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.
OVRR 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
OVRR 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 OVRR 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
OVRR 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

- Senior Investigator
- Office IOD
- Lab Chief
- Research Management Committee
- Division Director
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