Global Supply Chain Impacts

Mary Lou Valdez, M.S.M.
Associate Commissioner for International Programs
U.S. Food and Drug Administration
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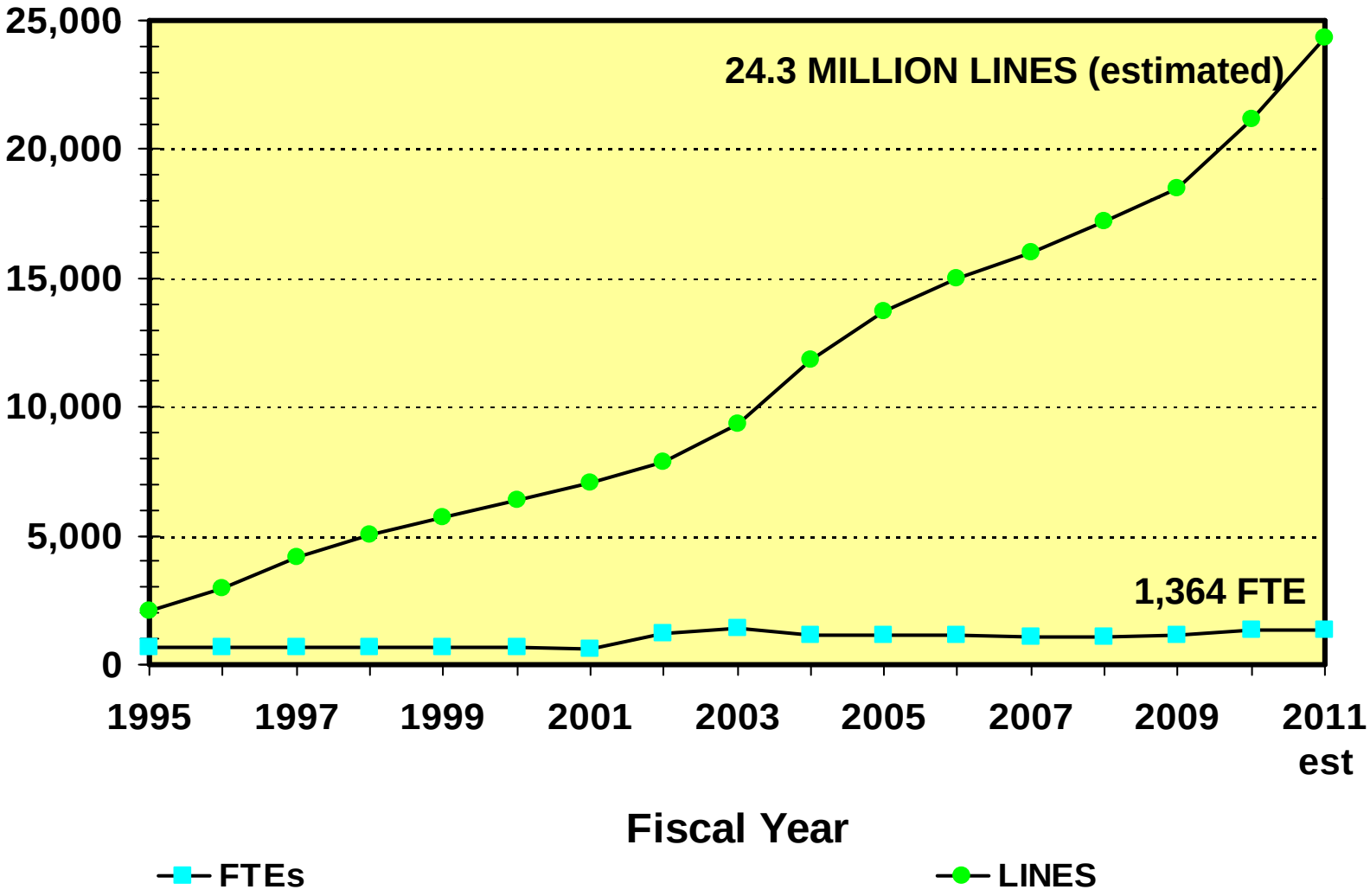
Import Volume History vs. Import FTE History (FTE include Foreign Inspections)



What do we import?

- Types of Products
  - 45% of fresh fruits
  - 75% of seafood
  - 40% of finished drugs
  - 80% of active pharmaceutical ingredients in drugs
  - 48% of higher risk medical devices
- Variety of Sources
  - 150 countries exporting FDA-regulated products
  - 300,000 foreign facilities
    - 222,000 foreign food manufacturers

Globalization and New Regulatory Challenges

- Greater volume of imported products;
- Greater number of foreign facilities supplying the U.S.;
- Increased complexity of products, manufacturing methods and supply chains;
- Greater opportunities for economic fraud.

FDA Issues in a Globalized World

- Strategic and efficient use of limited resources and better leveraging of external resources.
- Data/information gaps;
- Continued migration of research and development / clinical trials and manufacturing outside U.S. borders;
- Creating harmonized standards out of divergent ones;
- Some regulatory counterparts have an economic mission that may conflict with FDA's public health mission;
- Cultural / linguistic / national differences.

Issues Developing Countries Face

- Inadequate regulatory authority and systems to assess and regulate
- Lack of resources to establish/maintain effective regulatory and scientific review systems
- Regulatory systems not historically part of development assistance agenda
- Unstable governments/regulatory environments

Developing Countries Issues (cont.)

- Lack of adequate civil and criminal ability
- Two-tiered approaches: domestic market and markets for exported product;
- Lack of a consumer protection culture.
- Prohibitively high costs can result in susceptibility to low cost counterfeit/ substandard products
- Developing countries concern that over-regulation will stifle economic growth while others view it as an enabler

FDA Global Engagement

- Building collaborative partnerships and alliances;
- Strengthening capacity of foreign regulatory counterparts – “systems approach”;
- Creating a robust system for collecting, analyzing and using information; and,
- Increasing frequency/timeliness of inspections and increasing reliance on other sources of information.

FDA Global Engagement (cont.)

- FDA continues bilateral, regional, and multilateral engagement with counterparts and other stakeholders overseas through:
  - Regulatory Capacity Building
  - International Standards Development and Harmonization
  - Confidentiality Arrangements/Memoranda of Understanding
  - Inspections and Enforcement Cooperation
  - Enhanced Communications – better knowledge base about others' systems and capacity
  - Work-sharing and better leveraging of resources

FSMA Capacity Building Highlights

FSMA builds a system of collaboration w/ domestic and foreign government agencies, recognizing that all food safety agencies need to work together in an integrated way to achieve public health goals. Examples:

- Section 305. Capacity Building: FDA mandate to work with foreign governments to build food safety capacity where needed and where collaboration can be agreed.
- Section 308. FDA Foreign Offices: Establish offices in foreign countries to provide assistance on food safety measures for food exported to the United States.

Better Understanding the Global Landscape through Information and Data

- **IOM consensus study to:**
  - Identify core elements of viable, robust regulatory systems in developing countries;
  - Prioritize needs with respect to regulatory system development; and,
  - Recommend a strategic approach to address regulatory capacity needs in the context of globalization.

- **2010 Cooperative Agreements/Contracts:**
  - Global Food Safety Plan for an Information Platform by WHO
  - Global Information System for Counterfeit Medicines by WHO
  - Information Hub for Medical Products in the Americas
  - Antimicrobial Initiative (AGISAR) – WHO
  - World Animal Health Organization (OIE) – working with countries to implement VICH guidelines at country-level
  - Contract to scope the global training landscape

- **2011 Cooperative Agreements:**
  - Umbrella Agreement with WHO in Food Safety
  - WHO Vaccines: review of existing data and surveillance

What is the Benefit?

- Strengthening a country's regulatory capacity has both domestic and international benefits:
  - Enhances public health locally and abroad;
  - Enhances safety/quality of products reaching U.S.;
  - Enhances overall economy/national prosperity
  - Increases security of supply chains and security overall;
  - Provides better information for FDA regulatory decision making;
  - Increases a science-and evidence-based approach to product regulation, and
  - Fosters innovation

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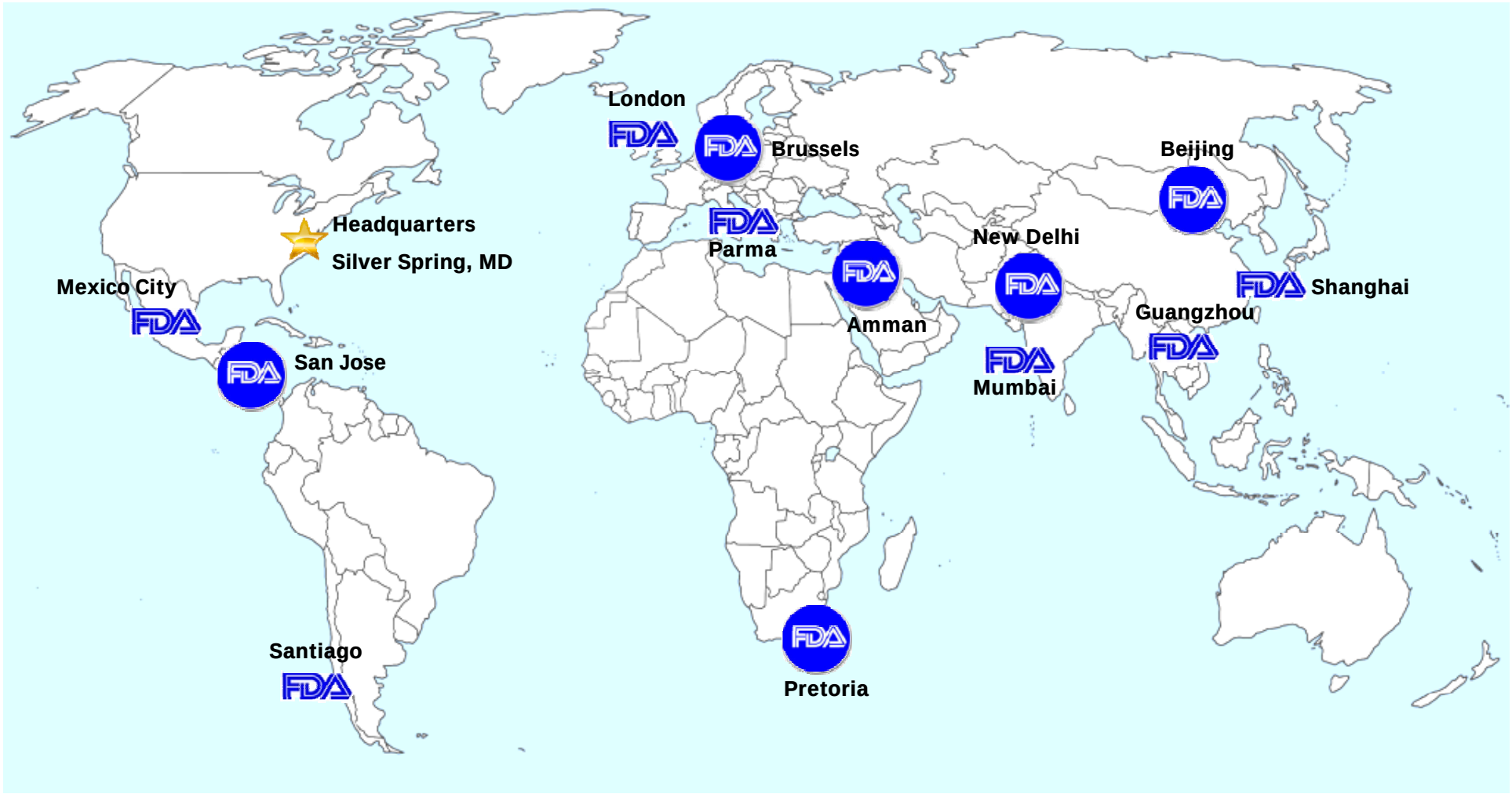
FDA Foreign Offices



FDA Foreign Offices

- Build capacity though improved knowledge about product manufacturing and transport to U.S. ports;
- Coordinate with foreign regulatory counterparts to better leverage knowledge and resources and strengthen their capacity to better assure product safety;
- Work with regulated industry to better understand FDA regulations, standards and guidance;
- Coordinate with USG colleagues in-country (USDA, CBP, USTR, DOC, DOS, DoD) on approaches to enhance product safety; and
- Increase capacity to perform more timely FDA overseas inspections, especially of high risk products.

The Path Forward

Paradigm Shift

- Focus on prevention, risk-based approaches
- Improve industry accountability and verify compliance
- Harmonized science-based standards implemented globally
- Use data/information for better decision-making
- The border as a final checkpoint, not the primary line of defense

Greater Global Safety

- Global alliance of regulators that includes the public and private sectors, industry and other stakeholders
- Greater reliance on trusted foreign government authorities
- Collaboration with international organizations and others to strengthen regulatory systems, surveillance, and decision-making

New Authorities and Adequate Funding

Thank you!

For more information:

http://www.fda.gov/InternationalPrograms/default.htm