Future Research Needs and Industry Incentives for Health & Nutrition Research

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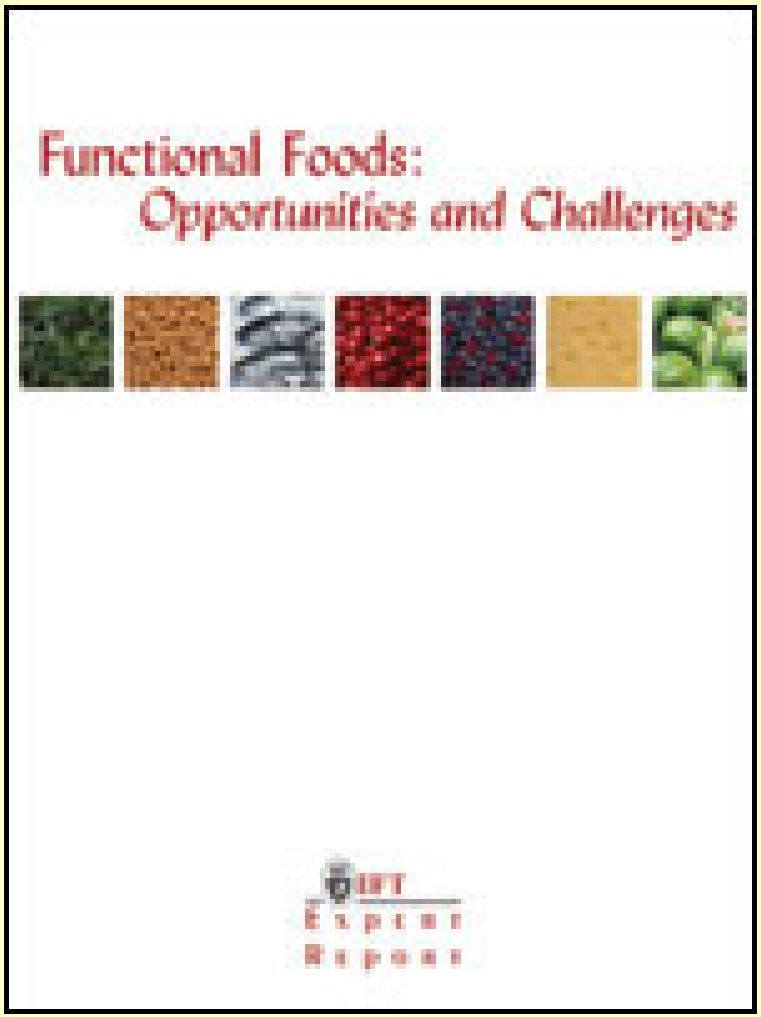
"Medicine today focuses on suppressing the symptoms of disease. A truly preventive medicine, capable of tackling degenerative diseases like arthritis and Alzheimer's, will be based on diet supplements, not drugs."

Paul Clayton, Nutrition the new medicine. Prospect Magazine, June 2003

IFT Expert Report on Functional Foods



IFT
EXPERT
REPORT

Functional Foods:
Opportunities and Challenges

While food has long been used to improve health, our knowledge of the relationship between food components and health is now being used to improve food. Strictly speaking, all food is functional, in that it provides energy and nutrients necessary for survival. But the term "functional food" in use today conveys health benefits that extend far beyond mere survival. Food and nutrition science has moved from identifying and correcting nutritional deficiencies to designing foods that promote optimal health and reduce the risk of disease.

The costly and complex process of translating these scientific advances and nutritional innovations into consumer products is not without pitfalls. Sound science must underlie the development, marketing and regulation of these new functional foods to protect and inform consumers. Regulatory policies must ensure the safety and efficacy of products and the accuracy of their marketing claims.

To advance the scientific perspective on these issues, the Institute of Food Technologists (IFT), the 26,000-member non-profit society for food science and technology, convened a panel of internationally renowned experts to review the science related to functional foods and the regulatory environment for developing and marketing such products.

This IFT Expert Report contains insight from the extensive deliberations of this multidisciplinary panel. As such, it joins two previous IFT Expert Reports—Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century and Biotechnology and Foods—and an authoritative report, Managing Food Safety: Use of Performance Standards and Other Criteria in Food Inspection Systems. The IFT Office of Science, Communications, and Government Relations coordinated the development of these publications as part of its mission to promote regulatory policies that are based on sound science.

This Expert Report provides a comprehensive review of functional foods that emphasizes the importance of functional foods, summarizes the applicable U.S. laws and regulations, and presents scientifically based guidance for demonstrating both safety and efficacy. The report recommends approaches for improving the regulatory framework to better address evolving science and food composition. In addition, the report identifies potential incentives to expand the availability of new products and facilitate consumer understanding of the benefits of functional foods.

Founded in 1939, the Institute of Food Technologists is an international not-for-profit scientific society with 26,000 members working in food science, technology, and related professions in the food industry, academia, and government. As the society for food science and technology, IFT brings sounds science to the public discussion of food issues.

IFT

Important Considerations Regarding Functional Foods

- Safety
- Efficacy
- Ethics
- Legal considerations
- Research
- Regulatory impediments/incentives

Hill's Criteria

- Strength of association
- Consistency of the observed association
- Specificity of the association
- Temporal relationship of the observed association
- Dose response
- Biological plausibility
- Coherence of the evidence

Identified Research Areas

The IFT Functional Food panel identified the following areas for research focus:

- **Identification of nutrients and bioactives**

Evidence For Bioactives Reducing Risk of CVD

Bioactive	Food(s)	Evidence	Strength of Evidence	Health Claim
Sterol / Stanol	Spreads, OJ, yogurt	Clinical	Very Strong	NLEA
Soluble Fiber	Psyllium, Oat Products	Clinical	Very Strong	NLEA
Soy Protein	Beverages, tofu, etc	Clinical	Very Strong	NLEA
Omega-3 Fatty Acids	Fish & supplements	Clinical Epi	Strong to Moderate	QHC for CVD

Modified from: ADA Report, JADA 104:814, 2004, & C. Hasler, J.Nutr. 132:3772, 2002

Evidence For Bioactives Without Approved Health Claims

Bioactive	Food(s)	Evidence	Health Benefit	Strength of Evidence
Proantho-cyanidins	Cranberry Juice	Clinical / Epi	Reduced UTI	Moderate
Lycopene	Tomato products	Epi, *in vitro, in vivo*	Reduced Prostate Cancer Risk	Moderate
Resveratrol	Grape Juice, red wine	Epi, *in vitro, in vivo*	Reduced platelet aggregation	Moderate to Strong
Lutein / Zeaxanthin	Spinach, Kale, etc.	Epi and *in vivo*	Reduce risk of AMD	Moderate
MUFA	Tree Nuts	Clinical Trial	Reduced risk of CHD	Moderate QHC

Modified from: ADA Report, JADA 104:814, 2004, & C. Hasler, J.Nutr. 132:3772, 2002

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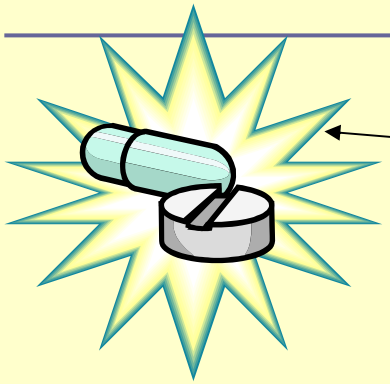
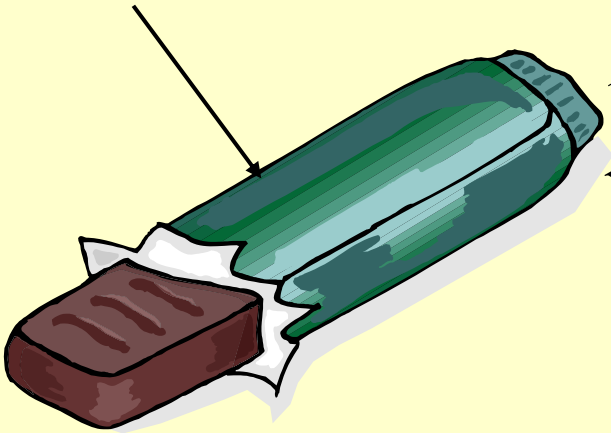
- **Identification of biomarkers**
- **Food delivery vehicles**

Consumer Options
Supplements vs. Foods



Bioactive



Foods Permit A Variety of Delivery Forms

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- **Food delivery vehicles**
- **Food composition and dietary intake data bases**
- **Nutrigenomics and function of bioactives**

Effect of β-Sitosterol In Patients With Benign Prostate Enlargement

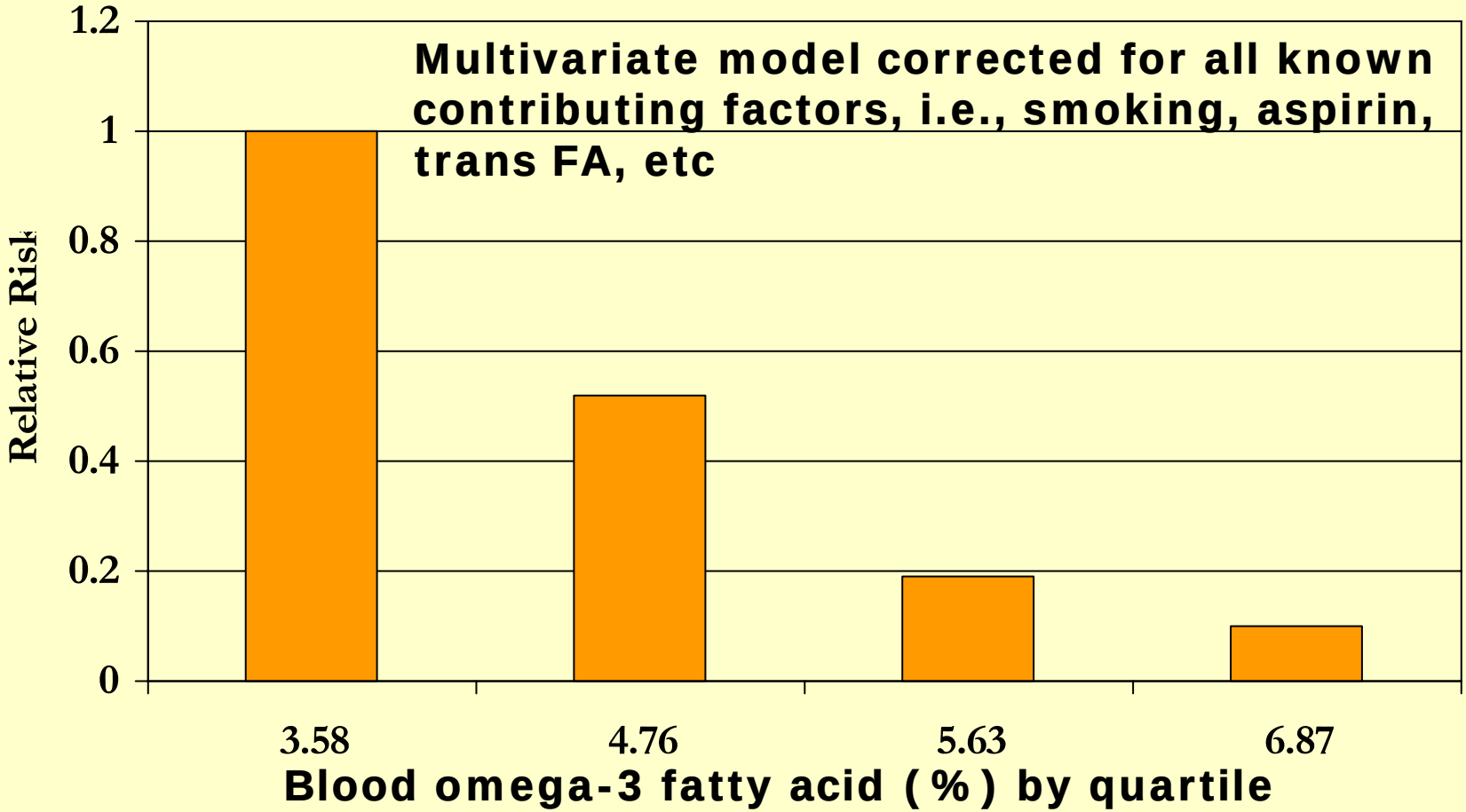
	Klippel, et al	Berges, et al	Wilt, et al
Agent	Beta-sitosterol	Beta-sitosterol	Beta-sitosterol
# Patients	177	200	519
Daily Dose	130 mg	60 mg	NA
IPSS	-5.4	-5.3	-4.9
QMax (ml/sec)	+4.5	+5.3	+3.9
PVR (ml)	-33.5	35.4	28.6

IPSS=International Prostate Symptom Score; QMax=max. urinary flow rate; PVR= Post-void residual volume

Klippel et al, BJU 80:427, 1997; Berges et al, BJU Int 85:842, 2000; Wilt et al, Cohrane Database Syst Rev. 2000.

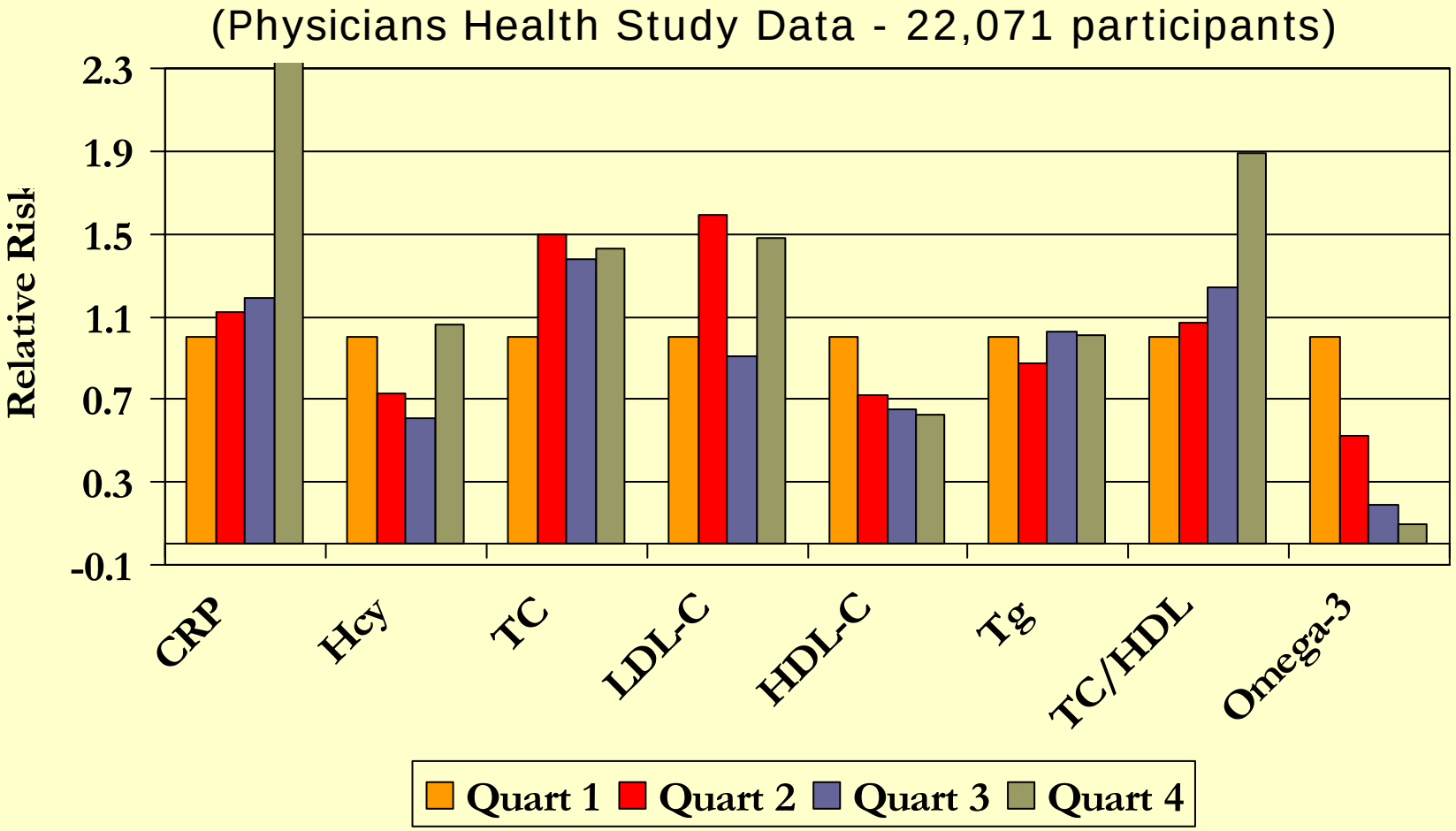
Blood Levels of Long-chain n-3 Fatty Acids and Risk of Sudden Death

(Physicians Health Study Data - 378 participants)



From: Albert et al, NEJM 346:1113,2005

Value of Omega-3 Blood Levels Compared To Traditional Risk factors



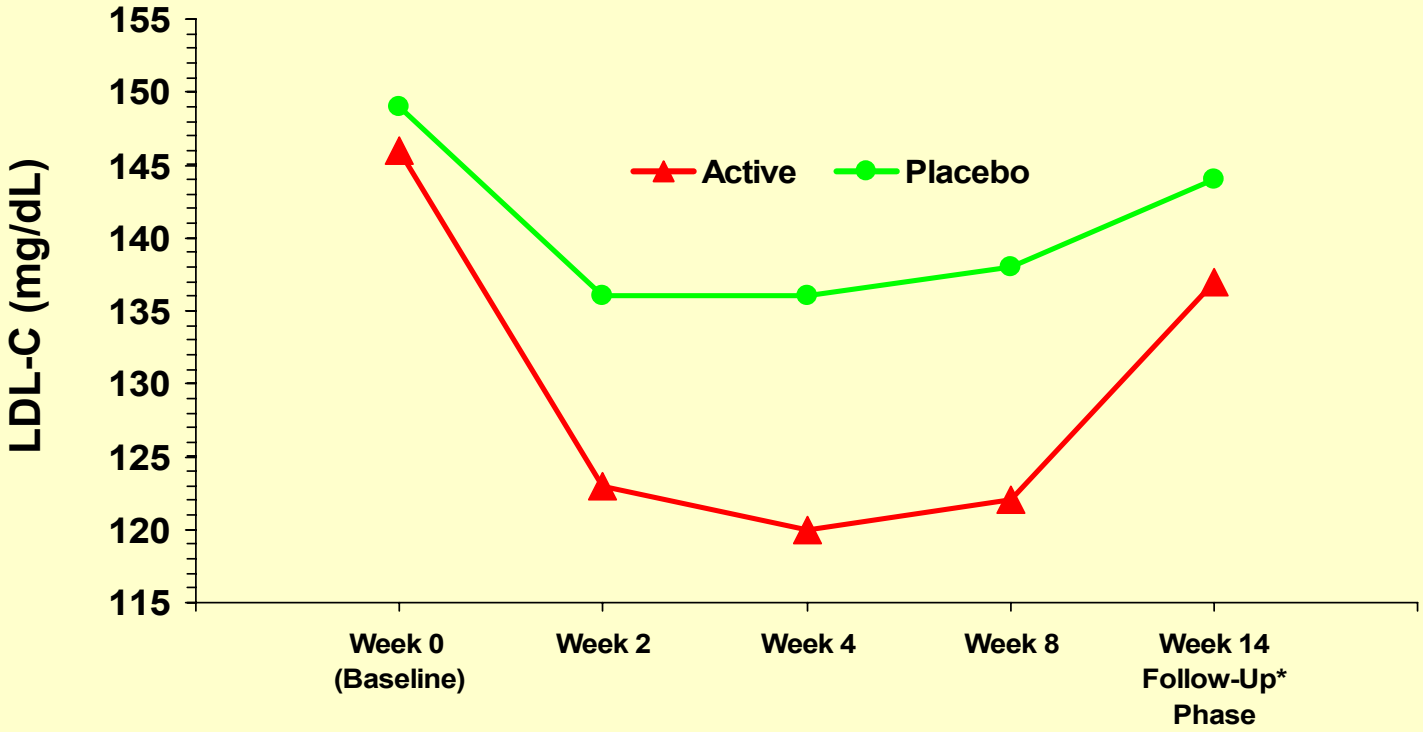
From Albert et al, Circulation 1052595, 2002 and NEJM 346:1113,2005

Effects of Omega-3 Fatty Acids on Mortality GISSI – Prevenzione Trial

Deaths	Omega-3	Control	Rel. Risk	% Change
	Includes ± Vitamin E and n-3 FA			
# Patients	5666	5668		
Total	472	545	0.86	-13
CV	291	348	0.83	-16
Sudden	122	164	0.74	-26
	n-3 fatty acid groups only			
# Patients	2876	2828		
Total	236	293	0.80	-20
CV	136	193	0.70	-30
Sudden	55	99	0.55	-45

Lancet 354:447-455, 1999

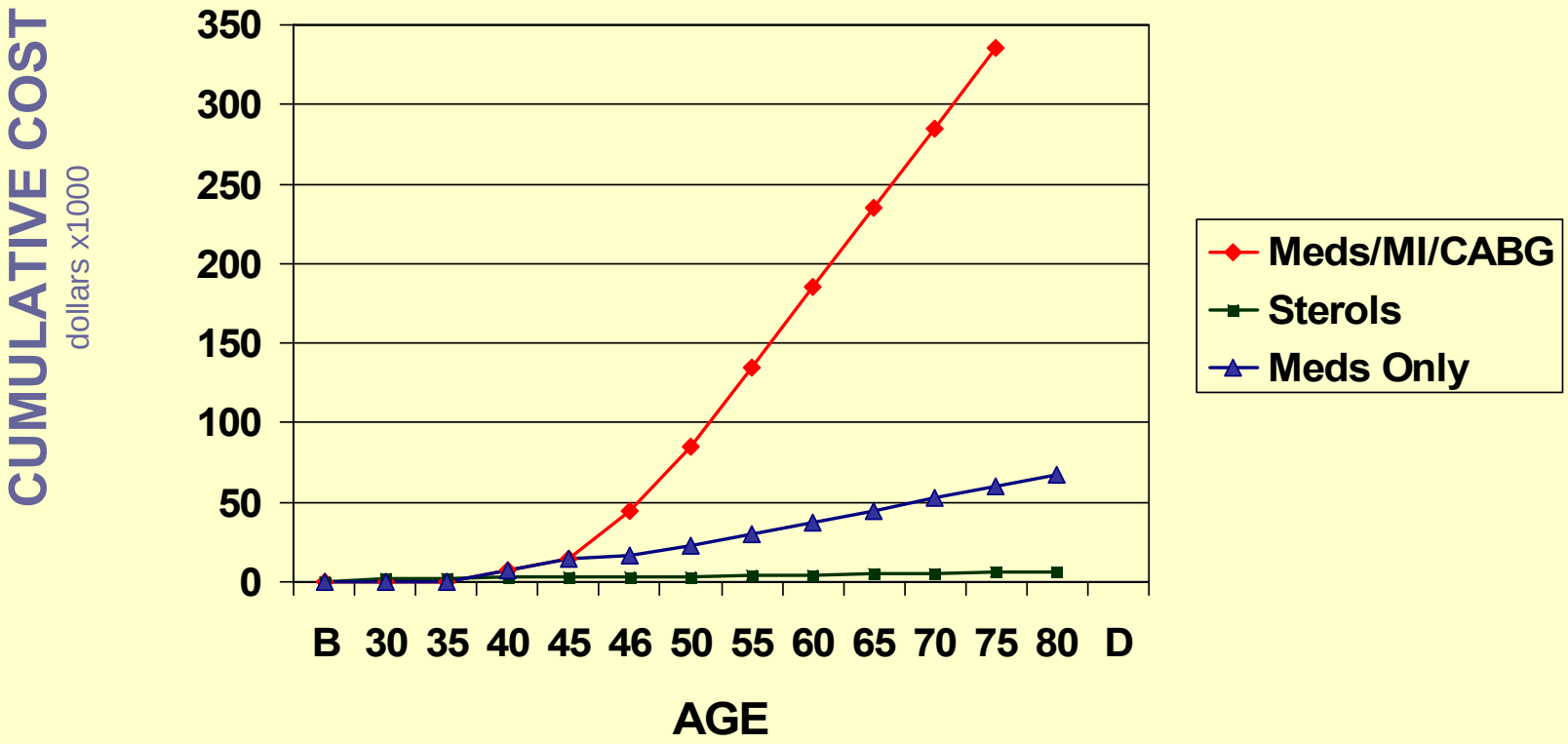
Serum LDL-C Levels Over Time In Stable Statin Users



*No test spread was consumed between Week 8 & Week 14.

Am J Cardiol 2000; 86: 46-52

Hypothetical Cost Model



From Kanter, M., personal communication

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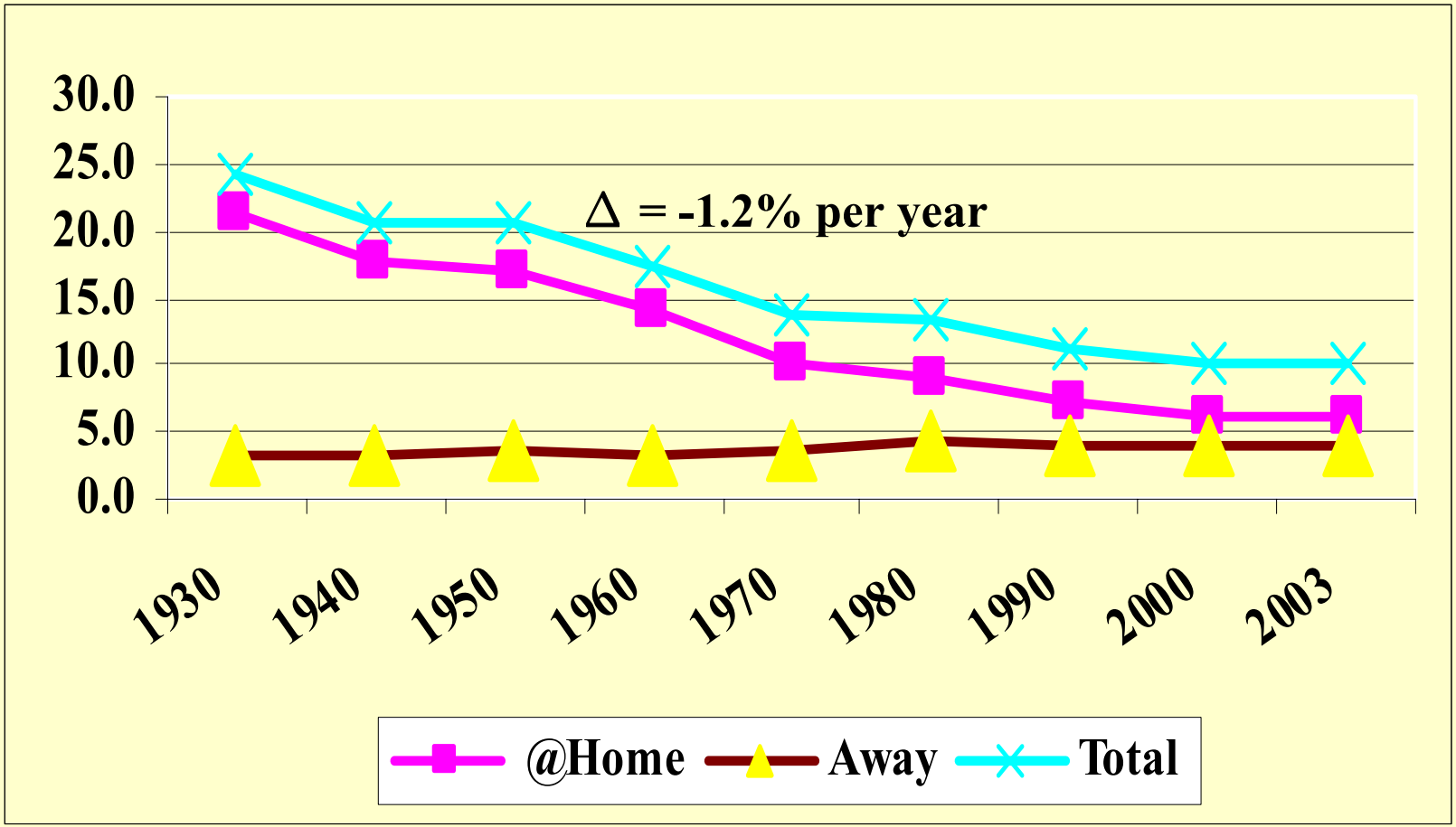
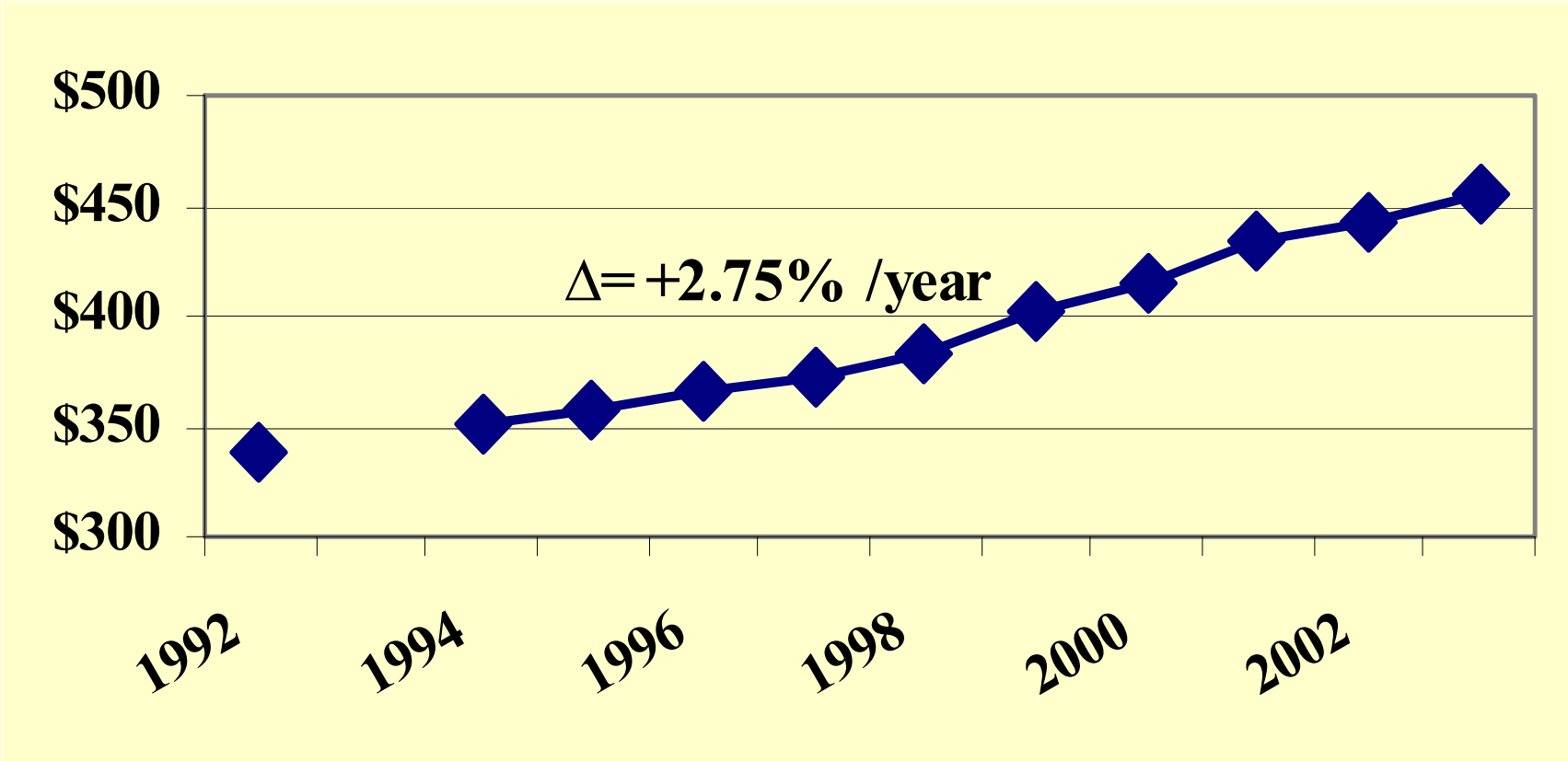
- **Food composition and dietary intake data bases**
- **Nutrigenomics and function of bioactives**
- **Incentives for industry research and development**

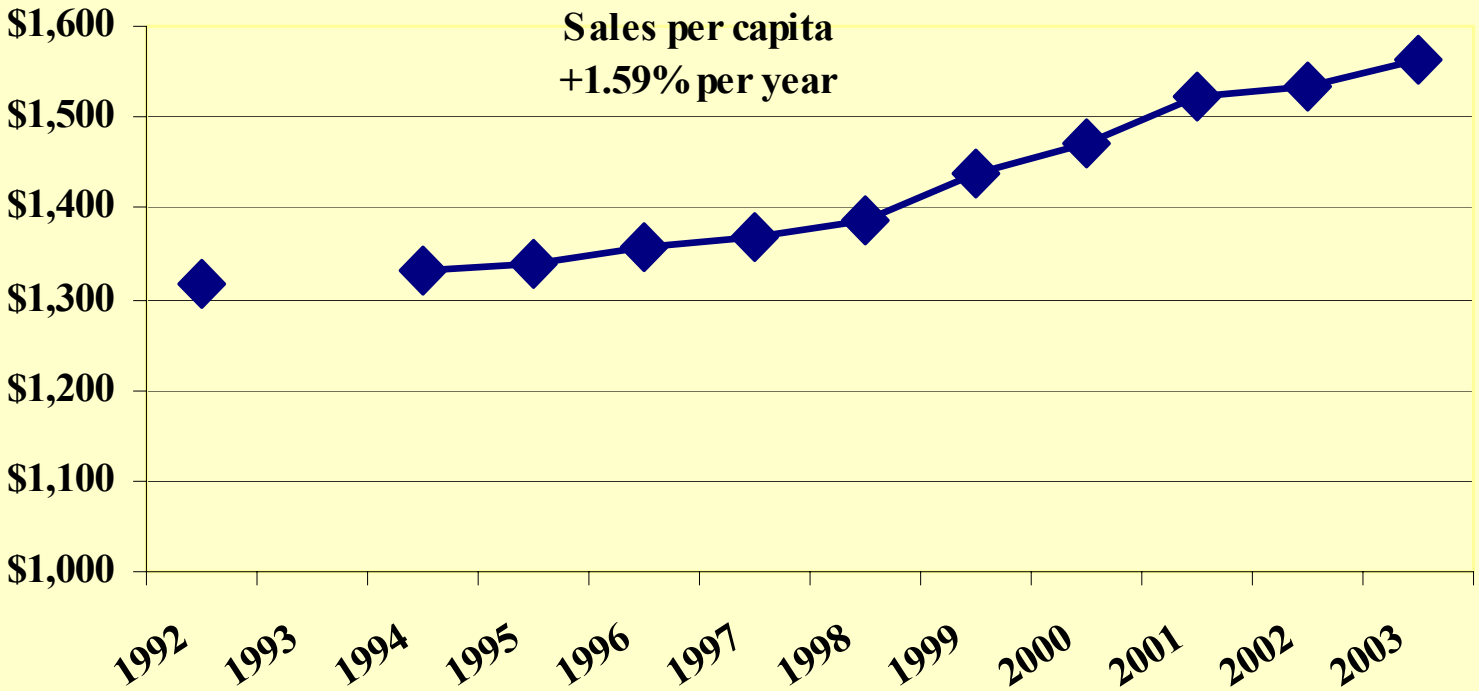
US Food Expenditures – Percent of Disposable Income



Retail Food Sales ($Billions)



Per Capita Retail Food Sales 1992 - 2003



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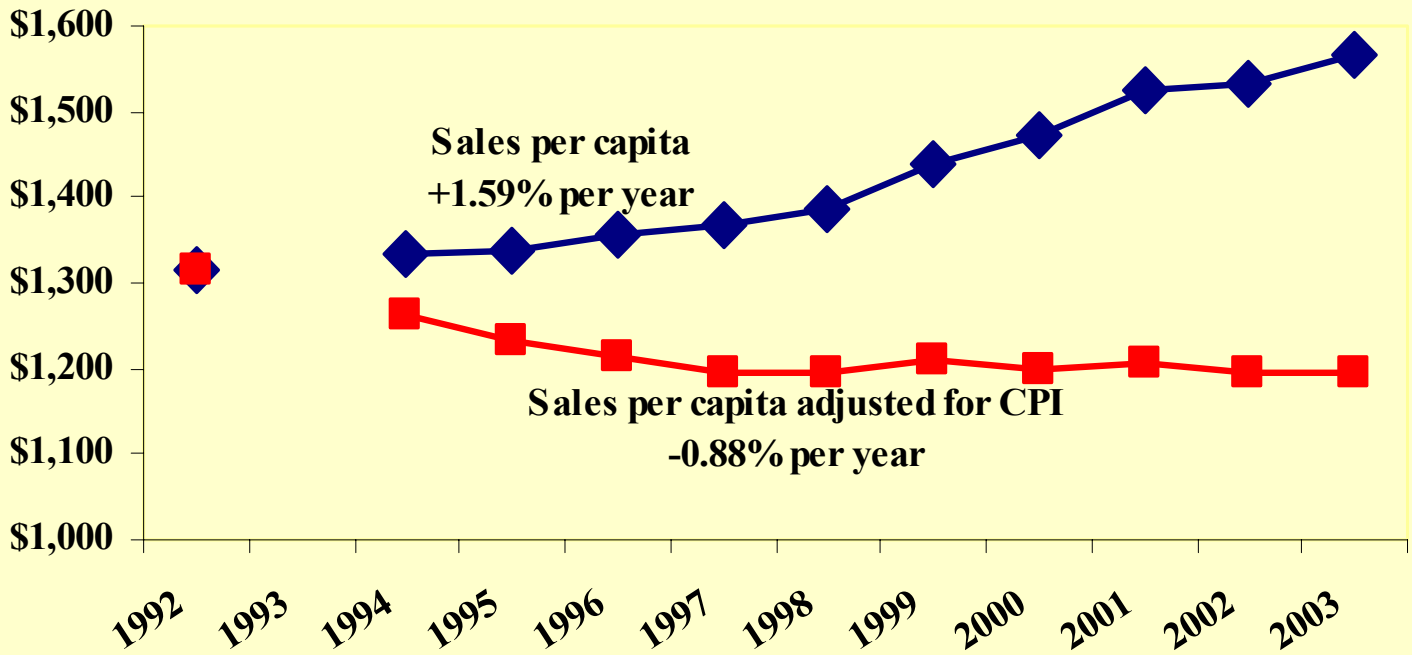

Consumers of tomorrow

"Mass Customization"

Will the Science Community & the Food Industry be ready?