



# Office of Vaccines Research and Review

## Division of Bacterial, Parasitic and Allergenic Products

Jay E Slater, MD  
Director, DBPAP

Laboratory of Bacterial Polysaccharides Site Visit, 13-14 May 2021  
VRBPAC review, 30 September 2021

# OVRR Regulates

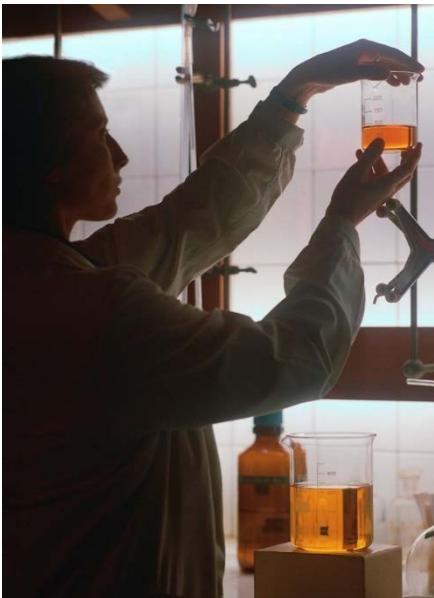


- Vaccines
- Allergenic products
- Live biotherapeutic products (probiotics, FMT)
- Phage

## OVRR Mission

- To protect and enhance public health by assuring the availability of safe and effective vaccines, allergenic extracts, and other related products

# OVRR Core Activities



- **Review, evaluate, and take appropriate actions on INDs, BLAs, amendments, and supplements for vaccines and related biological products and participation in inspections**
- **Develop policies and procedures governing the pre-market review of regulated products**
- **Conduct research related to the development, manufacture, and evaluation of vaccines and related products**

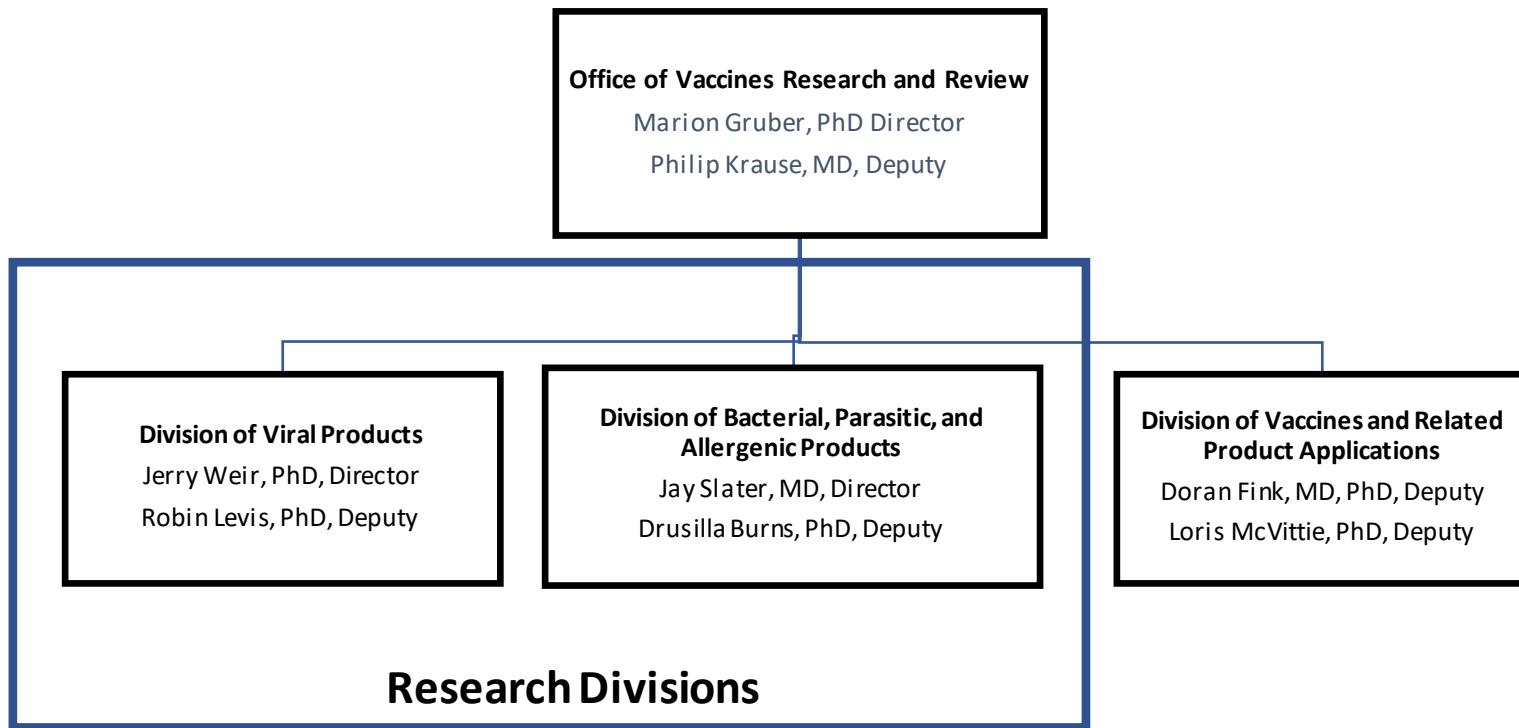


# OVRR Research Mission



- **The OVRR Research Program** is designed to complement and support the regulatory mission by focusing on issues related to the development of safe and effective products.

# OVRR Organizational Chart



# OVRR Research Goals

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## Research Goal 1: Safety

- Enhance the safety of preventive vaccines and related biological products through the development of models, methods and reagents needed in the manufacture and evaluation of these products

## Research Goal 2: Efficacy

- Improve the effectiveness of vaccines and related biological products through the development of models, methods and reagents needed to measure and predict the effectiveness of these products

## Research Goal 3: Availability

- To develop and study approaches to enhance the availability of vaccines and related biological products

# Importance of Research In Regulation of Vaccines and Related Products

## Emphasis on Safety

- Products for mass use (often universal)
- Recipients are healthy individuals, often children

## Keeping pace with technology

- New manufacturing technologies are rapidly evolving

## High level of Scrutiny by Public

- Regulatory decisions must be based on science
- Increasing number of anti-vaccine organization and groups

## Responding to Public Health Threats

- Antibiotic resistance
- Clostridium difficile
- Emerging adventitious agents

## Keeping results in public domain

- Our research benefits not just individual companies but the entire industry sector, and therefore the American consumers

# OVRR's Research Is



# Research-Regulator Model

## Integration of Regulation and Science

- The research-regulator model integrates regulatory review responsibilities with mission-directed research.
- Research-regulators review IND and BLA applications, participate as product-related subject matter experts in inspections, and perform research relevant to evaluation of specific product safety, efficacy, or manufacturing issues.



# Division of Bacterial, Parasitic and Allergenic Products



## Immediate Office of the Director

**Jay E. Slater, MD – Director**

**Drusilla Burns, PhD – Deputy Director**

### Laboratory of Bacterial Polysaccharides

**Willie Vann, PhD – Chief**

Mustafa Akkoyunlu, MD, PhD

Margaret Bash, MD

John Cipollo, PhD

Daron Freedberg, PhD

Florencia Haurat, PhD

### Laboratory of Respiratory and Special Pathogens

**Michael Schmitt, PhD – Chief**

Drusilla Burns, PhD

Tod Merkel, PhD

### Laboratory of Mucosal Pathogens & Cellular Immunology

**Scott Stibitz, PhD – Chief**

Paul Carlson, PhD

Siobhán Cowley, PhD

Karen Elkins, PhD

Heather Painter, PhD

### Laboratory of

### Immunobiochemistry

**Ron Rabin, MD – Chief**

Jay E. Slater, MD

Alexander Zhovmer, PhD

# DBPAP regulatory/research portfolio

## Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

## Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

## Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

## Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

## Parasite

- *Plasmodium* spp

## Other/emerging

- *Staphylococcus aureus*
- Allergenic products
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

# DBPAP regulatory/research portfolio

## Respiratory and Special Pathogens (LRSP)

### Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

### Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

### Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

### Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

### Parasite

- *Plasmodium* spp

### Other/emerging

- *Staphylococcus aureus*
- Allergenic products
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

# DBPAP regulatory/research portfolio

## Mucosal Pathogens and Cellular Immunology (LMPCI)

### Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

### Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

### Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

### Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

### Parasite

- *Plasmodium* spp

### Other/emerging

- *Staphylococcus aureus*
- Allergenic products
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# DBPAP regulatory/research portfolio

## Immunobiochemistry (LIB)

### Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

### Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

### Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

### Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
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- *Shigella dysenteriae*

### Parasite

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### Other/emerging

- *Staphylococcus aureus*
- **Allergenic products**
- Live biotherapeutic products (probiotics)
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- Microbiome-related products

# DBPAP regulatory/research portfolio

## Bacterial Polysaccharides (LBP)

### Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

### Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
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### Intracellular

- *Francisella tularensis*
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- *Campylobacter jejuni*
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- *Shigella dysenteriae*

### Parasite

- *Plasmodium spp*

### Other/emerging

- *Staphylococcus aureus*
- Allergenic products
- Live biotherapeutic products (probiotics)
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- Microbiome-related products

# LBP presenters

- **Willie Vann, Ph.D.; Chief, LPB; (Principal Investigator)**
  - **Shonoi Ming, Ph.D., (Staff Scientist)**
- **Mustafa Akkoyunlu, M.D., Ph.D., (Principal Investigator)**
  - **Ji Yeon Yang, Ph.D., (Staff Scientist)**
- **Margaret Bash, M.D., (Principal Investigator)**
  - **Kathryn Matthias, Ph.D., (Staff Scientist)**
- **John Cipollo, Ph.D., (Principal Investigator)**
  - **Lisa Parsons, Ph.D., (Staff Scientist)**
- **Daron Freedberg, Ph.D., (Principal Investigator)**



Thank you

Questions?