



Attendance

Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i>	✓
Kenneth Berns, MD, PhD – <i>Co-Chair</i>	✓
Debra L. Hunt, DrPH, CBSP	✓
Thomas V. Inglesby, MD	✓
Patricia Olinger, RBP	
Michael Pentella, PhD, D(ABMM)	✓
David Relman, MD, PhD	
Heather J. Sheeley, BA, MS, CBiol, MSB, CMIOSH, FISTR	✓
Fred Sparling, MD	✓
Jill Taylor, PhD	✓
Domenica (Dee) Zimmerman	✓
Sarah Wiley, MPH, <i>Designated Federal Officer</i>	✓
✓ In attendance	

Meeting Summary

Call to Order, Welcome, and Introductions

Dr. Kristine Leiphart, DASHO, DCOO

Brief History of Variola Discovery on NIH Campus

Dr. Peter Marks

Dr. Marks presented the overview of the *Variola* discovery and the root cause analysis. Dr. Marks emphasized the FDA's responsibility for the discovery and indicated that a new cold room policy was put in place since the incident.

- **ELSW Comments**

- Dr. Joseph Kanabrocki praised the handling of the discovery of *Variola* and how the incident was addressed. Other members commented on the job well done in reporting the findings and addressing the issue.

Overview of policy elements and implementation of the draft SMG

Dr. Jeffrey DeGrasse

Dr. Degrasse clarified the FDA's definition of hazardous biological agents and toxins. He highlighted the need for agency wide documentation, as well as policies for biosecurity and inventory control in all agencies and centers. Dr. Degrasse indicated that if a lab moves, storage units are left empty and an audit is performed to confirm.

- **ELSW Discussion**

- Inventory control standards and compliance mechanisms.
 - Standards for working stock storage of HBATs.

- **ELSW Comments**

- Must ensure that HBATs are definitively transferred from one researcher to another to avoid "orphans."
- Agency needs to increase training and provide hands-on training, in addition to online training.

Open Discussion with FDA Laboratory Safety Practices and Policies Workgroup (LSPPW)

ELSW Members and LSPPW Members

ELSW members discussed the Institutional Biosafety Committee (IBC) and noted that a major function of IBC is risk analysis of applications. Staff and supervisors are also evaluated for safety performance.



- **ELSW Comments**
 - Agency needs to identify outreach methods to staff to evaluate effectiveness of the safety program and increase monitoring for compliance with IBC.
 - The ELSW requested an IBC mission statement.

Review of Laboratory Safety Training Programs

ELSW reviewed findings from FDA's Employee Safety Engagement Sessions, FDA University, and Center Level Safety Training Programs

- **ELSW Comments**
 - FDA employees are comfortable reporting safety issues.
 - Officials should make periodic observations to ensure safety procedures are followed.
 - Employees are seeking an evaluation of their competency in safety functions.
 - Agency should look for opportunities to standardize and improve efficiencies in delivering training (i.e. training employees on new equipment).

Discussions with Safety Program Officers

ELSW Members, ESEM Director Matt Amann and Center Safety Officers

- **ELSW Comments**
 - FDA should transition to an authoritative central safety program where safety officers report to that chain of command instead of reporting to Center Directors.
 - Safety budget should come from a central account; Centers should not have to decide between a safety budget and other expenses.
 - FDA should reconsider its plan to hire a Director of Laboratory Science and Safety and develop a clear sense of what the roles and responsibilities are for this position.

Discussion with the Acting Commissioner of FDA

ELSW Members and Dr. Stephen Ostroff

Dr. Ostroff provided an overview of FDA's mission and organizational structure. He reported that the discovery of *Variola* was a wakeup call and since then, the agency has taken a fair number of steps but is still a work-in-progress.

- **ELSW Comments**
 - FDA must rank safety priorities and raise visibility of safety within labs.
 - Inventory management needs to be a number one focus.
 - ELSW disagrees with plans to establish the position of Director of Laboratory Safety and Science and suggests that FDA create a central safety program.
 - Employees feel they belong to a Center instead of FDA as an agency.
 - The agency needs to enhance coordination with the occupational health service.

Overview of FDA Laboratory Security Operations

Barry Smith

Mr. Smith provided an overview of personal and physical security branches at the agency including the BSL-3 physical security layers and laboratory locations. It is a nationwide security command Center with means to conduct several levels of investigation. Mr. Smith also led a discussion of the federal protective service, security officers, and security training.

Overview of Animal Care and Use Committee (ACUC) and the Institutional Biosafety Committee (IBC)



Dr. Steven Rubin and Dr. Ira Berkower

Drs. Rubin and Berkower reviewed the charters and responsibilities of the ACUC and IBC. They provided an overview of the types of animal studies conducted, reported on the IBC Application System, and discussed roles of the committees on supervising hazardous agents and identifying hazards in labs.

Overview of OSHA Compliance Activities and Occupational Medicine Program (OMP)

Matt Amann and Dr. Kang Chan

Mr. Amann and Dr. Chan provided an overview of the Safety Inventory Protocol System. They reviewed program governance of the OMP and provided an overview of clinical services and capabilities (after hours care, on-call physician, lab kits, flu vaccines, etc.)

Laboratory Staff Engagement Sessions

ELSW Members, CBER and CFSAN Research Principal Investigators, and Senior Technical Laboratory Staff

ELSW members interviewed a diverse range of laboratory staff members to gain further insight into a variety of laboratory activities and issues across the agency.

Laboratory Visits

ELSW Members

ELSW toured the following laboratories:

- Vivarium (White Oak Campus)
- Unoccupied BSL-3 Lab (White Oak Campus)
- BSL-2 Lab (White Oak Campus)
- CFSAN Laboratories (College Park Campus)

Development of Recommendation Themes

ELSW Members

The following recommendation themes emerged from discussions:

- Risk Assessment
- Training
- Governance
- Communication
- Central Safety Program
- New Position - Director of Laboratory Safety and Science

Debriefing Comments and Recommendations

ELSW Members and FDA Executive Leadership

- ELSW observations have generated the following comments and recommendations:
 - **Central Safety Budget and Governance:** FDA is a complex organization with dedicated individuals and facilities at various locations. However, each Center operates as an independent entity and has a sense of program ownership; some are more fully developed and robust than others. It may be beneficial for Center leaders to meet on a regular basis to discuss experiences. Furthermore, agency should move to a central safety program with a central account to support the safety budget. Safety officers should report to a central safety program rather than Center directors.



- During efforts to centralize, FDA should strive not to lose or destroy what works well. Consistency across the agency is important and will help for sharing of best practices and IT, as well as maximizing economies of scale.
- **Communication and Training:** There is evidence of high commitment to the FDA mission; employees are satisfied overall. However, contractors do not seem to receive the same information as FTE's. All workers should be protected along the same standards. Training, mentoring, and auditing processes need further development. Agency should provide more hands-on training in addition to online training.
- **Risk Assessment:** The value of the HQ's ESEM is not appreciated at the Centers. The internal working group provides continuity and works great. Cross fertilization between IBC and ACUC would benefit FDA. The IBC application process can be developed more fully to help with risk assessment.
- **New Position:** The description and title for the new job position, *Director of Laboratory Safety and Science* may not strengthen the FDA; ELSW provided concerns over the position causing "chaos". If the agency proceeds with the position, the organization should be well-coordinated. The individual needs to be accessible and approachable to lab workers.

Wrap up and Adjournment

Dr. Joseph Kanabrocki and Dr. Kenneth Berns, ELSW

- The ELSW identified their next steps, indicating that they will gather their observations into a coherent report.
- Additional conference calls will be scheduled as needed to assist the ELSW as the group drafts recommendations.



FDA Staff Present:

Stephen Ostroff, MD
Acting Commissioner of FDA

Kristine Leiphart, Ph.D.
Office of Operations
Deputy Chief Operating Officer
Designated Agency Safety and Health Official

Matt Amann
Office of Operations
Director, Employee Safety and Environmental
Management Staff

Robert Califf, M.D.
Deputy Commissioner
Office of Medical Products and Tobacco

Howard Sklamberg, J.D.
Deputy Commissioner
Global Regulatory Operations and Policy

Melinda Plaisier
Associate Commissioner for
Regulatory Affairs

Karen Midthun, M.D.
Director
Center for Biologics Evaluation and Research

Peter Marks, M.D.
Deputy Director
Center for Biologics Evaluation and Research

Vikram Patel, Ph.D.
Deputy Division Director
Division of Applied Regulatory Science
Center for Drug Evaluation and Research

Patrick Faustino, Ph.D.
Lab Chief
Division of Product Quality Research
Center for Drug Evaluation and Research

***Laboratory Safety Practices and Policies
Workgroup***

Jeffrey DeGrasse, Ph.D.
Co-Chair, LSPPW
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