

LSRO



# Life Sciences Research Office (LSRO)

**Michael Falk**  
**Executive Director**

# Brief History

- **Formed by FASEB in 1962**
- **60's – 70's clients: Army, Navy, NASA, FDA**
- **72 – 82 GRAS Reviews**
- **80's – 90's clients: USDA, FDA, Health Claims**
- **1997 FASEB → ASNS**
- **2001 ASNS → LSRO, Inc**

# LSRO Inc

- **Non-profit 501(c)(3)**
- **Affiliations with scientific professional societies (ASNS, APS, ASPET, ASIP, ASBMR, ISRTP, etc.)**
- **Independent, objective, respected**
- **National, international impact**
- **Biomedical, environmental, biological science issues**



# What We Do

- **We identify problems and provide solutions using:**
  - **Comprehensive Reviews**
    - **ad-hoc Expert Panels**
  - **Authoritative Reports**
  - **Conferences, Workshops, Symposia**
  - **Programmatic and Proposal Peer Review**
  - **Scientific Support Services**



# Clients

- FDA
- USDA
- ONR
- Army Med R &D
- HHS
- FAA
- NASA
- NIH
- ASNS
- APS & ASPET
- Monsanto
- California Walnut Commission
- National Dairy Council
- Calorie Control Council
- Philip Morris

# Board of Directors (2005)

- **Sam Enna** (ASPET)  
University of Kansas Medical Center
- **Michael Falk**  
LSRO
- **Arnold Kahn** (ASBMR)  
University of California-SF
- **Eileen Kennedy** (ASNS)  
Tufts University
- **William MacLean**  
Consultant
- **Terry Quill** (ISRTP)  
Duane Morris, LLP
- **Thomas Stagnaro**  
Americas Biotech
- **Jacob Steinberg** (ASIP)  
Albert Einstein College of Med
- **Taffy Williams** IMCOR  
Pharmaceutical



## Board of Directors Oversight

- Selection of new projects
- Selection of expert panels
- Review of final report
  - Conforms to scope of work
  - Meets or exceeds our standards of workmanship, objectivity, & credibility

## Criteria for New Projects

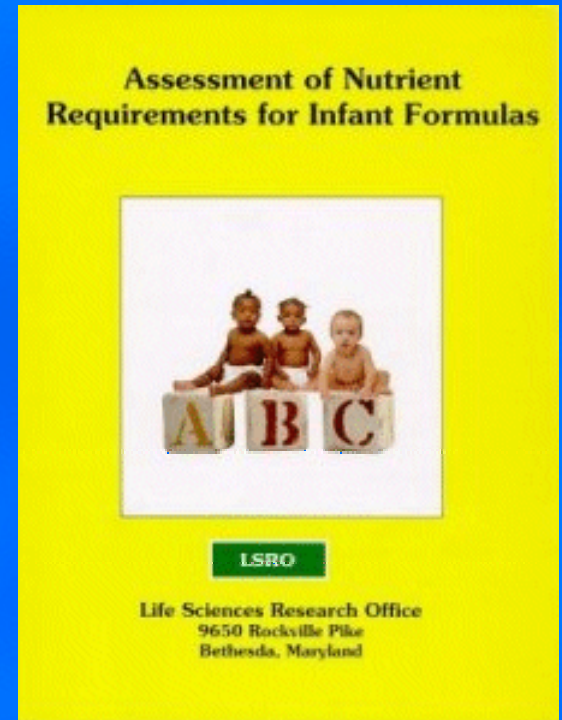
- Fulfill a general public benefit
- Fall within our expertise
- Allow LSRO complete control
- Approval of the Board of Directors



# LSRO Reports

## National Health Issues

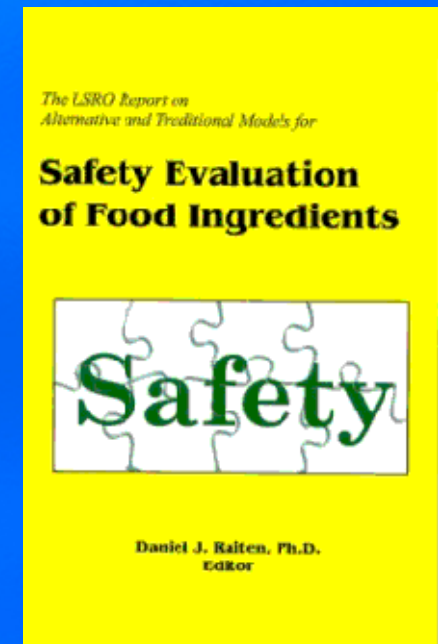
- Nutrient Requirements for Infant Formulas
- Nutrition Monitoring Report(s)
- Dietary Guidelines for Children



# LSRO Reports

## Food Safety / Toxicology

- Safety Evaluation of Food Ingredients
- Adverse Reactions to MSG
- Carcinogenicity of BHA
- Emerging Issues in Food Safety and Quality
- Predicting Neurotoxicity from Preclinical Data

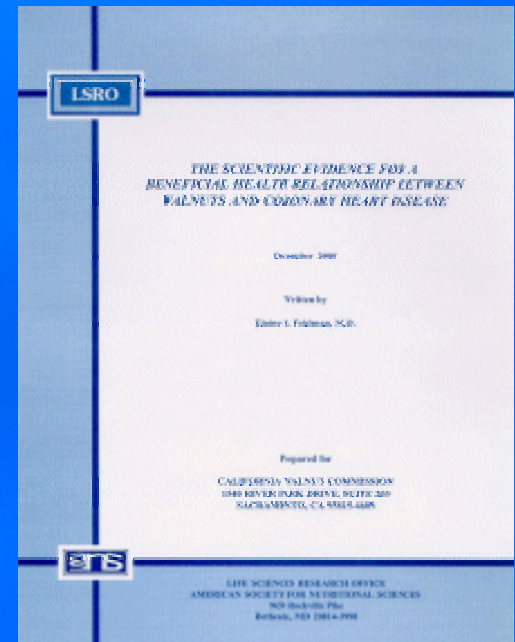




# LSRO Reports

## Food Labeling / Health Claims

- Walnuts and Coronary Heart Disease
- Dairy Foods/Calcium and Colorectal Cancer
- Energy of Sugar Alcohols
- Dietary Fiber and Cancer
- Antioxidants and Cancer





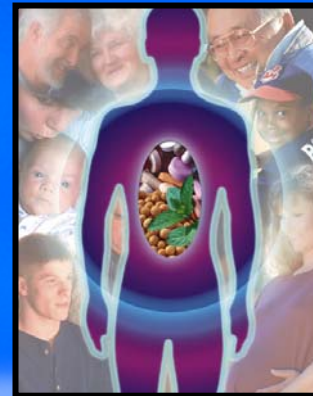
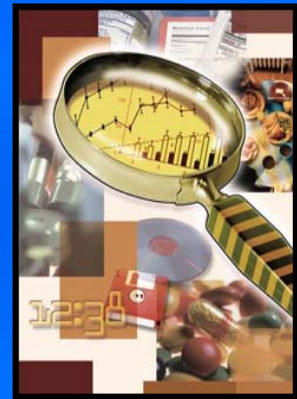
# Evaluating the Risk of Tobacco Products

- The Feasibility of Testing Ingredients Added to Cigarettes
- Scientific Criteria for Evaluating Ingredients Added to Cigarettes



# LSRO Reports Workshops/Symposia

- Food Biotechnology: Benefits & Concerns
- 3<sup>rd</sup>-Party Review of Food & Supplement Claims
- Bioavailability of Dietary Supplements
- Nutrition in Pediatric HIV Infection



# LSRO Reports GRAS

- **SCOGS**
  - Reviewed 238 cmpds
  - Produced 151 reports
- **Guar Gum**
- **Psyllium**
- **Salatrim**
- **Caprenin**
- **Sulfiting Agents**



# LSRO Reports Program/Peer Review

- Sediment Biodegradation of Pollutants Prgm (ONR)
- Military Dental Research Review
- Ag Biotech Risk Assessment Prgm (USDA)
- Aeromedical Research Prgm (FAA)
- Research Opportunities in Space Prgm (NASA)

# Ongoing Projects

- Resuscitation Fluid Adjuvants Review (US Army & Navy)
- Evaluating the Scientific Evidence for Reduced-Risk Tobacco Products (Philip Morris)



# History of Tobacco Risk Reviews

- Discussions with Philip Morris begun in Feb 2000
- Due diligence through fall 2000
- Reviewed and approved by SAC fall 2000
- Master Agreement signed Jan 2001
- 1st Project Agreement (Feasibility) signed Feb 2001
- Panel concludes it is feasible Feb 2002
- 2nd Project Agreement (Criteria) signed Apr 2002
- Final feasibility report complete Jan 2004
- Final scientific criteria report complete Aug 2004
- Awaiting 3rd Project Agreement (Ingredient Reviews)



## History (cont)

- Reduced Risk Review (RRRvw) discussions begun 2002
- Master Agreement signed Sep 2003
- RRRvw Project Agreement signed Jul 2004
- Expert Panel approved by LSRO BOD Jan 2005
- First meeting Feb 2005
- Project completion date July 2006

## Role of Expert Panel

- Provide guidance and assistance
- Provide oversight of all aspects of study
- Review, amend and concur with final report (although not necessarily with all conclusions)
- Individual conclusions are not attributed
- The report is an LSRO report
- Expert Panelists are consultants to LSRO

## Rules & Information for This Session

- Purpose: to inform LSRO & Expert Panel
- Questions: only by LSRO & Expert Panel
- Speakers: will keep on time
- Additional comments will be accepted
  - Orally at the end of the meeting and/or
  - In writing until May 15
- Speaker bios provided in handouts
- Info posted on web site
- Breaks
  - Bio breaks mid morning and mid afternoon
  - Box lunch provided around noon



LSRO



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