Using Economic Analysis in FDA Nutrition Regulations

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Requirements for Federal Agencies to Analyze Regulations

- Paperwork Reduction Act (1980)
- Executive Order 12866 (1993)
- Unfunded Mandates Reform Act (1995)
- Regulatory Flexibility Act (as amended 1996)
- Congressional Review Act (1996)
Basic Requirements for Economic Analyses of Federal Regulations

- Identify Need for Regulation
- Identify Regulatory Options
- Estimate Costs and Benefits of Options
Elements of Good Regulatory Analysis

- Public health problem
  - baseline impact of hazard
  - baseline practices that potentially contribute to or mitigate the problem
- Why regulation is the best way to address the problem
- Regulatory options for addressing the problem
- Specific changes in behavior of all affected
- Costs of changes in behavior
- Effectiveness of changes in behavior
- Value of the reduction in the public health problem
- Variability and uncertainty in estimates
Narrow Purpose of Regulatory Analysis

• Informing
  – not deciding, not advertising

• Regulatory
  – not clinical practice

• Policy
  – sufficient for law and decision making
Economic Analyses of Major Nutrition Regulations

• Nutrition Labeling (1993)
• Folic Acid Fortification (1996)
• Trans Fat Labeling (2003)
Nutrition Labeling (1993)

• Standardized labeling of nutrition information, established standards for and authorized nutrient content claims and health claims
• Baseline (over 20 years):
  – nutrition-related CHD & cancer:
    • 725,000 cases; 308,000 deaths
    – life-years lost: 2,281,000
• Costs (over 20 years discounted at 5%): $1.4 - $2.3 billion
• Health effects of rule (over 20 years):
  – CHD & cancer prevented:
    • 39,000 cases; 13,000 deaths
    – life-years saved: 81,000
• Benefits (over 20 years, discounted at 5%): $3.6 billion
Folic Acid Fortification (1996)

• Required fortification of enriched grain products with folic acid to prevent neural tube defects

• Annual costs:
  – $27 million in product changes and
  – possible unquantified health costs from masked anemia associated with vitamin B12 deficiency (breakeven number of cases between 390-1,230)

• Health effects of rule:
  – prevent 25-125 neural tube defects; 5 - 30 deaths

• Annual monetized benefits: $220 million - $700 million
Trans Fat Labeling (2003)

- Required reporting of *trans* fat in Nutrition Facts and authorized a “*trans* fat free” claim
- Annual costs: $140 million - $275 million
- Health effects of rule:
  - prevent 600 - 1,200 heart attacks; 250 - 500 deaths
  - life-years saved: 2,000 - 4,000
- Annual monetized benefits: $1 billion - $2 billion
FDA Methodology for Cost Estimation

• Engineering cost model for product changes
  – number of products
  – cost per product
• Cost of any negative health consequences
• Cost of behavioral changes
FDA Methodology for Benefit Estimation

• Product of
  – number of illnesses prevented
  – number of QALYs saved per illness prevented
  – monetary value of a statistical life year

• Same data used for cost-effectiveness measures (cost/illness, cost/QALY)
Contributions of Economic Analysis

• Social Science
  – human behavior, not just molecular behavior

• Quantification
  – exposure
  – health effect
  – behavioral change

• Best estimate of consequences
  – apply data beyond clinical trial data
Resources


