# Report of the Blue Ribbon Panel to Review the 2014 Smallpox Virus Incident on the NIH Campus

**Kenneth K. Bernard**
**RADM, U.S. Public Health Service (Ret.)**
**Chair, Blue Ribbon Panel**

# Background

- FDA leased NIH Building 29A on the Bethesda campus for many years
- In July 2014, FDA staff were cleaning out their facilities in preparation for a move to new FDA facilities in White Oak, Maryland
- A FDA researcher found several old boxes in a cold room that contained 327 vials of abandoned biological materials
- This included six vials that appeared to contain smallpox virus (variola), later confirmed, and other vials, some of which appeared to contain additional select agents
- The incident raised serious concerns and led to much activity in the USG, including several investigations with written reports
- NIH undertook a review of the incident by appointing a Blue Ribbon Panel

# Blue Ribbon Panel Charge

- BRP appointed by NIH Director; constituted as a working group of the NSABB

- Charge
  - To determine how the smallpox virus vials came to be improperly stored and overlooked for years
  - To identify any systemic issues and factors that contributed to the lapse
  - To evaluate whether NIH had taken adequate corrective actions in response to this incident

# Blue Ribbon Panel Roster

- BRP has seven members with diverse expertise in biosafety and biosecurity

***Kenneth Bernard, M.D. (Chair)**
RADM, U.S. Public Health Service (Ret.)
Former Special Assistant to the President for Biodefense, Homeland Security Council, White House

**David R. Franz, D.V.M., Ph.D.**
Former Commander, United States Army Medical Research Institute for Infectious Diseases (USAMRIID)
Professor, College of Veterinary Medicine
Kansas State University

**Gigi Kwik Gronvall, Ph.D.**
Senior Associate
UPMC Center for Health Security
Associate Professor, University of Pittsburgh School of Medicine and Graduate School of Public Health

**Debra Hunt, Dr.P.H., CBSP**
Director of Biological Safety
Assistant Professor, Division of Occupational Medicine, Department of Community and Family Medicine, Duke University

***Joseph Kanabrocki, Ph.D., NRCM(SM)**
Associate Vice President for Research Safety
Professor of Microbiology
University of Chicago

***James W. LeDuc, Ph.D.**
Director, Galveston National Laboratory and
Professor, Department of Microbiology and Immunology
University of Texas Medical Branch

**Melissa A. Morland, MS, CBSP, RBP**
Biosafety Officer
Environmental Health and Safety, University of Maryland
Past-President, American Biological Safety Association (ABSA) International

*****Current/incoming NSABB member

# Approach

The BRP:

- Reviewed the incident and the immediate response
- Reviewed and documented the response to the incident by NIH and other federal entities
- Studied current and previous NIH biosafety policies and evaluated the changes made since 2014

# Information Gathered

- Reports from other investigations
  - Centers for Disease Control and Prevention—Federal Bureau of Investigation
  - Food and Drug Administration
  - CDC Advisory Committee to the Director External Laboratory Safety Workgroup
  - Government Accountability Office
  - House Energy and Commerce Committee
- Interviews with individuals associated with incident and response
- NIH biosafety and biosecurity policies, procedures, and other guidance
- Other relevant federal policies and documents

# Contributing Factors

- Lack of responsibility for infectious materials in shared space (the cold room)
- Failure to find all variola virus samples in the 1980s when WHO requested that all smallpox samples be destroyed or transferred to one of the two official WHO repositories
- Failure to account for all select agents in 2003 when the first Select Agents Registration was done by NIH
- Lack of complete, regular inventory of potentially hazardous biological materials throughout all NIH laboratories
- Lack of policy for abandoned materials in NIH and FDA laboratories
- History of NIH lapses following implementation of the Select Agents Regulations prior to the 2014 incident
- Missed opportunities to find the samples before 2014
- Lack of clarity regarding responsibilities between NIH and FDA

# Problem Issues

- Improper packaging and transfer at the time of the incident of the materials from the site where they were found to a secure facility on the NIH campus
- Inadequate chain-of-custody records and failure to maintain a log of events at the time of the incident
- Lack of clear and detailed policy about the presence of cardboard in cold rooms

# Conclusions

- The BRP concludes that the events leading up to and during the 2014 smallpox virus incident are as well-documented and understood as is possible at this time, and the contributing factors have been clearly documented.
- The incident response involved NIH and several other federal agencies and was characterized by excellent cooperation. Overall, the response during the incident was appropriate, thorough, and effectively handled a highly unusual situation without further complications.
- The BRP found several problems related to the incident response at NIH.
- The follow-up response within the government was USG-wide and led to important biosafety changes and new policy activities that are on-going.

# Conclusions

- After the incident, NIH rapidly responded to address the underlying causes, and responded to the issues raised by internal and external reviews; NIH has reduced the probability of future incidents of this nature and has addressed or is addressing most of the systemic faults that previously existed.

- The BRP and multiple prior investigations could not determine who owned the samples and how they came to be where they were found, but there is no indication that there was malicious intent on the part of anyone at any time.

- No adverse health, safety, or security events were associated with the samples while they were abandoned or during the time period that surrounded their discovery.

# Recommendations

- First, with regard to specific steps NIH should take to remedy remaining gaps in biosafety policies and procedures, the BRP recommends NIH:
  - Revise several NIH biosafety policies and procedures, focused on more detailed procedural guidance and person-specific responsibilities, as detailed in the report
  - Rapidly finish the on-going space audit to ensure all research materials in each lab and shared space are assigned to individuals by name, and updated as required by personnel changes
  - Ensure that any shared research space arrangements include clear written agreements with responsibilities well defined
  - Carefully define in NIH policies and procedures, or eliminate when not clearly necessary, terms and categories that are not in general use, such as “high consequence pathogens” and “potentially infectious materials”

# Recommendations (cont.)

- Second, regarding more general approaches to improving biosafety and biosecurity at NIH, the BRP considers the following to be important considerations:
  - Effective and complete implementation of current policies, procedures, guidance and practices on an on-going basis will be critical to ensuring safety and security surrounding pathogen research at NIH.
  - Leadership at the highest levels and continuous efforts to develop and maintain a culture of safety and responsibility among research staff are critical.
  - There would be significant benefits to having consistent biosafety and biosecurity policies across the Department of Health Human Services (HHS) and the entire USG.

# Recommendations (cont.)

- Ideally, insofar as possible, these policies should be harmonized with efforts by governments and international organizations and institutions as well. On-going efforts to address these issues should continue.
- Response plans should be coordinated and routinely exercised with agencies outside of HHS, including the Federal Bureau of Investigation, the Environmental Protection Agency and others, as needed.
- The variola virus incident illustrates how changes in infectious disease epidemiology and biosafety practices over time can radically alter a situation from reflecting “standard lab practice” to potentially risking a major public health event.