



Life Sciences Research Office (LSRO)

**Michael Falk
Executive Director**

Brief History

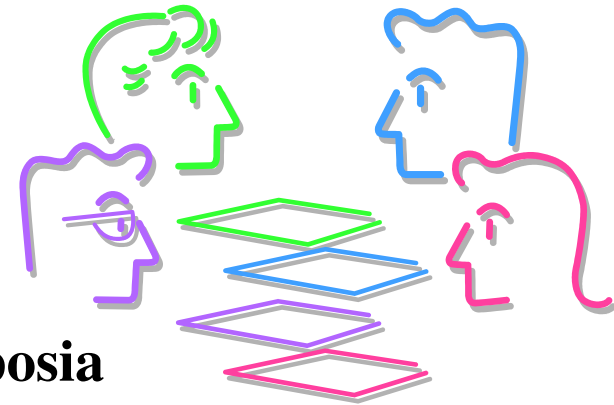
- **Formed by FASEB in 1962**
- **60's – 70's clients: Army, Navy, NASA, FDA**
- **72 – 82 GRAS Reviews**
- **80's – 90's clients: USDA, FDA, Health Claims**
- **1997 FASEB → ASNS**
- **2001 ASNS → LSRO, Inc**

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

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

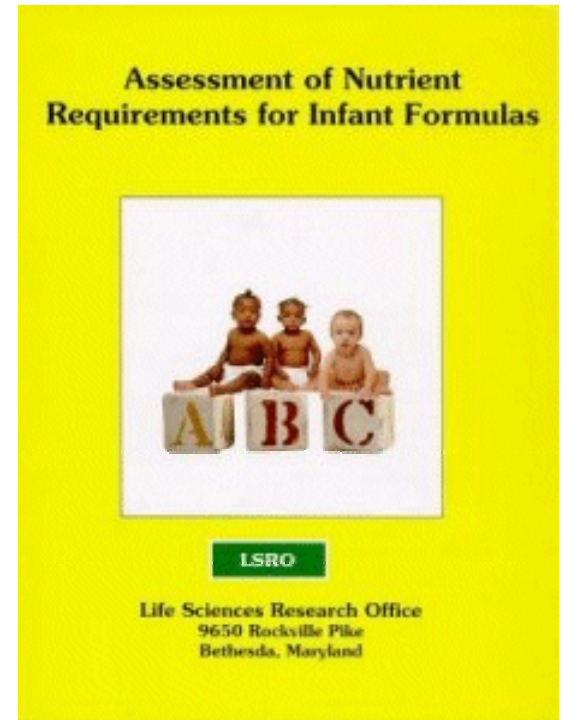
Criteria for New Projects

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

LSRO Reports

National Health Issues

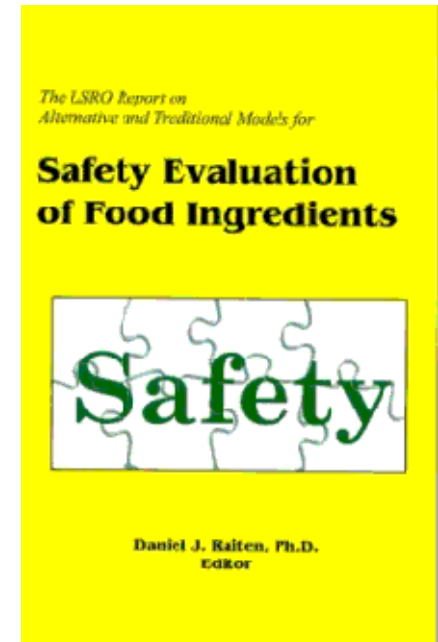
- Nutrient Requirements for Infant Formulas
- Nutrition Monitoring Report(s)
- Dietary Guidelines for Children



LSRO Reports

Food Safety / Toxicology

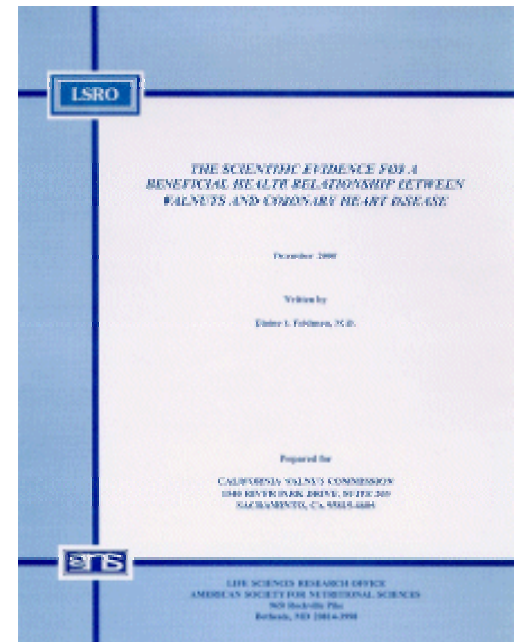
- Safety Evaluation of Food Ingredients
- Adverse Reactions to MSG
- Carcinogenicity of BHA
- Emerging Issues in Food Safety and Quality
- Predicting Neurotoxicity from Preclinical Data



LSRO Reports

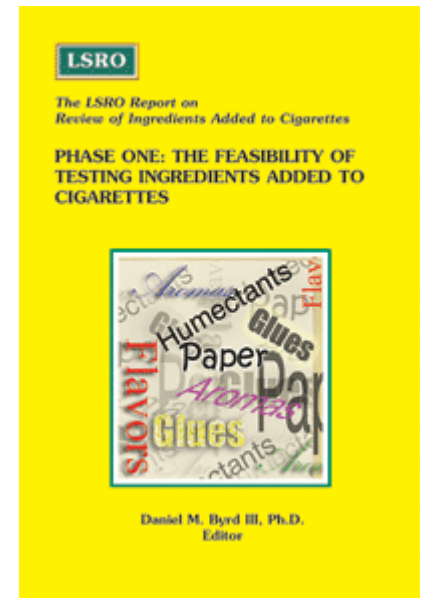
Food Labeling / Health Claims

- 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

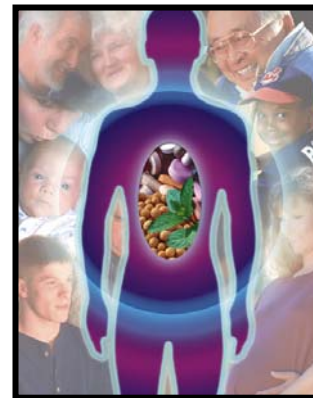
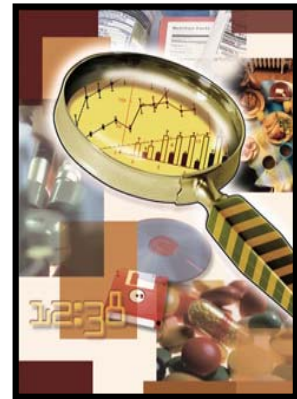
- The Feasibility of Testing Ingredients Added to Cigarettes
- Scientific Criteria for Evaluating Ingredients Added to Cigarettes



LSRO Reports

Workshops/Symposia

- Food Biotechnology: Benefits & Concerns
- 3rd-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
- 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



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