



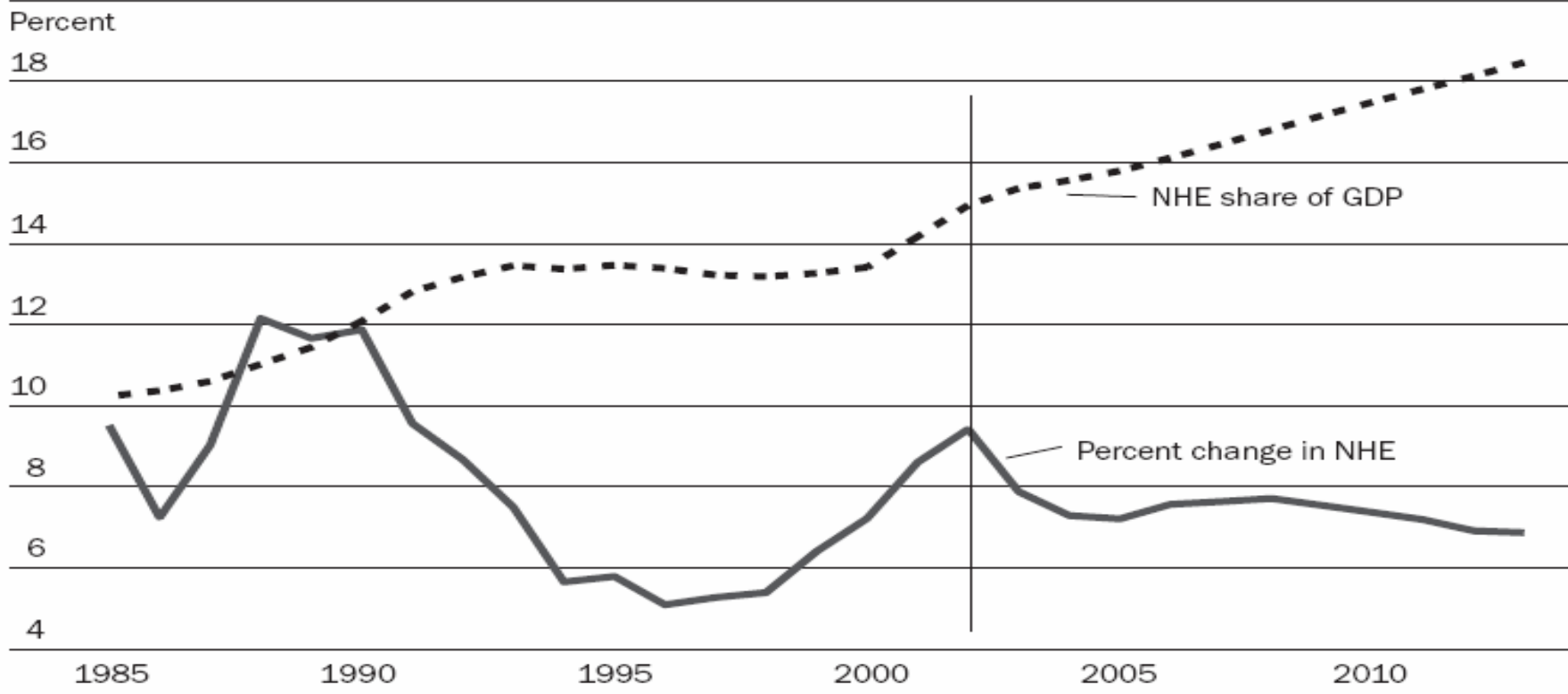
# Estimating the Economic Contribution of Dietary Components in Managing Health Costs

Patricia M. Danzon PhD  
The Wharton School  
University of Pennsylvania

# Rising health expenditures...

## EXHIBIT 3

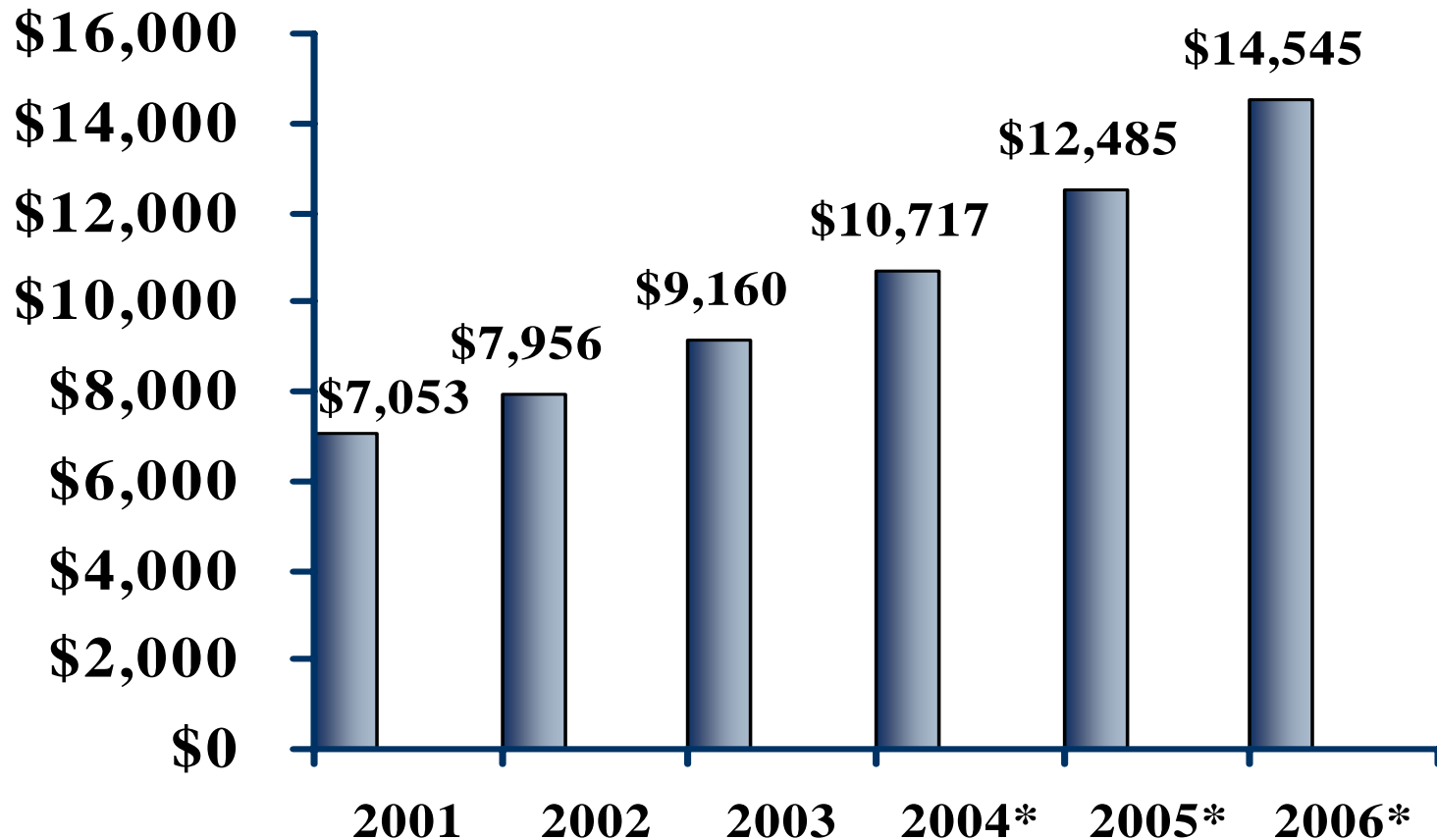
### National Health Expenditures (NHE): Percentage Change And Share Of Gross Domestic Product (GDP), Selected Calendar Years 1985–2013



**SOURCE:** Centers for Medicare and Medicaid Services, Office of the Actuary.

**NOTE:** Vertical line denotes beginning of projections; trend lines to the left of the vertical line represent historical data.

# Average Annual Premiums for Employer-Sponsored Family Coverage, 2001-2006



•Projected.

•Source: Kaiser/HRET Employer Health Benefits, 2001-2003; Towers Perrin 2003 Health Care Cost Survey, Report of Key Findings, 2003; Mercer US Health Care Survey Results, Mercer HR Consulting, December 9 2002; "Health Care Cost Increases Expected to Continue Double-Digit Pace in 2003, Hewitt Associates, Oct. 14, 2002; Sean Tunis "Medicare and Medical Technology Policy," Presentation at the Leonard Davis Institute, Philadelphia, PA, February 11, 2005.

# Leading Causes of Death, US 2000

**Table 1.** Leading Causes of Death in the United States in 2000\*

Cause of Death	No. of Deaths	Death Rate per 100 000 Population
Heart disease	710 760	258.2
Malignant neoplasm	553 091	200.9
Cerebrovascular disease	167 661	60.9
Chronic lower respiratory tract disease	122 009	44.3
Unintentional injuries	97 900	35.6
Diabetes mellitus	69 301	25.2
Influenza and pneumonia	65 313	23.7
Alzheimer disease	49 558	18
Nephritis, nephrotic syndrome, and nephrosis	37 251	13.5
Septicemia	31 224	11.3
Other	499 283	181.4
<b>Total</b>	<b>2 403 351</b>	<b>873.1</b>

\*Data are from Minino et al.<sup>4</sup>

# Growth in Share of Deaths Attributed Directly to Obesity/Inactivity

**Table 2.** Actual Causes of Death in the United States in 1990 and 2000

Actual Cause	No. (%) in 1990*	No. (%) in 2000
Tobacco	400 000 (19)	435 000 (18.1)
Poor diet and physical inactivity	300 000 (14)	400 000 (16.6)
Alcohol consumption	100 000 (5)	85 000 (3.5)
Microbial agents	90 000 (4)	75 000 (3.1)
Toxic agents	60 000 (3)	55 000 (2.3)
Motor vehicle	25 000 (1)	43 000 (1.8)
Firearms	35 000 (2)	29 000 (1.2)
Sexual behavior	30 000 (1)	20 000 (0.8)
Illicit drug use	20 000 (<1)	17 000 (0.7)
<b>Total</b>	<b>1 060 000 (50)</b>	<b>1 159 000 (48.2)</b>

\*Data are from McGinnis and Foege.<sup>1</sup> The percentages are for all deaths.

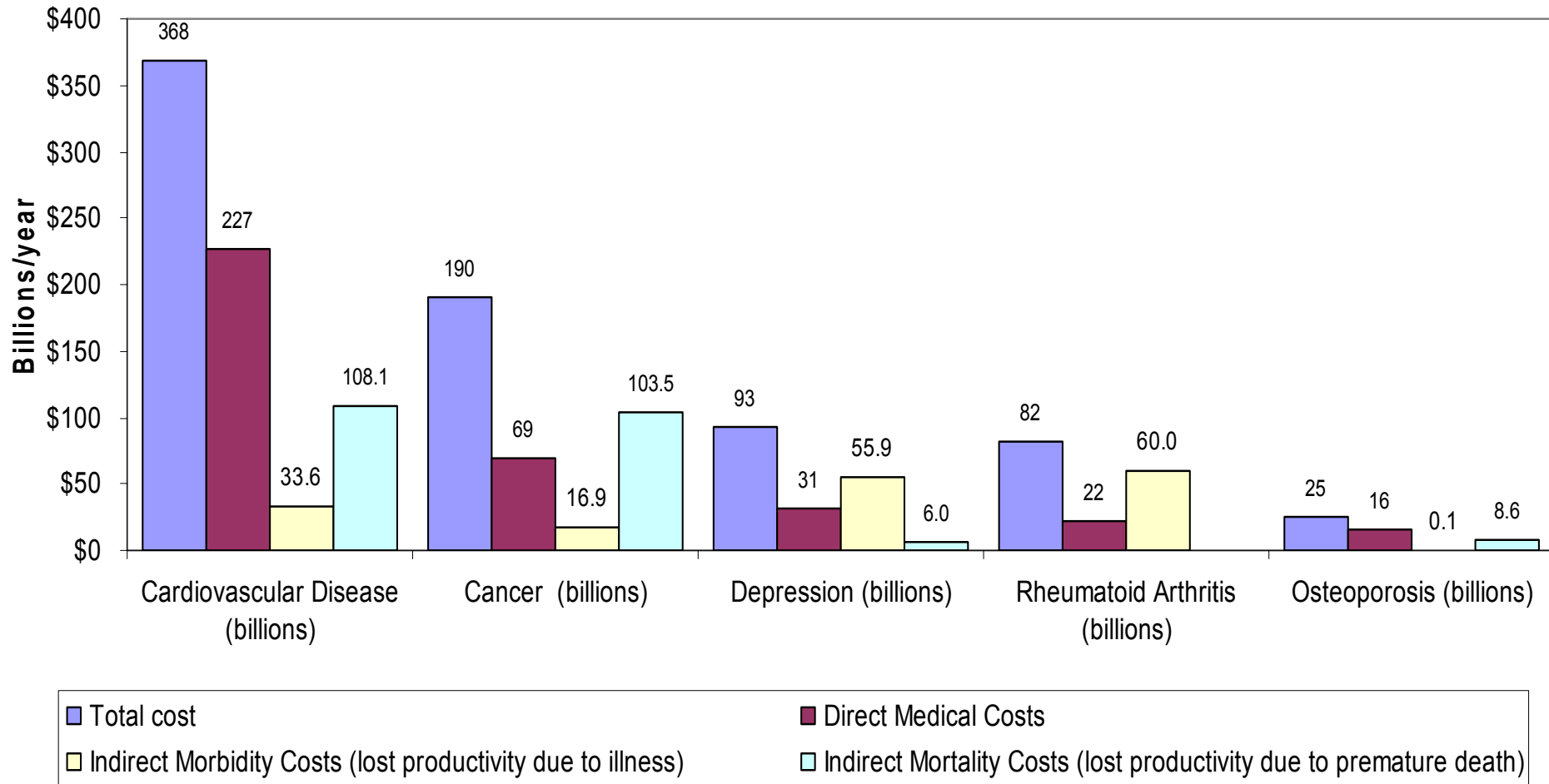
<b>Bioactive</b>	<b>Potential Disease Targets</b>
<p><b>Lycopene</b>            Found in: Tomato, apricot, pink grapefruit, guava, watermelon, papaya</p>	<p>Cancer (prostate, lung, stomach), atherosclerosis</p>
<p><b>Omega-3 Fatty Acids</b>            Found in: Fish, walnuts, flax</p>	<p>Inflammatory disease (rheumatoid arthritis), depression, heart disease</p>
<p><b>Epigallocatechin Gallate (EGCG)</b>            Found in: Green Tea</p>	<p>Hormone-related abnormalities (baldness, acne), obesity and appetite control, cancer, allergies, heart disease</p>
<p><b>Isoflavones</b>            Found in: Soy</p>	<p>Hormone-related cancers (breast, prostate), menopausal symptoms, osteoporosis, cardiovascular disease, high cholesterol, Alzheimer's, diabetes</p>
<p><b>Sulphorophane (Sulforaphane)</b>            Found in: Broccoli</p>	<p>Cancer, macular degeneration, ulcers</p>
<p><b>Resveratrol</b>            Found in: Red wine, peanuts, red grapes, raspberries</p>	<p>Coronary heart disease, cancer, atherosclerosis, Alzheimer's</p>

Source: WebMD, <http://www.webmd.com>, accessed March 16, 2005

# Partial Economic Costs of Major Diseases: Rough 2004 Estimates (\$Billions)

	<b>Cardiovascular</b>	<b>Cancer</b>	<b>Depression</b>	<b>Rheumatoid Arthritis</b>	<b>Osteoporosis</b>
<b>Total Cost</b>	<b>368.4</b>	<b>189.8</b>	<b>92.8</b>	<b>82.0</b>	<b>25.1</b>
<b>Direct Medical</b>	226.7	69.4	30.9	22.0	16.4
<b>Indirect Morbidity</b> (productivity loss due to illness)	33.6	16.9	55.9	60.0	0.1
<b>Indirect Mortality</b> (productivity loss due to premature death)	108.1	103.5	6.0		8.6

# Medical Cost Share of Total Costs Varies by Disease

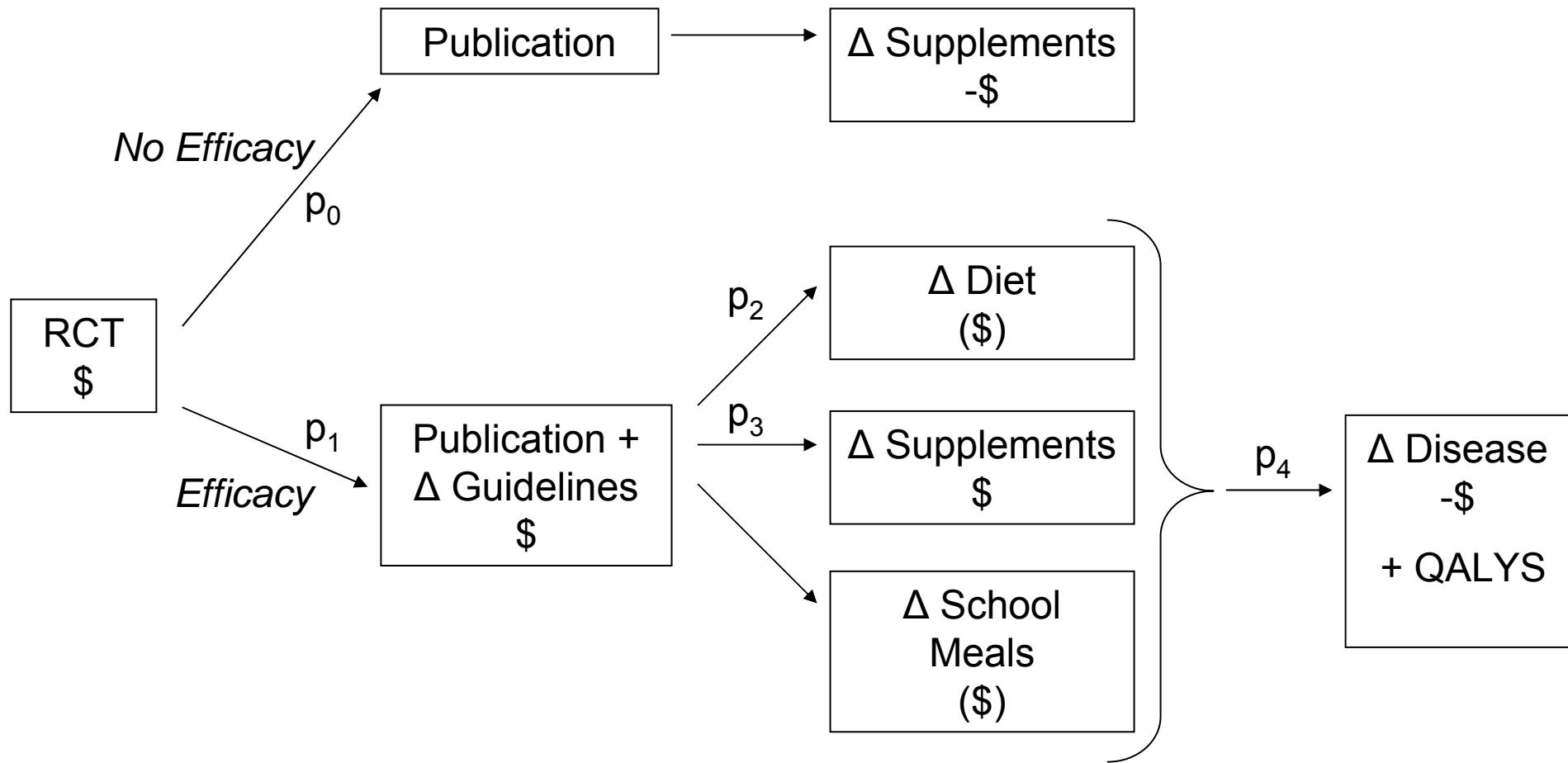




# Estimating the Marginal Cost Effectiveness of a Biofoods RCT: A Multi-Part Intervention

- RCT for biofoods (supplements and foods)
  - AND, *If* RCT shows efficacy ( $p_1$ )
- Change food guidelines (and school meals)
  - ⇒ Consumers change diet ( $p_2$ ) and/or supplement use ( $p_3$ )
  - ⇒ Change in disease incidence ( $p_4$ ) and/or severity ( $p_5$ )
  - ⇒ Change in medical + nonmedical costs + quality of life

# Cost-Effectiveness of Combined Intervention vs. Status Quo



# Cost-Effectiveness of Biofoods RCT vs. Status Quo

$$\frac{\Delta \text{Costs}}{\Delta \text{Effects}} = \frac{C_{\text{rct}} + p_1 \{C_{\text{gl}} + V_{\text{sm}} + p_2 V_{\text{f}} + p_3 V_{\text{s}} - p_4 V_{\text{coi}}\}}{\Delta \text{Qalys}}$$

$V_{\text{sm}}, V_{\text{f}}, V_{\text{s}}, V_{\text{coi}}$  = (discounted) present value of future costs/cost savings

- Includes all future cohorts

# Public Sector Components of Costs and Cost Savings

- $C_{\text{rct}}$  = cost of RCT of supplements and foods  
=  $\sum_i \sum_t n^{it} \times c^{it}$  ,  $n$  = participants,  $t$  = year  
 $i$  = supplement/foods/observational study
  - *IF trials show efficacy*
- $C_{\text{gl}}$  = Cost of revising food guidelines
- $V_{\text{sm}}$  = change in school meals:  $\sum_i \sum_t [K^{it} \times \Delta c^{it}] e^{-rt}$
- $V_{\text{coi}}^M$  = Medicare, Medicaid:  $\Delta \sum_i \sum_t [S^{it} \times m^{it}] e^{-rt}$ 
  - $S$  = number of cases,  $m$  = cost per case
- Social security effects of longer life expectancy?

# Private Sector Components of Costs and Cost Savings

- $V_f =$  change in food costs:  $\sum_i \sum_t [N^{it} \times \Delta f^{it}] e^{-rt}$
- $V_s =$  change in supplement costs
  - $\sum_i \sum_t \{N^{it} [p_0 c_0^{it} \times p_1 p_2 c_1^{it}] \} e^{-rt}$
  - Cost may decrease ( $c_0$ ) or increase ( $c_1$ ) as trials show efficacy/no efficacy
- $V_{coi}^p = \Delta \sum_i \sum_t [S^{it} \times m^{it} \times w^{it}] e^{-rt} =$  private COI
- $\Delta Qalys = \Delta \sum_i \sum_t [\text{change in quality of life}^{it}] e^{-rt}$

## *Implications of CE Analysis:*

### 1. Information is a public good

- RCT is a global public good
  - Information benefits future generations globally
  
- Science-based change in US dietary guidelines is a US public good
  - benefits future US generations
  - some spillovers abroad

## *Implications of CE Analysis:*

### 2. Potential savings are large but delayed: not a short term fix for medical costs

- Effects of dietary change may be cumulative
- Disease incidence greatest at older ages => delay in observing change in lifetime diet
- Short term impact could be significant if bioactives affect disease progression/severity, as well as incidence
  - Can be estimated in RCT
- Full CE analysis must estimate expected net savings (discounted) to all future cohorts

## *Implications of CE Analysis:*

### 3. Whole foods approach is potentially more cost-effective than supplements

- Substitution of healthy foods for unhealthy foods has low *incremental* out-of-pocket cost
  - Tofuburger vs. hamburger
  - Potential additional benefits of reducing unhealthy foods
  
- Supplements are ongoing, incremental costs
  - Yearly costs vary by supplement, source
  - Prices could come down, if increased induces more suppliers and/or scale economies



# Prices of supplements

Ingredient	Brand, Product Name	Count	Cost	# Days Duration	Yearly cost
<u>Omega-3</u>	Nature Made, Fish Oil 1200 mg Softgels Omega-3/Omega-6, 180 cp	180	12.74	45	103.34
	Natrol, Omega Solutions Softgels Osteo, 80each	80	16.99	20	310.07
	CVS, Natural Super Omega-3 Softgels, 60CP	60	4.49	30	54.63
	Natrol, Omega-3 Complex Softgels Flax/Borage, 90CP	90	12.99	30	158.05
	Natrol, Omega-3 Softgels, 150 CP	150	8.49	37.5	82.64
<u>Lycopene</u>	Symtec, Liquid MultiVitamin Plus Lutein and Lycopene, 16 OZ	16	12.99	16	296.33
	Nature's Bounty, Lycopene 5 mg Softgels, 60 CP	60	6.56	60	39.91
	Centrum, Silver Tablets, 100 TB	100	10.49	100	38.29
	One-A-Day, Men's Health Formula Tablets, 100 TB	100	8.99	100	32.81
	Centrum, Tablets, 130 TB	130	9.49	130	26.65
<u>Isoflavones</u>	Natrol, Women's Soy Isoflavones Capsules, 120 EA	120	9.34	30	113.64
	Caltrate, 600+Soy Tablets, 60 TB	60	14.99	30	182.38
	Soy Care, SoyCare For Menopause Capsules, 60 CP	60	12.99	30	158.05
	New Phase, NewPhase COMPLETE Caplets, 30 CP	30	12.69	30	154.40
	Estroven, Calcium Advantage Caplets, 90 CP	90	10.99	45	89.14

Source: [www.CVS.com](http://www.CVS.com), accessed March 2005

## *Implications of CE Analysis:*

### 4. Cost-effectiveness of prevention greater for high-risk diseases and subpopulations

- Prevention is cheaper than cure if
  - $B \times N < i \times N \times M$ 
    - $B$  = prevention cost       $N$  = population
    - $i$  = disease incidence       $M$  = treatment cost per case
  - i.e. Prevention is cheaper if  $B/M < i$
  
- Prevention is more cost effective if targeted to subgroups at high risk of disease
  
- Stratification, to identify subgroups most likely to benefit, is likely to enhance cost-effectiveness

# Ideally, the studies should include ...

- Biomarkers for all relevant diseases
- Population stratified by risk subgroup
- Supplement vs. whole food
- Dose
- Duration of treatment
- Duration of effect, after discontinue treatment
- Modelling to extrapolate to incidence and severity/progression of disease

## *Implications of CE Analysis:*

### 5. Efficacy vs. Effectiveness Gap is Large

- RCT measures efficacy of bioactives on clinical endpoint, *conditional on compliance*
- Effects of change in national dietary guidelines depends on uncertain behavioral response
- Effects of adding biofoods to school meals could be measured by RCT
  - but would yield downward biased estimates of full effect if guidelines also change

# Response to bioactive guidelines may exceed response to food group guidelines

- Manufacturers will market benefits of enhanced foods and proprietary supplements
  - Producer ads stimulated consumer knowledge and reduced consumption of fats/cholesterol (Ippolito and Matthios, 1995,6)
  - RCTs for Rx supplements already underway
    - Concentrated omega-3s
  - Disutility of supplements may be lower than dietary change for some consumers, despite higher out-of-pocket cost
- => Need RCTs for supplements AND whole foods, since bioresponse and behavioral response may differ

Consumer self-selection in response to guidelines => RCT efficacy could over- or underestimate actual effectiveness

RCT => Overestimate effectiveness

- If health-conscious consumers are more likely to follow guidelines AND healthy behaviors have decreasing marginal effects

RCT => Underestimate effectiveness

- If health-conscious consumers are more likely to follow guidelines and healthy behaviors have synergistic marginal effects
- If healthy foods displace harmful foods

# Running An Observational Study + RCT Has Multiple Potential Benefits

- A cohort-controlled observational study, simultaneous with RCTs, could measure
  - Correlation in healthy behaviors
  - Multivariate regression to identify incremental effect of different healthy behaviors for subpopulations
  - Bias in other observational studies of diet
  - Potential effectiveness-efficacy gap of biofoods RCT
  - Identify populations in need of special counseling etc.
  - Longer term effects, if cohort control study costs less than RCT



## Observational study could contribute cost components not available from RCT

- Market cost of food substitution and supplements
- Treatment costs by disease and disease state
- Data to analyze consumer biofood and supplement choices
  - Confounding health and risk behaviors
  - Income, education effects
  - Other demographics



# Conclusions

- Cost-effectiveness of combined intervention seems likely, given
  - Information is a global public good
  - Foods may affect multiple, high-incidence/high cost diseases
  - Intervention costs are small, if bioactive foods substitute for other foods and/or manufacturers supplement other foods
  
- RCT for bioactive foods and supplements is necessary but not sufficient to estimate cost-effectiveness of combined intervention
  - Consumer and producer response to change in dietary guidelines is highly uncertain
  
- Observational cohort study would be useful add-on to RCT
  - To assess likely non-random behavioral response and gaps between efficacy and effectiveness