CBER’s Global Health Lens (1)

- CBER’s portfolio of regulated products addresses the threat of infectious diseases to the US – infectious diseases know no borders
  - Prophylactic vaccines
  - *In vitro* test kits to screen the donations from blood and tissue donors for infectious agents
CBER’s Global Health Lens (2)

• CBER contributes to USG efforts against biologic threats to US
  – Natural threats, e.g., pandemic influenza
  – Man-made threats

• Infectious diseases not currently circulating in the US pose a risk to DoD, other US agencies, and travelers
Focus on Developing Countries

• Infectious disease threats of interest commonly endemic in developing countries

• Clinical trials are typically undertaken in disease endemic areas, i.e., developing countries
Why Regulatory Capacity Building?

• Control of diseases before they reach our borders protects the US; effective oversight by local NRAs of products intended to control such diseases contributes to this protection

• CBER has an interest in promoting data integrity and human subject protection for clinical trials conducted in these areas; best accomplished with functioning local NRA

• Strengthening local NRA can enhance regulatory oversight and complement CBER oversight

• Cooperation/collaboration with NRAs in developing countries, often in the context of regulatory capacity building activities, provide a mechanism for scientific exchanges of benefit to CBER
Current Approach

• CBER’s preferred strategy is to support multilateral efforts, e.g.,
  – CBER is PAHO/WHO Collaborating Center for Biological Standardization
  – ICH/ICH Global Cooperation Group
  – APEC/Life Sciences Forum Regulatory Harmonization Steering Committee

• Coordinate with peer NRAs to achieve synergies
Select Activities (1)

• WHO Developing Countries’ Vaccine Regulators Network (DCVRN)
  – a WHO-funded network of NRAs
    • Brazil, China, Cuba, India, Indonesia, Republic of Korea, Russia, South Africa, and Thailand
  – Builds regulatory capacity among vaccine-producing developing countries through information-sharing, training, and organizing activities
  – Meets ~2x/yr to gain timely information from independent experts & developers on issues relating to vaccine trials occurring in developing countries
  – Devises institutional plans & other activities that seek to strengthen regulatory capacity
Select Activities (2)

- WHO/African Vaccine Regulatory Forum (AVAREF)
  - To help define the role of African NRAs in regulating clinical trials of vaccines, in interactions with national & local IRBs & ethical committees, & in strengthening NRA capacity to regulate new products
  - FDA & other mature NRAs (e.g., EMA and Health Canada) participate as expert advisers, particularly to share the regulatory mechanisms used to evaluate the safety and efficacy of investigational products
  - Includes Botswana, Burkina Faso, Cameroon, Ethiopia, Gabon, Gambia, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, Senegal, Tanzania, Uganda, and Zimbabwe, and growing
Select Activities (3)

- Pandemic preparedness
  - Co-sponsored series of 3 meetings with Health Canada to develop WHO guideline on regulatory considerations for pandemic vaccines (issued 2007)

- 2009 H1N1 pandemic
  - Supported WHO efforts for global regulatory dialogue in multiple ways
  - Technical support, bilaterally and multilaterally, to developing country NRAs, among others, for pandemic influenza vaccine oversight (issues re product testing and evaluation, clinical trials, adverse events)
WHO Assessment Efforts

- WHO undertakes NRA assessments in part to support its vaccine prequalification program
  - Assessments against a set of criteria defining a functional NRA
  - Weaknesses and gaps identified
  - Results in Institutional Development Plan (IDP), as needed, to address weaknesses and gaps
  - CBER has served multiple times on WHO assessment teams

- Assessment tool for national blood regulatory systems is under development by WHO Blood Regulators Network
  - CBER is key contributor as member of WHO BRN
Safety of Imported Products

• CBER’s current product inventory does not include products sourced from developing countries so safety of imported products from these countries not a high profile concern at this time

• However, we can anticipate that this will change over time
The End Game

Strengthening NRAs in developing countries has the potential to improve both global and US public health.