

# SERCEB

## Policy, Ethics and Law Core: Biosecurity and Dual-use Education Activities

Southeastern Regional Center of Excellence for  
Emerging Infections and Biodefense  
(UNC, U FI, UAB, Emory, Vanderbilt, Duke  
& 20+ affiliated groups)  
[www.serceb.org/pel/](http://www.serceb.org/pel/)

# Members and staff

- *Allison Chamberlain, MS Duke University (position formerly held by Megan Davidson)*
- *Nikki M. Vangsnes, Duke University*
  
- *Robert M. Cook-Deegan, MD Duke University*
- *Ross McKinney, MD, Duke University*
- *Ruth Berkelman, MD, Emory University*
- *Arri Eisen, PhD, Emory University*
- *LouAnn C. Burnett, MS, CBSP, Vanderbilt University*
- *Elizabeth Heitman, PhD, Vanderbilt University*
- *Nancy M P King, JD, Wake Forest University*
- *Rebecca Walker, Ph.D., University of North Carolina – Chapel Hill*
- *Paul Gulig, PhD, University of Florida*
- *James Thomas, PhD, MPH, UNC School of Public Health*
- *Samuel Tilden, MD, JD, LL.M., University of Alabama*

# Mechanisms

- Talk to investigators and staff
- Meet with IRBs, IBCs, IUCACs, etc.
- Online education module
- Biosecurity/dual-use education panels (Duke 2006; Emory 2008)
- Policy Engagement (NSABB, NRC, ASM, etc.)
- International Engagement (South Africa, Poland, Japan, Hungary)
- Presence at relevant conferences (ABSA, ASM Biodefense, ICEID)
- White papers (BWC, role of scientists, IRB review snags, animals in research, etc.)
- Active dual-use review of SERCEB-funded projects through Steering Committee

# Summary of PEL experience

## POLICYFORUM

SCIENCE AND SECURITY

### Practical Experiences in Dual-Use Review

The U.S. government is debating how to handle national security risks posed by bioscience research. A research consortium shares lessons learned from their research oversight scheme.

E. Megan Davidson,<sup>1</sup> Richard Frothingham,<sup>2</sup> Robert Cook-Deegan<sup>3\*</sup>

**B**ioscience is under increased scrutiny for “dual-use” concerns. Dual-use in this sense refers to research with the potential both to generate valuable scientific knowledge and to be used for nefarious purposes, with serious consequences for public health or the environment (*1*). In April 2007, the U.S. National Science Advisory Board for

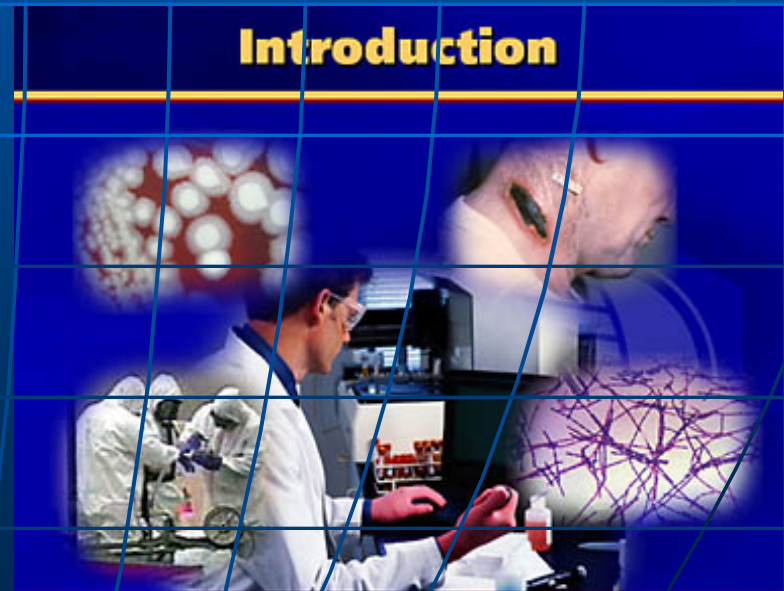


ifying hypervirulence in a pathogen that is nearly 100% fatal in the animal model. The PI proposed methods to manage the risk by attenuating the virus. Although the PI proposed to deal with publication issues raised by a dual-use discovery by suppression and

*Science* 316 (8 June): 1432-33, 2007.

# SERCEB PEL Dual-use Educational Module

- Developed as a tool to teach scientists (PIs, post-docs, lab techs, grad students) about biosecurity and the dual-use dilemma
- Launched in 2005
- 650+ users to date
- Survey of users



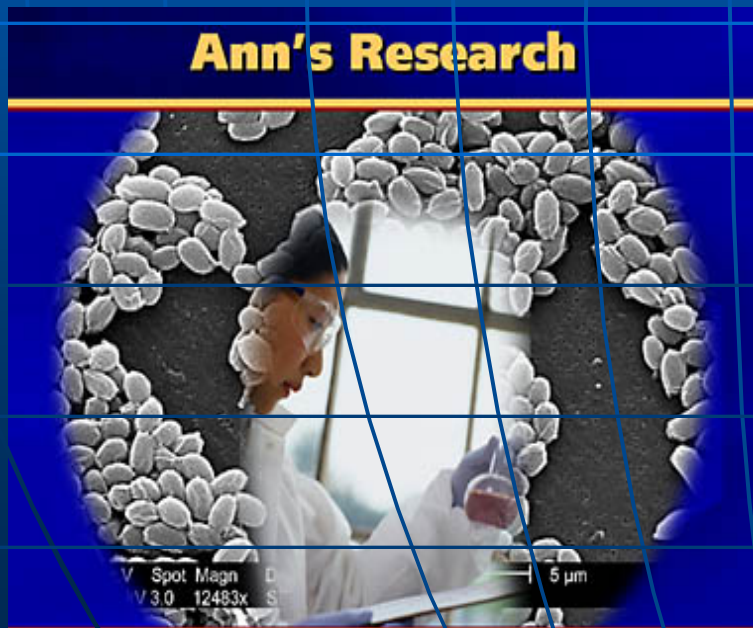
# SERCEB Dual-use Educational Module

## ■ Expert Reviewers

- **Eileen Choffnes, PhD** - Senior Program Officer, National Academies
- **Gigi Kwik Gronvall, PhD** - Associate, Center for Biosecurity, Assistant Professor of Medicine, University of Pittsburgh Medical Center
- **Phil Hanna, PhD** - Assistant Professor of Microbiology and Immunology, University of Michigan
- **Stephanie Loranger, PhD** - Director of Biology Issues, Federation of American Scientists
- **Heather Lynch** - Graduate Student in Molecular Genetics and Microbiology Duke University
- **Richard W. Moyer, PhD** - Senior Associate Dean for Research Development, Chair, Department of Molecular Genetics and Microbiology, University of Florida College of Medicine
- **Shelley Payne, PhD** - Distinguished Lecturer and Professor of Microbiology, University of Texas at Austin, Director of Graduate Education Program, American Society for Microbiology

# SERCEB PEL Dual-use Educational Module

- Walks user through a scenario
  - Dual-use concerns identified when a Ph.D. candidate (Ann Lee) attempts to submit thesis work for publication



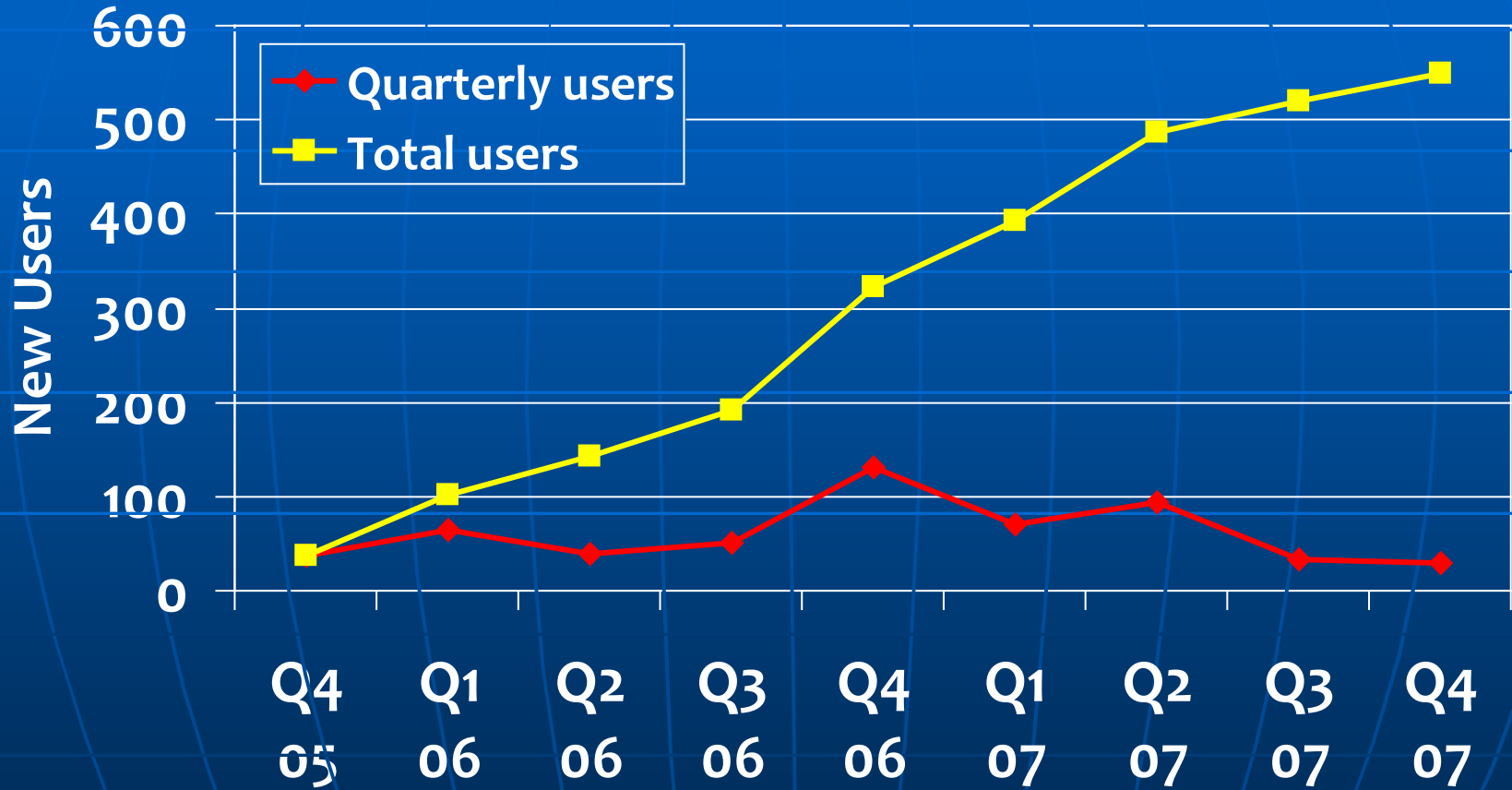
- Provides user with background on legal, ethical and policy implications that affect Ann's work

# Education Module: Learning Objectives

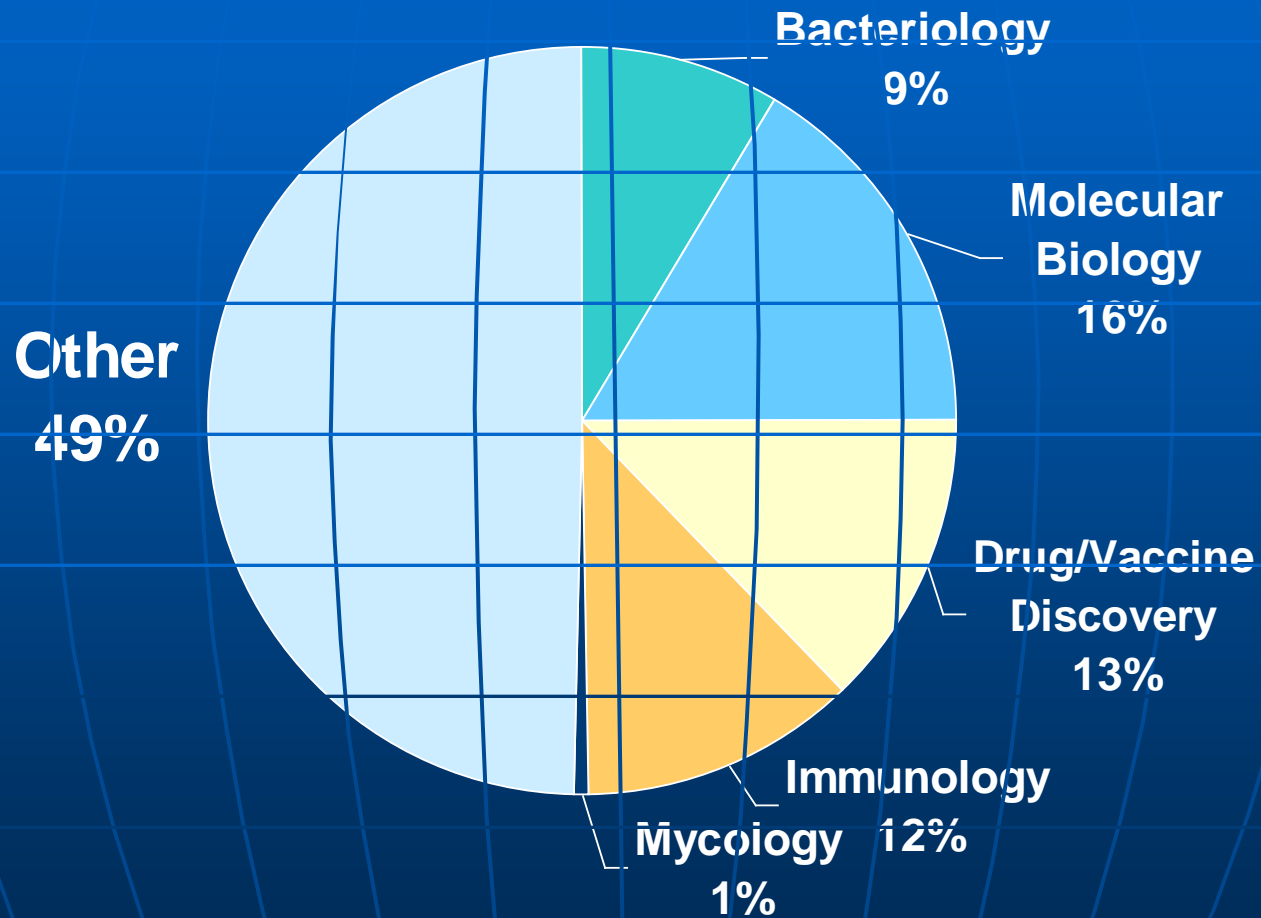
- Identify ethical problems that scientists and lab workers may encounter
- Describe principles and strategies to use in dealing with such problems
- Analyze how biosecurity and bioterrorism relate to the biological sciences
- Describe new policies affecting bioscience
- Address practical and complicated questions affecting scientists



# Module Activity



# Module User Demographics



# Institutional Demographics

- Boston University
- Florida Gulf Coast University
- Georgetown University
- Georgia Institute of Technology
- Harvard Medical School
- Iowa State University
- Oregon Health and Science University
- Rocky Mountain College
- University Chieti (Italy)
- University of Kentucky
- University of Medicine & Dentistry of NJ
- University of Michigan
- University of Nebraska-Lincoln
- University of Washington
- University of Pennsylvania
- University of Pittsburgh
- University of Vienna (Austria)
- Uniformed Services Univer. of Health Sciences
- University of Witwatersrand (South Africa)
- AAAS
- American Society for Microbiology
- Center for Arms Control and Non-Proliferation
- CDC
- Colorado Information Analysis Center
- Italian Ministry of Defense
- National Academies
- National Institutes of Health (NIH)
- Nuclear Threat Initiative
- Sandia National Laboratories
- South African National Defence Force
- U.S. Army Medical Research Institute for ID (USAMRIID)
- U.S. Food and Drug Administration (FDA)
- Wadsworth Center, NY State Department
- Academy of Science of South Africa
- NYPD Counterterrorism Division

# Module Survey

- 2007 collaboration with Dr. Brian Rappert, University of Exeter, UK
- User feedback on structure, content, and usefulness
- Survey findings submitted for publication
- Guiding current module revision

# Module Survey Findings

- Interviewed 40+ PIs, post-docs, graduate students, IBC members, laboratory technicians and managers
- Wide disparities in assessment of dual-use risk, including inter-laboratory contradictions
- Awareness of dual-use dilemma still lacking
- Interest in issues impacting foreign researchers and international collaborations in particular
- Lessons learned:
  - **Awareness raising must be ongoing**
  - **Consider IBCs and biosafety staff**
  - **Scientific leaders are key**

# Module Revisions

- Revisions Feb 2008 – April 2008
- Update background material and references
  - NSABB recommendations and activity
  - More synbio discussion (MIT/Venter/CSIS Options for Governance)
- Move scenario timeline up
  - Dual-use concerns now identified at research proposal stage as well as at time of publication
- Target Release: Summer 2008

# **Dual-use Educational Panel**

**Duke University**

**October 31, 2006**

# Dual-use Educational Panel

- Panel held at Duke in October 2006
- Planned in collaboration with Duke RCR training of graduate students and post-docs
- Expert Panel:
  - **Bob Cook-Deegan** – PEL PI and Director, IGSP Center for Genome Ethics, Law & Policy
  - **Matthias Gromeier** - Assistant Professor of Molecular Genetics and Microbiology (MGM) and former member of Eckard Wimmer's lab;
  - **David Pickup** - Professor of MGM and SERCEB investigator;
  - **Scott Alderman** - Biosafety Officer helping to devise Duke's dual-use review mechanism;
  - **Heather Lynch** - 5th year graduate student in David Pickup's lab who helped us with the module;
  - **Rich Frothingham** - Co-Chair of Duke IBC, Director of soon-to-open Global Health Research Building/RBL, and Assoc. Prof. of ID and MGM; and
  - **Matt DeCamp** - MD/PhD student in bioethics.



# Panel Structure and Agenda

- 2 hour session; 59 students
- All students required to take dual-use module in advance of class
- Panel discussion of dual-use research issues moderated by BCD
- Case study presentation: Polio virus synthesis
- Small group discussions each led by one of the 6 panelists
- Reconvene and discuss comments and questions from groups

# Lessons-learned from Panel

- 55 of 59 attendees completed survey at the end of class
  - 93% of respondents rated the panel as "excellent" or "good."
  - Most helpful information learned from the panel: awareness of the dual-use issue
  - Liked the diversity of panelists and small group discussions led by panelists
- Having well-respected scientists and institutional officials participate helped raise the importance of the topic

# Dual-use Educational Panel: Emory University

- Planning a second panel at Emory for Fall 2008
- Similar structure to Duke panel
- Allison Chamberlain planning it with Arri Eisen and Ruth Berkelman
- Preliminary buy-in from 3 departments:
  - Graduate Div of Bio and Biomedical Sciences
  - Emory Ethics Center
  - Emory Science & Society Program

# Other Educational Activities

- International Dialogue
  - South Africa---M. Davidson Nov. 2007
  - Poland---A. Chamberlain Nov. 2007
  - Japan---A. Chamberlain Jan. 2008
  - Hungary---R. Berkelman Mar/Apr. 2008
- Participation in Emory's BSL-3 Training Program
  - Lead sessions on biosecurity and dual-use
- Creation of downloadable dual-use education packet
  - Posted on SERCEB PEL website
- Helping other colleagues with dual-use review and education
  - RCR Education Committee of the Association of Practical and Professional Ethics (APPE)
  - Gets more airtime for our module
  - Berkeley/Maryland/Northwestern "web portal" pilot project



# Future Research and Education: Biodefense and Global Health

- Ensuring information reaches users where infectious diseases are endemic
- Developing and deploying vaccines and drugs for those where diseases are endemic or affected by an attack outside the United States
- Anticipating intellectual property and other impediments to use in resource-poor countries
- Engaging with nonprofits and others working on global infectious disease policy

# Thank You

For more information, please see our  
website:

[www.serceb.org/pel](http://www.serceb.org/pel)