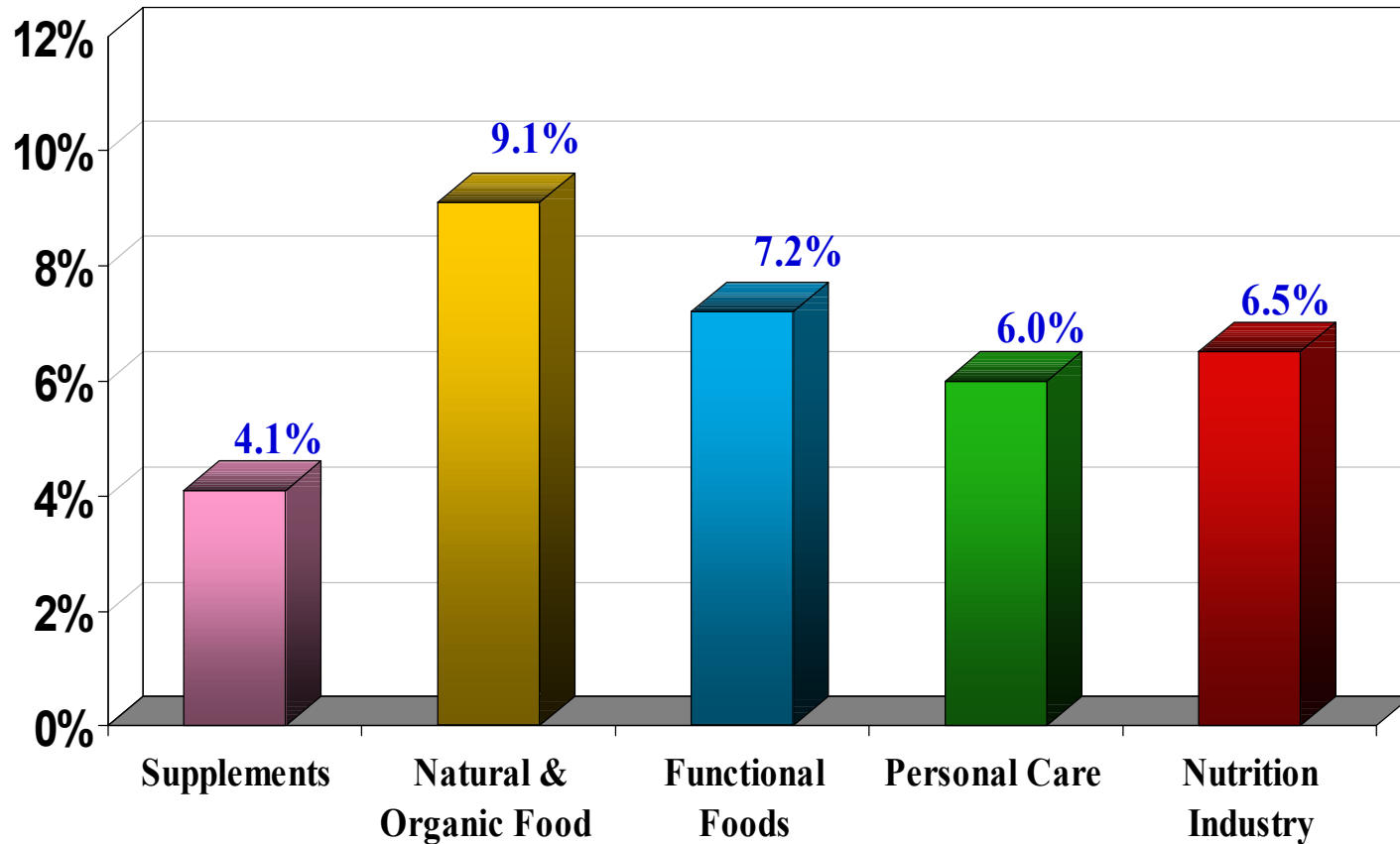
1998 U.S. Retail Food Sales Category and Growth Review (Billions)

FOOD	Nat/Org Food	'97-98 %	Funct. Food	'97-98 %	Lesser Evil	'97-98 %	Standard	'97-98 %	Total Bio \$	'97-98 %
Dairy	1.1	15	1.7	14.3	13.7	4	33.3	3	49.8	3
Fruit/Vegs	1.6	13	0	0	0.3	0	76.7	2	78.6	3
Bread/Grain	1.8	10	6.1	1	1.3	2	46	3	55.3	2
Meats	0.4	10	0	0	1.0	2	97.1	3	8.5	2
Beverages	1.5	14	4.9	12	17.3	.4	54.7	-1	78.4	1
Snacks	0.4	18	0.8	32	2.7	0	22.4	-2	26.3	0
Prepared Food	1.6	12	1.1	9	5.2	4	41.4	2	49.3	4
Condiments	0.3	12	0.1	0	1.9	1	14.5	1	16.8	1
Totals	8.8	13	14.8	8	3.3	2	386.1	1.7	453.0	2

2000 USA Category Growth



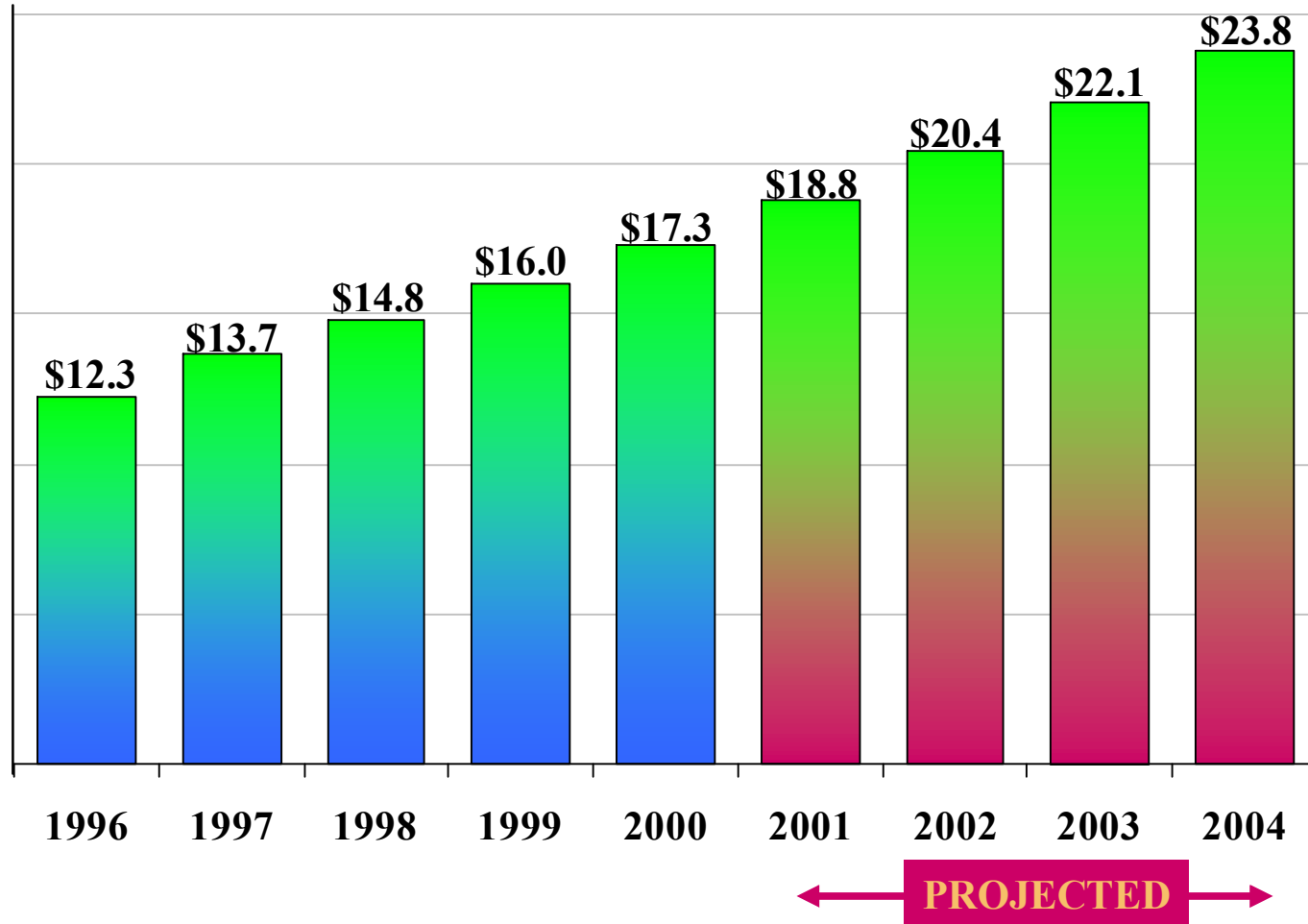
2001-2004 Annual Growth USA



The \$17.3 Billion U.S. Functional Food Market Is Expected to Grow at 8.3% Through 2004

U.S. FUNCTIONAL FOOD RETAIL SALES

(\$ US billion)



Functional Food

What are we learning?

- Safety of ingredients
- Science based decisions
- Physiological amounts of substance
- NGO/academic support (credibility)
- Consumer understanding
- Dose needs to be from 1-2 servings

Functional Food

What are we learning?

Development rationale need

- Fill dietary “gap”
- Deliver 25-100% of RDI/AI
- Compete against dietary supplement
- health, “quality of life” reasons
- Scientifically targeted “health concern”
 - Woman’s needs
 - Men’s needs
 - Elderly
 - CVD
 - Eye sight
- Delivery matrix - match to nutrient, e.g. Ca with dairy
- Convenient, excellent taste, does not change behavior, reasonable price premium

U.S. Nutrition Industry: Key Issues

- **Growth rate 'maturing' from 10-12% to 6-8%**
- **Products**
 - **Supplements growth: 10-14% per year in 1994-1998**
 - **Supplements growth: 4-6% per year in 1999-2001**
 - **Functional Foods an emerging category**
 - **Organic food set for highest growth**
 - **Niche products and niche mentality prevails**
 - **Still great potential to penetrate mainstream**

Some Observations On U.S. Functional Foods

- **Functional food brands typically take a longer time to develop into a critical mass in the US than mainstream foods**
- **Due to consumer knowledge of functional foods, US NPD efforts have generally centered around fortifying existing foods, rather than introducing new types of products**
- **Health claim approvals also tend to push sales in key categories, as well as new product launches**

Observations on Canada's FF Developments

- **3/31/96.....Smith et al: Comparative Analysis Reg. Framework, Japan, Cda. Eu, USA.**
 - Canada has the most restrictive regulatory climate
 - Health Claims prohibited
 - Current system: opportunities only under “drug” category
 - Consumer access; investment and competition stifled
- **Recommendations:**
 - Develop a regulatory “vision” which acknowledges consumers right of access
 - Strike Industry Task Force for Regulatory reform
 - Establish Equivalent of Japan H Food Assoc.
 - Differentiate “Health Claims” from promotion of Health and Wellbeing
 - Harmonize with Other Jurisdictions
 - Consider foreign legislation as a model.

Observations on Canada's FF Developments

- **Government and Health Canada:**
 - No leadership position being taken
 - Very slow to react (NDMAC VMS task force 1983)
 - Under funding of dietary surveys and ability to get accurate data on Canada's nutritional health
 - Not willing to approach NAFTA/harmonisation proactively
 - Not willing to recognise benefits/cost savings from US reviews for Health Claim reviews and structure/function debates
 - Loss of food company research, development and investment due to lack of clear direction and policies
 - Relegation to a "backwater" in food regulatory development and position on world stage
 - Bureaucrats regarded as "frozen" in old ways and unwilling to change

Observations on Canada's FF Developments

- **Issues Noted from “The South”**

- Folic acid fortified cereals from USA would be “banned” at the border since this is was not possible under then current food laws. (1984?)
- Calcium added from “dairy source” to OJ OK, and drink is still a “food”. Calcium from “non dairy” source makes OJ a “drug” thus falling under drug regs. (2000). Example in US speeches
- Canada Rejects US “5 A Day for Better Health” Logo” It violates Food Regs since regarded as a “Health Claim”. (10/2001)

Does this mean the Canadians who are asked to eat “5-10 a day, are you getting enough? Are more undernourished?
5-10 a day of what?

....And The Winners Are!...

Those Companies That Offer Products That:

- Simple, messages that are clear and direct
- Positive messages, because consumers are interested in positive versus "disease" messages. (They also could lead to a "family" of products)
- Science based messages, not science fiction
- Have **Great Tasting** products with NO compromise
- Have a Demonstrable Benefit and Good Value
- Do not mean a behavior change for consumer to use product

**People prefer to get their health
from....**

the kitchen cabinet

rather than.....

the medicine cabinet