Estimating the Economic Impact of Nutrigenomics in Managing Health Costs

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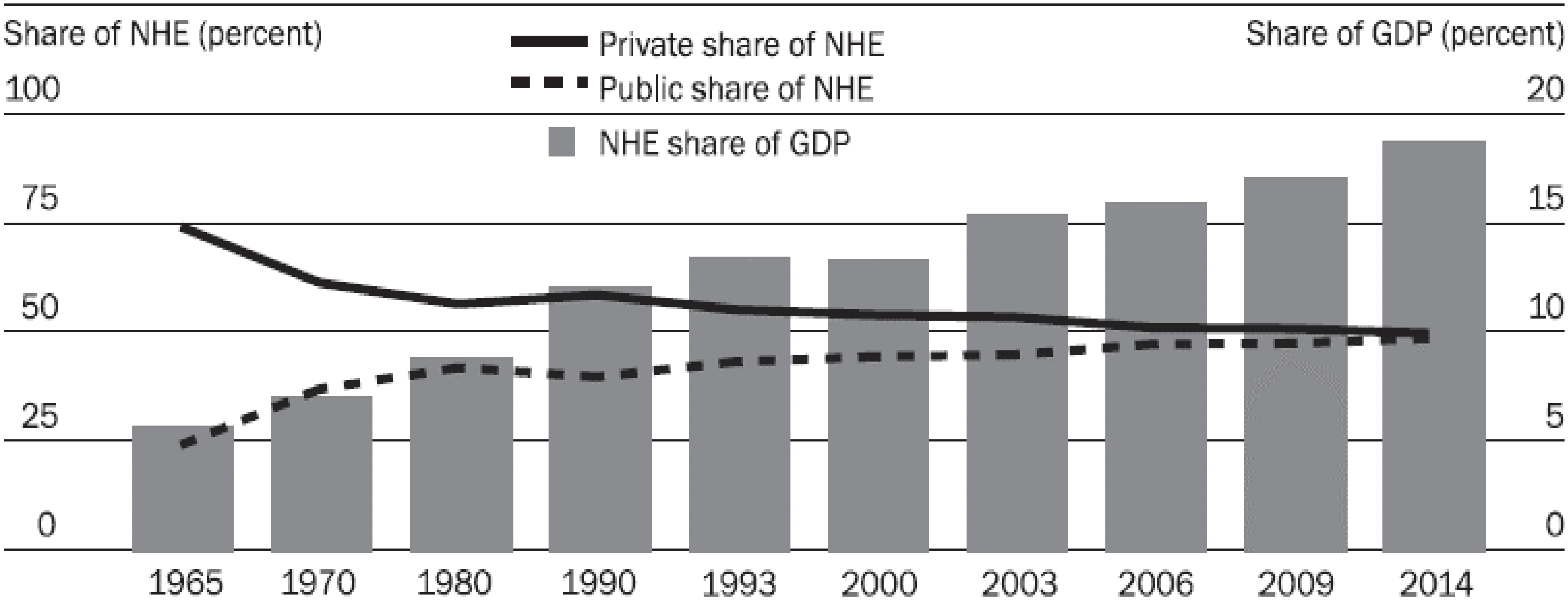
Rising health expenditures…

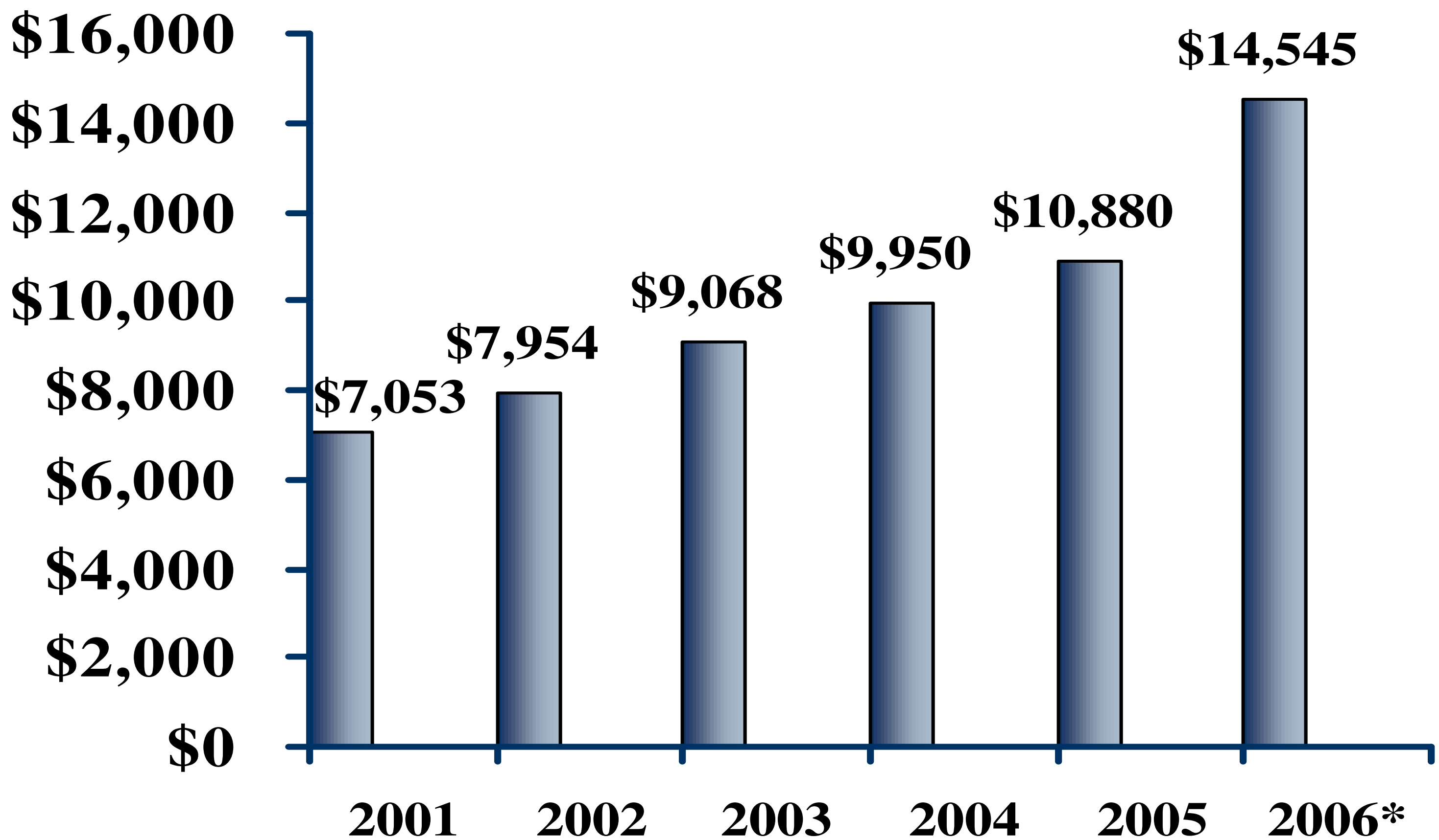
National Health Expenditures (NHE) Share Of Gross Domestic Product (GDP) And Private And Public Shares Of NHE, Selected Years 1965–2014



SOURCE: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group.
NOTES: The left axis (public and private spending's share of NHE) relates to the two line graphs. The right axis (NHE's share of GDP) relates to the gray-shaded bars. Data for 2006, 2009, and 2014 are projections.

Source: Stephen Heffler, et al. "U.S. Health Spending Projections For 2004-2014" Health Affairs We b Ex c l u s i v e W 5 - 7 4. February 23, 2005. http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.74/DC1

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



* Projected.

•Source: Kaiser/HRET Employer Health Benefits, 2002, 2003,2004,2005; Towers Perrin 2005 Health Care Cost Survey, Report of Key Findings, 2005

Leading Causes of Death Have Significant Life-Style and Genetic Components

Cause of Death	2000	2003		
	Death Rate per 100,000 Population	**Rate**	**Number of Deaths**	**Percent of Total Deaths**
Heart disease	258.2	235.6	685,089	28
Malignant neoplasm	200.9	191.5	556,902	22.7
Cerebrovascular diseases	60.9	54.2	157,689	6.4
Chronic lower respiratory tract disease	44.3	43.5	126,382	5.2
Unintentional Injuries	35.6	37.6	109,277	4.5
Diabetes mellitus	25.2	25.5	74,219	3.0
Influenza and pneumonia	23.7	22.4	65,163	2.7
Alzheimer’s disease	18	21.8	63,457	2.6
Nephritis, nephritic syndrome and nephrosis	13.5	14.6	42,453	1.7
Septicemia	11.3	11.7	34,069	1.4
Intentional self-harm (Suicide)	NA	10.8	31,484	1.3
Chronic liver disease and cirrhosis	NA	9.5	27,503	1.1
Essential hypertension and hypertensive renal disease	NA	7.5	21,940	0.9
Parkinson’s disease	NA	6.2	17,997	0.7
Assault (homicide)	NA	6.1	17,732	0.7
Other	181.4	143.4	416,932	17.0
TOTAL	**873.1**	**841.9**	**2,448,288**	**100.0**

Source: CDC/NCHS, National Vital Statistics System

Growth in Mortality Attributed to Poor Diet and Physical Inactivity

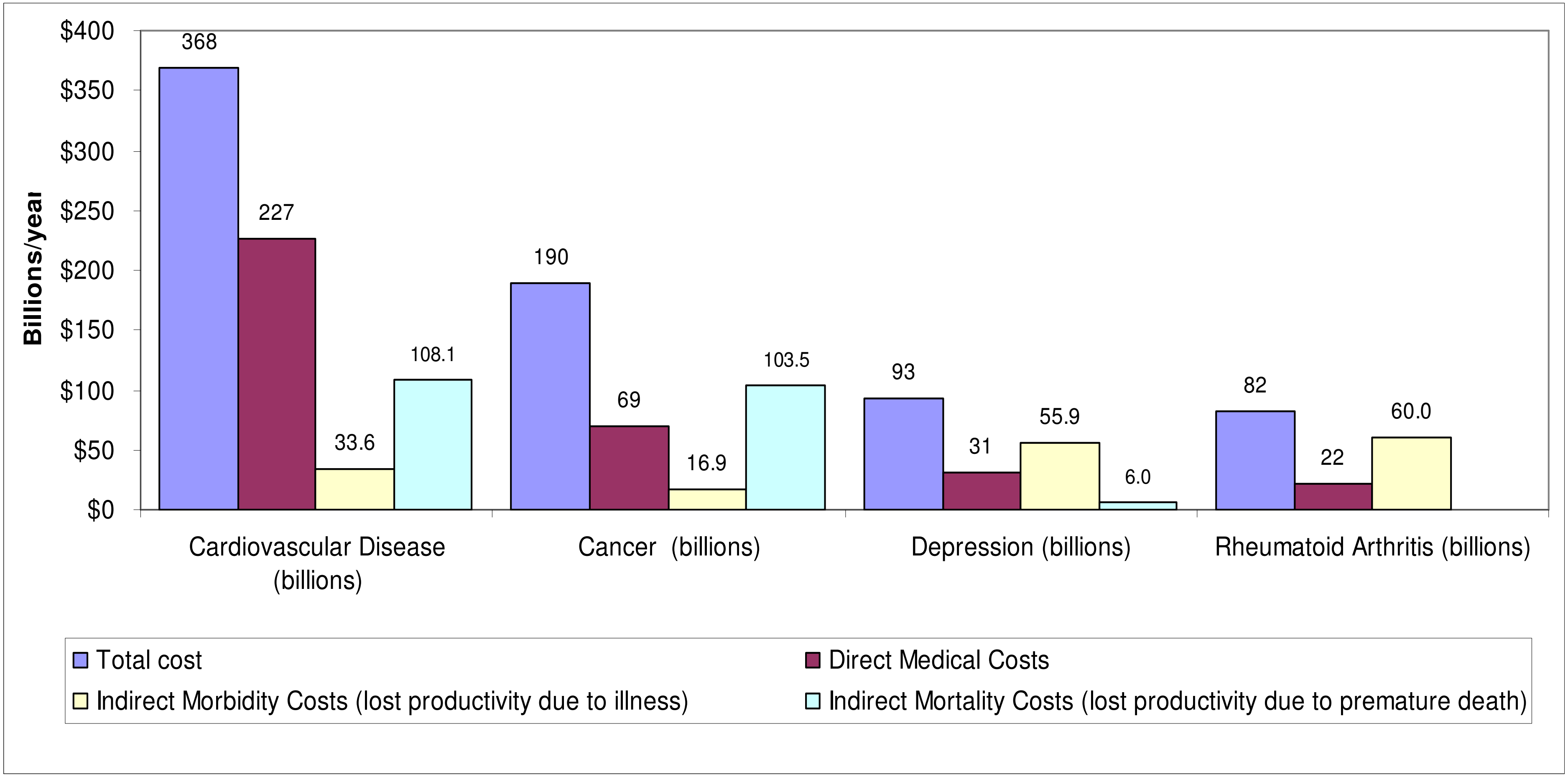
Table 2. Actual Causes of Death in the United States in 1990 and 2000

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)
Total	**1 060 000** (50)	**1 159 000** (48.2)

*Data are from McGinnis and Foege.[1] The percentages are for all deaths.

Source, Ali Mokdad et al., “Actual Causes of Death in the United States, 2000.” JAMA, March 10, 2004, Vol. 291 (10): 1238.

Medical Cost is only a Fraction of Total Economic Cost of Illness



Rough estimates based on various sources, inflation adjusted to $2004.

http://www.cancer.org/docroot/MIT/content/MIT_3_2X_Costs_of_Cancer.asp; http://www.nhlbi.nih.gov/about/03factbk.pdf (page 62); http://www.cdc.gov/nccdphp/overview.htm; Greenberg, PE, Kessler, RC, Birnbaum, HG, et al. 2003. The economic burden of depression in the United States: How did it change between 1990 and 2000? *Journal of Clinical Psychiatry* 64: 1465-75. (http://www.mindfully.org/Health/2003/Depression-Cost-Bigger31dec03.htm)

Strong *Prima Facie* Case for Investing in Prevention

“95 percent of all health care costs are spent on people who are already sick, while only 5 percent is spent preventing people from getting sick”

Tommy G. Thomson, former US Secretary of HHS, Presentation at Rutgers University, May 2006.

Including diet and lifestyle prevention costs would probably change the numbers, not the conclusion

Preliminary Caveats: (1) More Cost-effective Policies Exist to Influence Diet and Lifestyle

- Consumers don't optimally use existing diet and lifestyle knowledge

- Incentives and preferences matter
  - Low prices of high calorie/high fat/high sugar foods
  - Fast foods save time and money
  - Short run vs. long run optimization

- Taxes on harmful foods (e.g. eliminate sugar subsidies) could be good economics …but bad politics

- Tobacco tax rated a highly cost-effective intervention for developing countries (Jamison et al. 2006)

(2) Pharmacogenomics/Pharmacogenetics Has Delivered Much Less Than Expected

- 2001 Genome mapping => promise of new drug targets and “personalized medicine”, BUT

- 2006 Few drugs for novel targets
  - Unprecedented targets have higher failure rates
- Few (22) drugs reference genetic test in label, but most are anti-cancer therapies (Royal Society, 2005)
  - Acquired variation confined to tumor, not inherited

- Complexity of biology, data collection and analysis

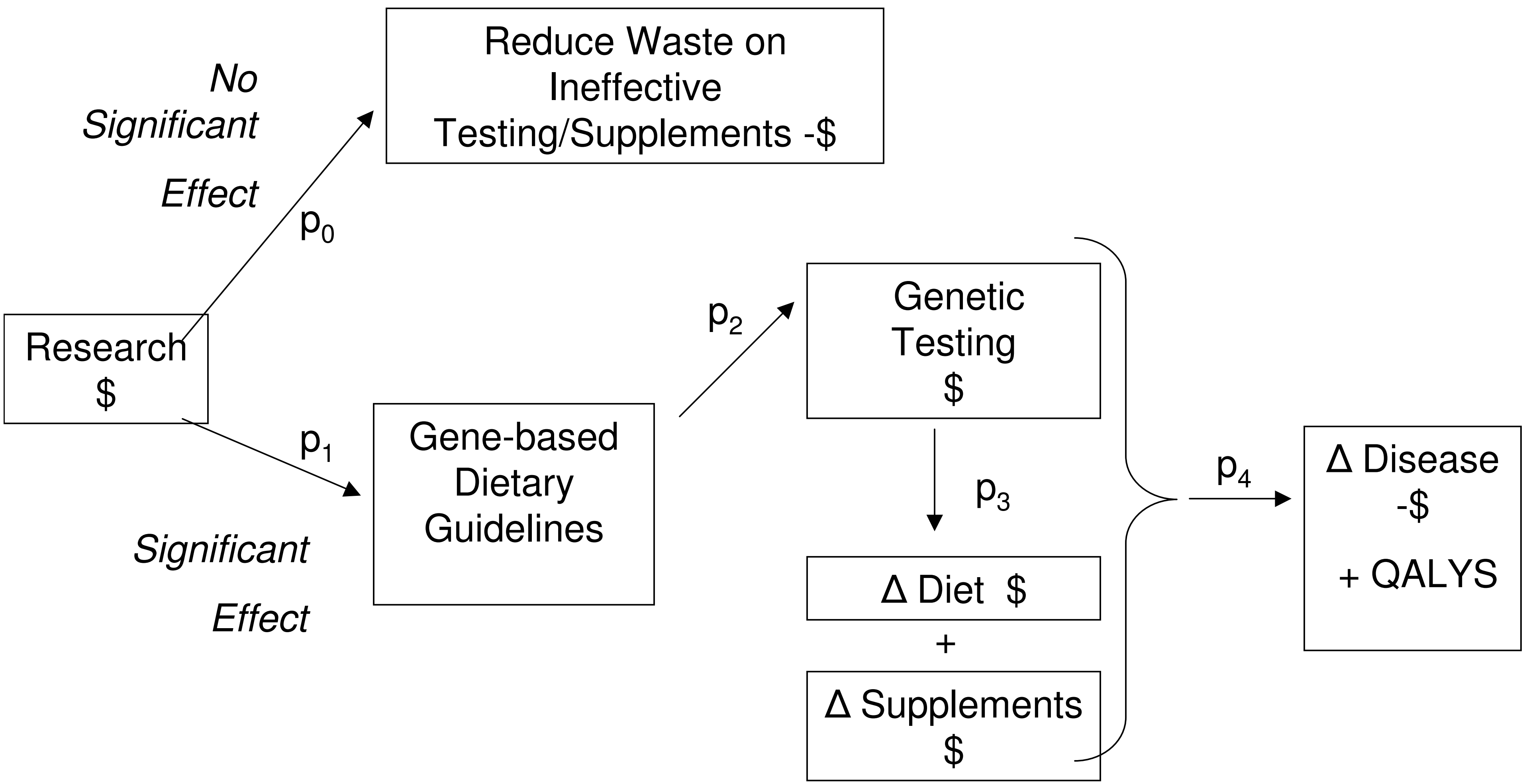
Nevertheless, nutrigenomics could yield significant economic benefits, if

- Gains in scientific knowledge are large

- Consumers understand and use the knowledge
  - And don’t substitute other, unhealthy behaviors

- Findings are applicable across cultures, countries and generations
  - Robust to environment and other factors

Economic Impact Model for Nutrigenomic Research



Cost-Effectiveness of Nutrigenomics Research (Societal Perspective)

$$\frac{\Delta \text{ Costs}}{\Delta \text{Effects}} = \frac{C_{nih} + p_1 \{p_2 [C_{gt} + \ p_3 [(V_f + V_s) - p_4 V_m]] \}}{\Delta \text{ Qalys}}$$

C_{nih} = cost of research

C_{gt} = cost of genetic testing

V_f , V_s , V_m = discounted present value of lifetime costs of food, supplements and medical care, respectively

Qalys = discounted present value of quality adjusted life years gained

- Probabilities convert to population frequencies
  - For current and future cohorts

Implications of Economic Analysis:
1. Information is potentially a public good

- Nutrigenomic knowledge may benefit current and future generations globally
  - Unless gene-nutrition effects are modulated by environment or other factors
- Genetic testing is a life-time investment for each individual
  - Unless modulated by environment or other factors
- Ideally, nutrigenomic research will document interactions with other environmental factors e.g. smoking

Implications of Economic Analysis: 2. Cost savings could be large but delayed: not a short term fix for medical costs

- Robust nutrigenomic knowledge will take years

- Dietary change have cumulative effects
  - Effects on disease incidence greatest at older ages

- Medium term impact could be significant if diet affects disease progression

Implications of Economic Analysis

3. In general, prevention is more cost-effective for high-risk diseases and subgroups

- Prevention is cheaper than cure if
  - $P \times N < i \times N \times M$ or $P/M < i$
    - P = prevention cost
    - N = population
    - i = disease incidence
    - M = treatment cost per case

- Testing and improved nutrition will be more cost effective if targeted to high-risk subgroups e.g. based on family history

Value of testing for personalized diet depends on cost of nonresponders + cost of test

- Assume effect of nutrition (e.g. lowfat diet) differs based on SNIPs:
  - N_1 get benefit β
  - N_2 have adverse effect α
  - P^T = cost of genetic test to identify N_2 adverse responders
  - F = cost of lowfat diet, $0 \leq F < \beta$
- Net social benefit B from lowfat diet:
  - Without testing: $B^0 = N_1 \beta - N_2 \alpha - FN$
  - With testing: $B^T = N_1 (\beta - F) - P^T N$
- Testing prior to diet intervention increases social welfare ($B^T > B^0$) if:
  - $P^T N < N_2 (\alpha + F)$ or $P^T / (\alpha + F) < N_2/N$
- Testing more likely worthwhile if:
  - test is cheap (P^T low) and longlived
  - Nonresponder cost is high: $(\alpha + F)N_2/N$ large

Implications of Economic Analysis: 4. 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
  - Eliminating unhealthy foods has additional benefit

- Supplements require lifetime increased spending

- But regulation + insurance may distort consumer choice towards supplements, rather than food (more later)

Implications of Economic Analysis: *5.* Efficacy vs. Effectiveness Gap is Large

- Studies measure effects of gene-diet interactions, *conditional on compliance*

- Effect of change in dietary guidelines depends on consumer understanding, incentives and compliance
  - Non-random response is likely

Consumer self-selection in response to nutrigenomic information will affect actual vs. predicted gains

If health-conscious consumers are more likely to get genetic test and change diet

- *Overestimate effectiveness* if healthy behaviors have *decreasing* marginal effects
- *Underestimate effectiveness* if healthy behaviors have *synergistic* marginal effects

- *Underestimate effectiveness* if reducing harmful foods has other benefits e.g. reduce CV + obesity

Producer marketing may stimulate (and distort?) consumer use of nutrigenomic information

- Producer ads stimulated consumer knowledge and reduced consumption of fats/cholesterol (Ippolito and Matthios, 1995,6)
- Manufacturers of proprietary tests and supplements have incentives to (over?) market benefits
- Current FDA regulation of supplements provides consumers little guidance on efficacy

Regulatory and Insurance Challenges of Genetic Tests and Supplements

- What product-specific trials are necessary, if NIH establishes basic results?
- Medicare, Medicaid, private insurance are unlikely to cover genetic tests and/or supplements without FDA approval of efficacy (+ physician prescription?)
- Will testing/supplement industry invest in clinical trials, to get insurance coverage?
  - high cost and risk, limited IP
- More research needed on optimal FDA regulation and insurance coverage of supplements vs. medicines vs. foods

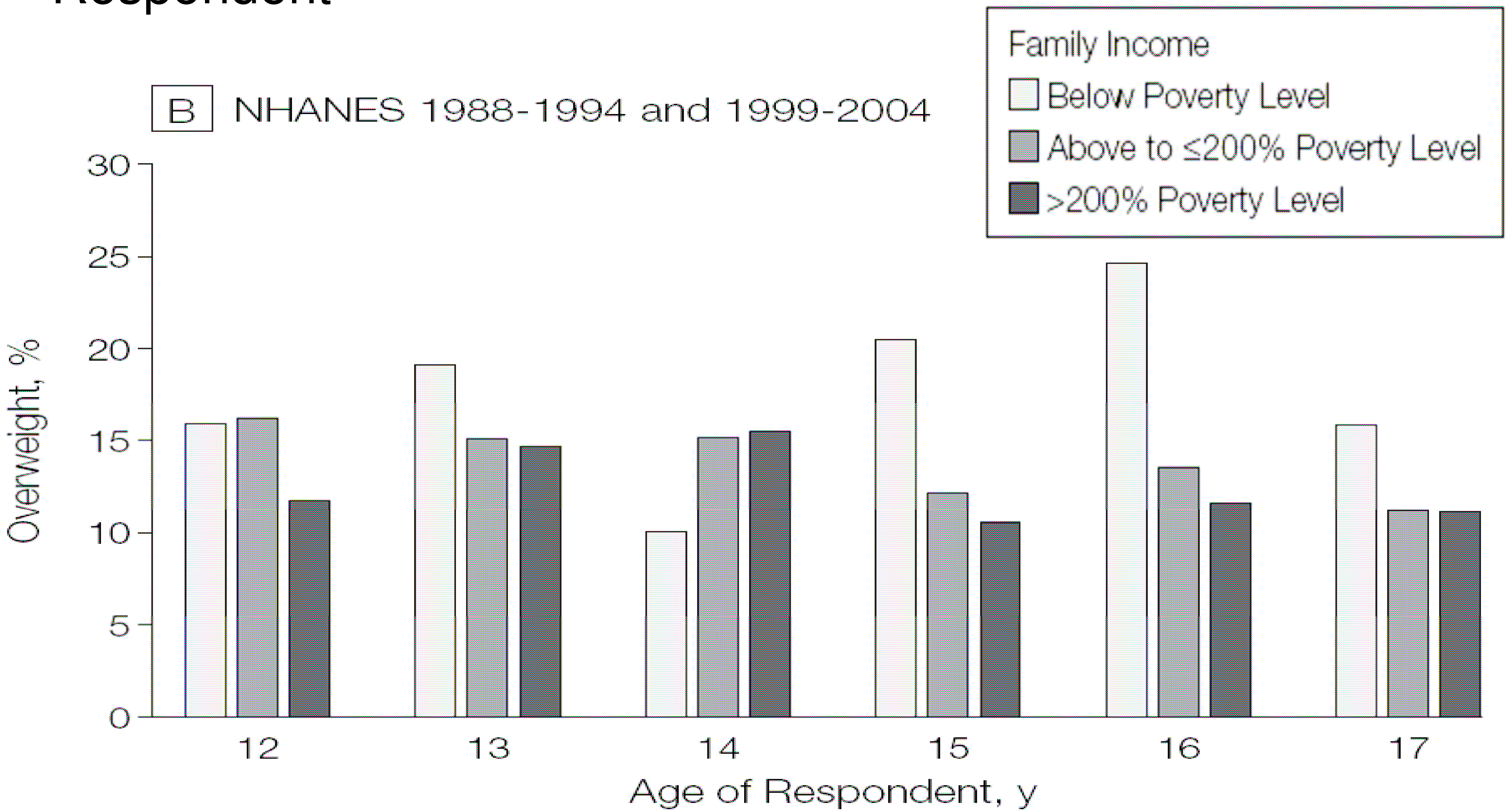
Nutrigenomics is Unlikely to Reduce Health Disparities

- Less-educated/low-income population is at higher risk of obesity/poor nutrition BUT

- Less likely to use nutrigenomic information if
  - Less informed
  - More price sensitive to cost of genetic tests and dietary change/supplements

- E.g. Food labeling legislation (calories and nutrients) was associated with a decrease in BMI and obesity only for white women, not for other ethnic/gender subgroups (Variyam and Cawley, 2006)

Adolescent Overweight by Poverty Status and Age of Respondent



NHANES indicates National Health and Nutrition Examination Survey. Overweight is defined as at least the 95th percentile body mass index for age, as defined by the 2000 Centers for Disease Control and Prevention growth chart.

Source: Miech et al. JAMA May 24/31 2006

International cooperation on study design, data measurement etc.

- Complex interactions will require very large population studies: many outcomes + many controls
  - Genetic subgroups
  - Supplement vs. whole food
  - Dose and duration of treatment
  - Environmental factors
  - Duration of effects, after discontinue treatment
  - Incidence and progression of disease
- Conclusions based on inadequate studies could be of limited value or misleading

Conclusions

- Nutrigenomics research has large potential economic benefit IF it can show statistically significant and large effects
  - Information potentially of global value
  - Genetic testing a lifetime investment for each person
  - Nutrition is potentially a low cost prevention strategy

- Economic value of nutrigenomic research greatest for high-risk diseases and population subgroups

- Economic value of nutrigenetics is greatest if variance of population response is large and testing is cheap

- Optimal regulatory and insurance strategy is a critical issue for further research