



# Office of Vaccines Research and Review

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# Office of Vaccines Research and Review

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## OVRR Mission Statement:

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

# OVRP Regulatory Portfolio

- Bacterial vaccines (inactivated) – 10
- Bacterial vaccines (live attenuated) – 2
- Viral vaccines (inactivated) – 10
- Viral vaccines (live attenuated) – 15
- Combination products (inactivated) – 4
- Allergenic extracts (diagnostic and therapeutic) >2,000
- Live biotherapeutic products – INDs only

# OVRP Core Activities

- Review, evaluate, and take appropriate actions on INDs, BLAs, amendments and supplements to these applications for vaccines and related products, conducting inspections, etc.
- Develop policies and procedures governing the pre-market review of regulated products
- Conducting research related to the development, manufacture, and evaluation of vaccines and related products

# OVRR Regulatory Challenges

- Emphasis on SAFETY:
  - Products for mass use (often universal)
  - Recipients are healthy individuals, often children
- Short regulatory cycle
  - Seasonal influenza vaccines
  - Response to emerging pathogens (pandemic vaccines)
- Many products are old
  - Innovative technologies
- Research plays a critical role in regulation of vaccines

# The purpose of OVRP research program is to:

- contribute to regulation of vaccines and related products by addressing **scientific aspects of critical regulatory issues**
- develop and maintain a scientific base for **establishing methods and standards** designed to ensure the continued safety, purity, potency and effectiveness of vaccines and related products
- **recruit and maintain highly trained scientists** who possess the expertise necessary for review of regulatory submissions and development of regulatory policies and guidance documents
- provide scientific expertise and **leadership to vaccine industry** to facilitate the development and introduction of new vaccines and related products

# OVRR Research Priorities

- **Safety**

To study factors affecting safety of regulated products, create and validate appropriate methods and standards

- **Efficacy**

To study biomarkers and introduce new methods and standards to evaluate and improve vaccine efficacy

- **Availability**

To develop new concepts and methods opening novel regulatory pathways to improve availability of vaccines and related products

# Research Management Challenge

To reconcile **Investigator-initiated research** model with **Agency mission** and enable rapid response to emerging public health threats



# Sources of scientific information used to shape our research program

- Researcher-regulator model
  - Investigators participate in review and are familiar with current challenges facing vaccine industry
  - Communicate with peers in academia, scientists in industry, other government agencies
  - Actively engage in International harmonization process
- Advisory committees recommendations
- Site visits

# OVRP Research Management Committee

- Coordinates research management process
  - Division Directors and Deputies
  - Two representatives from each research Division
  - Representatives from review Division
  - Office ADR
- Periodically reviews research priorities
- Identifies gaps and unnecessary redundancies
- Ensures uniform approach to allocation of resources

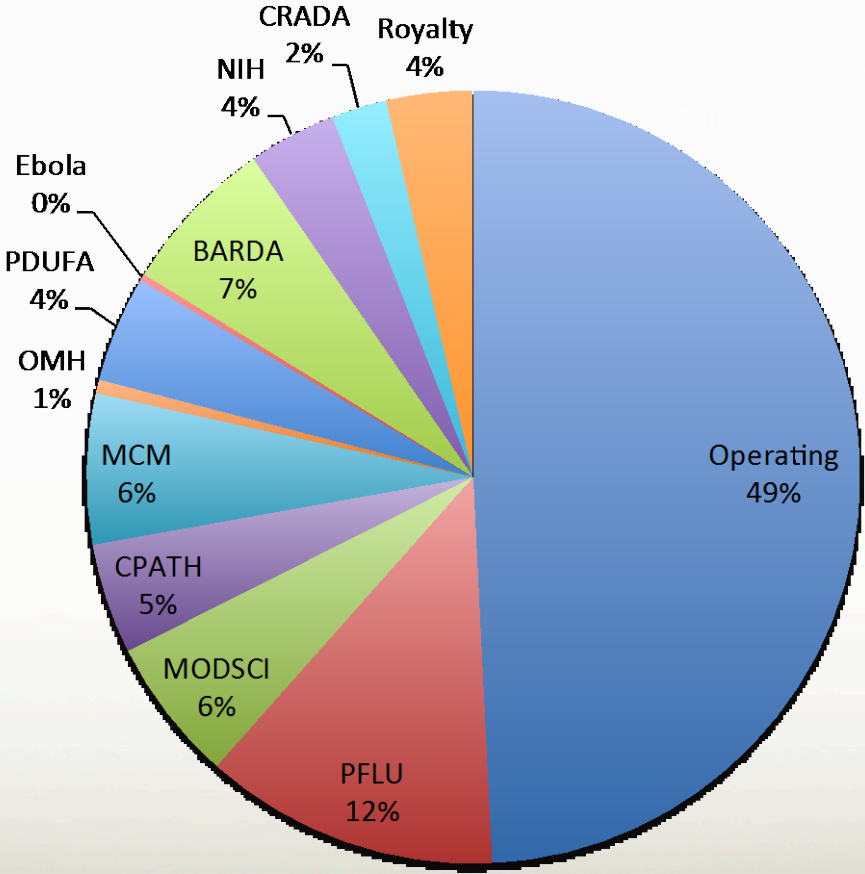
# Annual Program Review Cycle



# Scoring of Research Projects

- PUBLIC HEALTH SIGNIFICANCE
  - Public health need — dealing with high priority issue
  - Immediate regulatory relevance — pending applications exist
  - Strategic regulatory relevance — resolving general regulatory challenge of major importance
  - Office/Division needs — fills a gap in the overall research program
- SCIENTIFIC MERIT
  - Scientific rationale
  - Originality and innovation
  - Feasibility of research approach
  - Budget (affordability)
- QUALIFICATIONS AND PRODUCTIVITY
  - Necessary qualifications
  - Past productivity of investigator/impact

# Sources of Funding in FY15



Thank you