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
• 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 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