

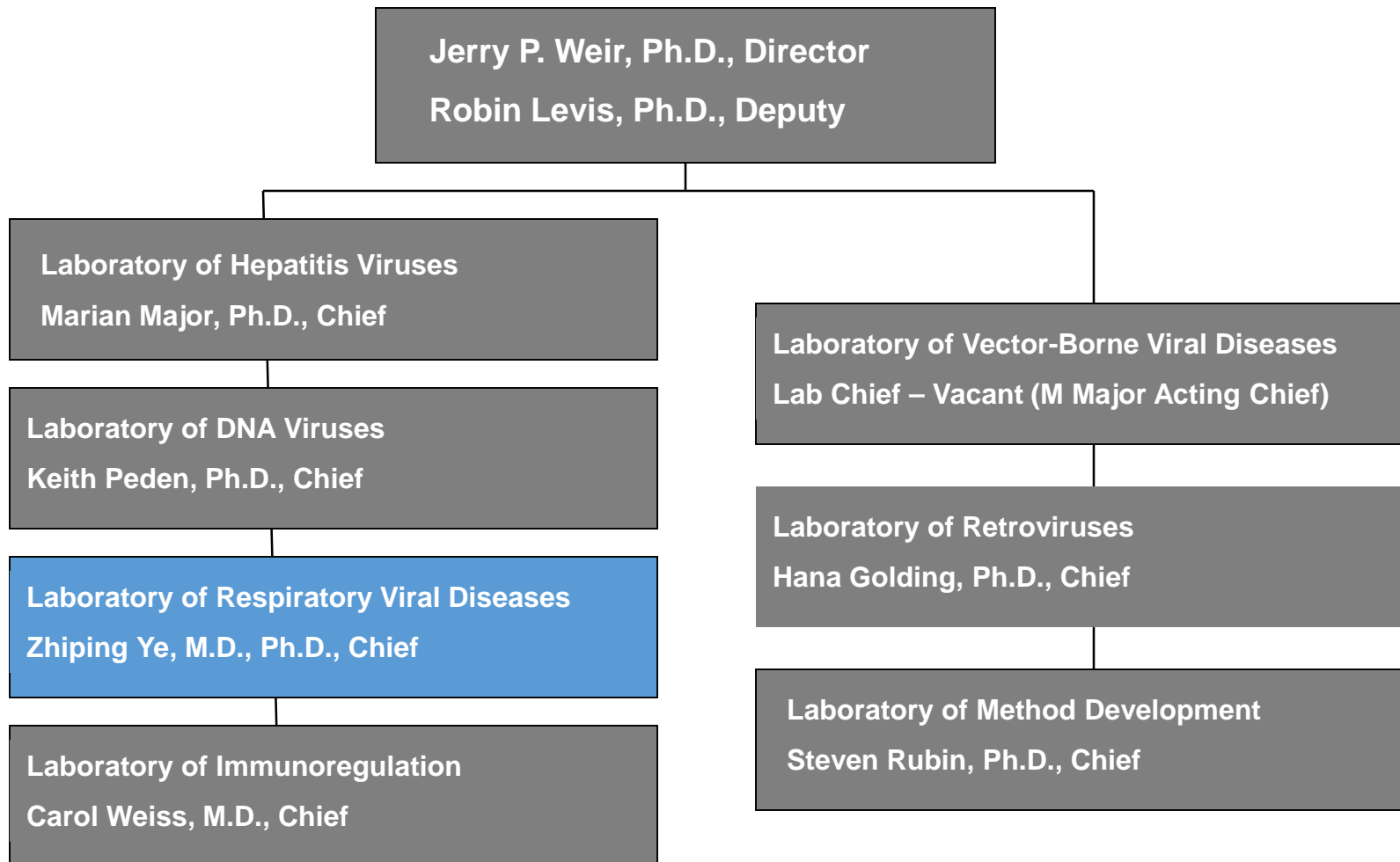
# **Overview of the Division of Viral Products**

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# Division of Viral Products

## Office of Vaccines Research and Review



# **Division of Viral Products**

## **Mission and Functions**

- 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

# **Division of Viral Products**

## **Major Responsibilities**

- Investigational New Drug (IND) and Biologics License Application (BLA) review, and other pre-marketing activities (e.g., pre-IND)
- BLA supplement review, lot release review, 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

# The Role of Research in the Division of Viral Products

- 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.)

# Division of Viral Products Staff and Budget Overview

- **Division Staff – FY17**
  - 75 FTEs
  - ~40 contractors (ORISE)
    - Postdoctoral fellows
    - Postbac students
- **Division Budget – FY17**
  - Basic operating budget - \$5,798,000
  - Targeted FDA support - \$567,000
  - External DVP support - \$2,832,000

# **Division of Viral Products Staff (FTEs) - by Laboratory**

- DVP IOD – 6
- Respiratory Viral Diseases – 11
- Hepatitis Viruses – 5
- Retrovirus Research – 10
- DNA Viruses – 17
- Vector-borne Viral Diseases – 4
- Method Development – 16
- Immunoregulation – 6

# Site Visit Evaluation

- Program review
  - Assessment of progress on projects pursued since previous site visit
- Individual review
  - Consideration for promotion
- Evaluation of future directions