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# Office of Vaccines Research and Review and Division of Viral Products

Tod Merkel, PhD  
Associate Director of Research, OVRR



# OVRP's Mission

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

## OVRP Regulates

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

# OVRP 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 and to better understand pathological processes.

# OVRB's Research Mission



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

## **High level of Scrutiny by Public**

- Regulatory decisions must be based on science

## **Keeping pace with technology**

- New manufacturing technologies are rapidly evolving

## **Responding to Public Health Threats**

- Antibiotic resistance
- Emerging agents

## **Generating results and placing them in the public domain**

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

## **Recruiting and retaining expert scientist to support Review**

# OVRB'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

## Excellent

- 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

## Investigator-initiated and Flexible

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



# Office of Vaccines Research and Review

Director: David C. Kaslow, M.D.

Deputy Director: Karin Bok, M.S., Ph.D.

## Associate Director of Research

Tod Merkel, Ph.D.

## Associate Director for Regulatory Policy

Theresa Finn, Ph.D.

## Health Science Advisor

Maureen Hess, MPH, R.D.

## Associate Director for Novel Clinical Investigations

Hector Izurieta, MD, MPH, Ph.D.

## Associate Director of Office Regulatory Initiatives

Sudhakar Agnihotram, Ph.D.

## Associate Director for Medical Countermeasures and Scientific Affairs

Peter Weina, M.D., Ph.D.

## Associate Director for Medical Policy and Vaccine Safety

Karen Farizo, M.D.

## Division of Viral Products

Director: Jerry Weir, Ph.D.

Deputy: Robin Levis, Ph.D.

*15 Principal Investigators*

## Division of Bacterial, Parasitic, and Allergenic Products

Director: Jay Slater, M.D.

Deputy: *Selection made*

*16 Principal Investigators*

## Division of Review Management and Regulatory Review

Director: Loris McVittie, Ph.D.

Deputy: Kirk Prutzman, Ph.D.

## Division of Clinical and Toxicology Review

Director: Rebecca Reindel, M.D.

Deputy: R. Douglas Pratt,  
M.D., M.P.H



# DVP's Mission



- Regulate viral vaccines and related biological products, ensuring their safety and efficacy for human use
- Facilitate the development, evaluation, and licensure of new viral vaccines that positively impact the public health

# DVP's Major Responsibilities

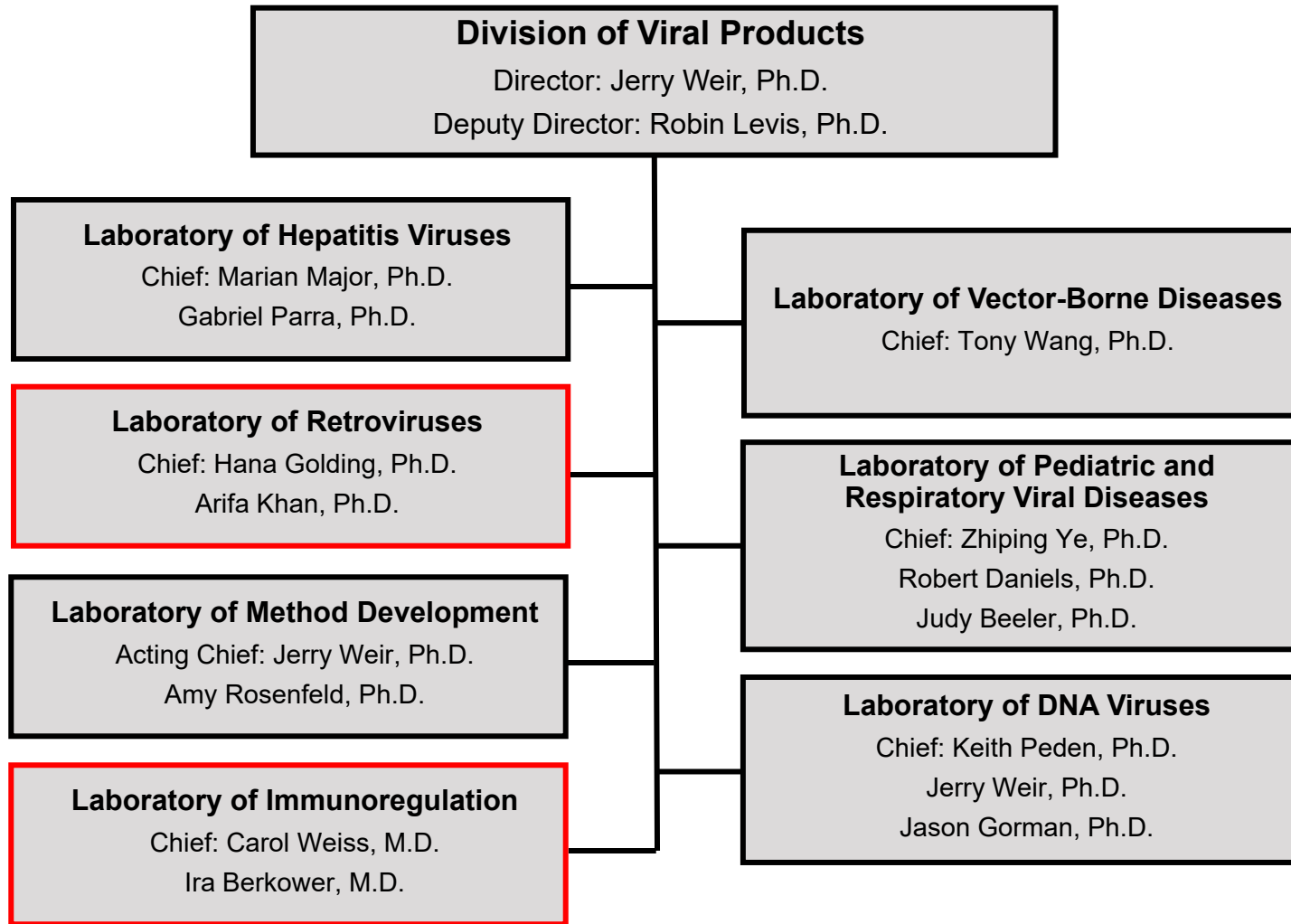


- Review of Investigational New Drug (IND) applications, Biologics License Applications (BLA), and other pre-marketing activities (e.g., pre-IND)
- Review of BLA supplements, lot release, and other post-marketing activities (e.g., Biological product deviations)
- Manufacturer inspections (pre- and post-licensure)
- Consultation with other public health agencies (e.g., WHO, CDC, NIBSC)
- Conduct research related to the development, manufacturing, evaluation, and testing of viral vaccines



# Role of DVP's Research

- Research and laboratory activities complement the regulatory mission
- Address issues related to regulated viral vaccines
- Anticipate and address issues related to the development and evaluation of new viral vaccine products
  - General issues applicable to many products or product classes (e.g., cell substrate issues, improved test methods, etc.)
  - Specific product issues (correlates of protection necessary for efficacy evaluation, animal models necessary for animal rule implementation, etc.)



Thank you

Questions?