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

Office of Vaccines Research and Review
Marion Gruber, PhD Director
Philip Krause, MD, Deputy

Division of Viral Products
Jerry Weir, PhD, Director
Robin Levis, PhD, Deputy

Division of Bacterial, Parasitic, and Allergenic Products
Jay Slater, MD, Director
Drusilla Burns, PhD, Deputy

Division of Vaccines and Related Product Applications
Doran Fink, MD, PhD, Deputy
Loris McVittie, PhD, Deputy

Research Divisions
OVRR Research Goals

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

Broad

Although we can’t cover everything, we need to cover as much as possible within the scope of our responsibilities.

Collaborative

Collaboration with scientists around the country and the world allows us to leverage our investments in research.

Investigator-initiated

This allows our researcher/reviewers to anticipate regulatory needs and proactively address important questions.

Excellent

- While our motivation is the regulatory mission, our research is published and broadly cited and used.
- Our research scientists are members of the broader scientific community, and many are well-known experts in their fields.

Flexible

Our scientists work on topics that allow rapid adaptation to emerging areas of scientific and regulatory need.
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.
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
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- Bordetella pertussis
- Clostridium botulinum
- Clostridium tetani
- Corynebacterium diphtheriae
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DBPAP regulatory/research portfolio
Mucosal Pathogens and Cellular Immunology (LMPCI)

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**Invasive, protective responses to polysaccharides**
- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

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

**Enteric**
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- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

**Parasite**
- *Plasmodium spp*

**Other/emerging**
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DBPAP regulatory/research portfolio
Immunobiochemistry (LIB)

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DBPAP regulatory/research portfolio
Bacterial Polysaccharides (LBP)

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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?