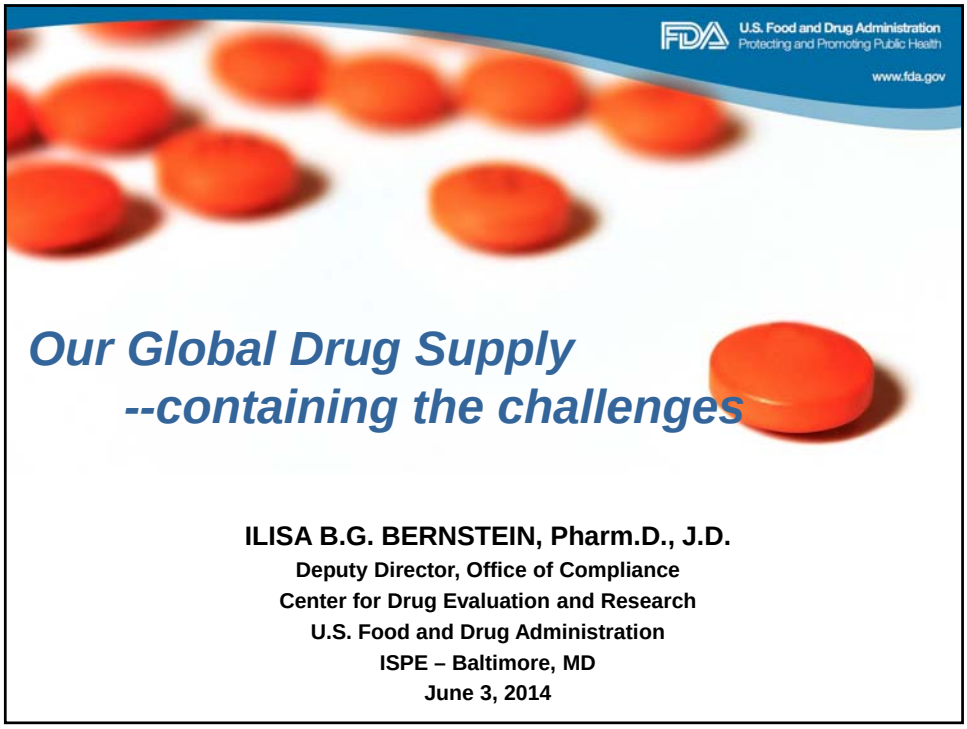
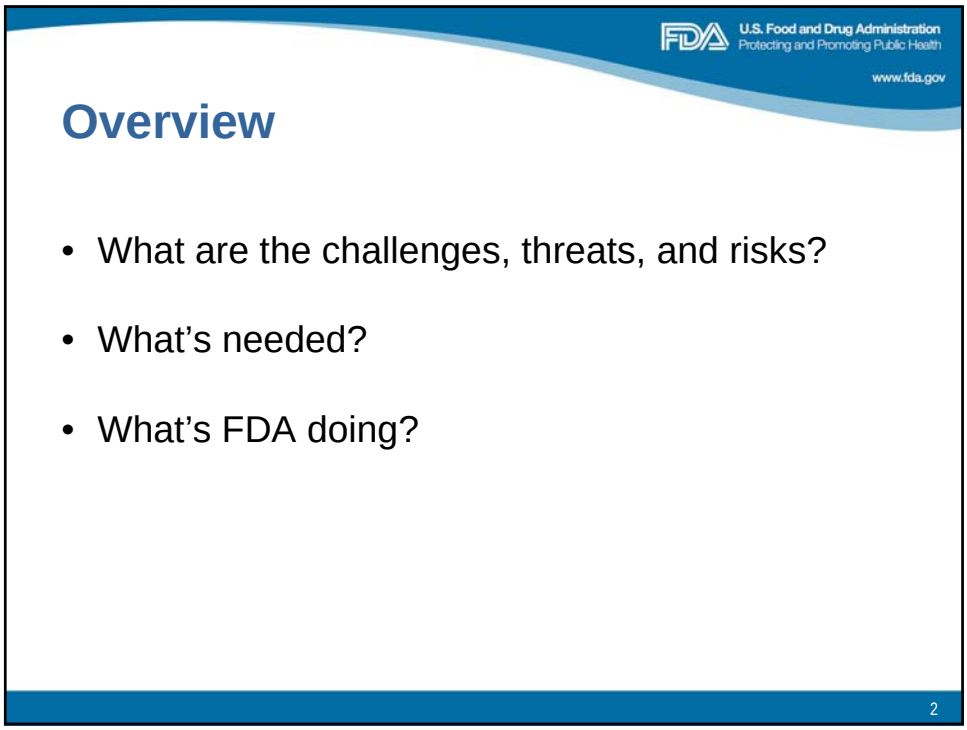


ILISA B.G. BERNSTEIN, Pharm.D., J.D.
Deputy Director, Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
ISPE – Baltimore, MD
June 3, 2014



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Global supply chain challenges

- Increased number of individuals, producers, and companies geographically dispersed
- Longer, complex supply chains
- Product mobility
- Growing availability of distribution channels for products (e.g. Internet)
- Intentional adulteration and counterfeiting for economic or other reasons
- Prevalence of substandard drug components
- Increasing data integrity concerns
- Weak regulatory systems and oversight

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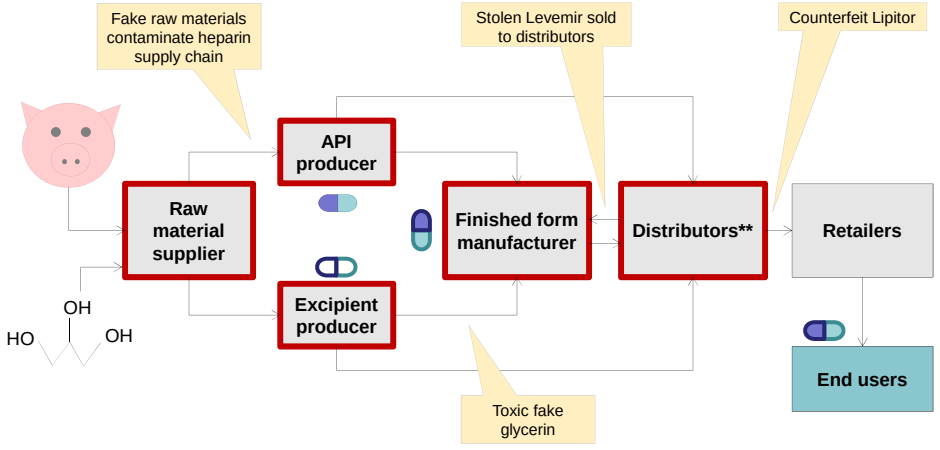
Threats throughout the drug supply chain



* Manufacturers and distributors may be foreign **or** domestic, exporters **or** importers

** Distributors may include any non-manufacturing intermediaries in the supply chain

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What's needed?

- Coordinated, strategic, global approaches
- New tools – legal/regulatory/enforcement
- Stronger global standards and convergence
- Leverage resources globally
- More…..

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Supply chain integrity strategy

- Prevention
  - Focus on securing legitimate supply chain
  - Ensure transparency and accountability
  - Understand, mitigate, and contain the risks
  - Enhance regulatory and legal infrastructure
- Detection
  - Increase surveillance
  - Improve information sharing
  - New tools
- Response
  - Enhance enforcement activities and tools
- Foundational
  - Improve vigilance and awareness
  - Increase global cooperation/coordination

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New authorities

- FDASIA Title VII – Food and Drug Administration Safety and Innovation Act (2012)
  - Supply chain authorities
- DSCSA – Drug Supply Chain Security Act (2014)
  - Drug Quality and Security Act (Title II)
  - Track and trace system

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FDASIA Title VII: Why it's important

- Allows FDA to collect more comprehensive, accurate and timely information
- Helps level the playing field for foreign and domestic manufacturers
- Allows for better coordination with foreign counterparts
- Helps ensure safer drugs by giving FDA critical new tools to protect the integrity of the global supply chain
- Accelerates FDA's transformation to an agency fully prepared for a rapidly changing global environment

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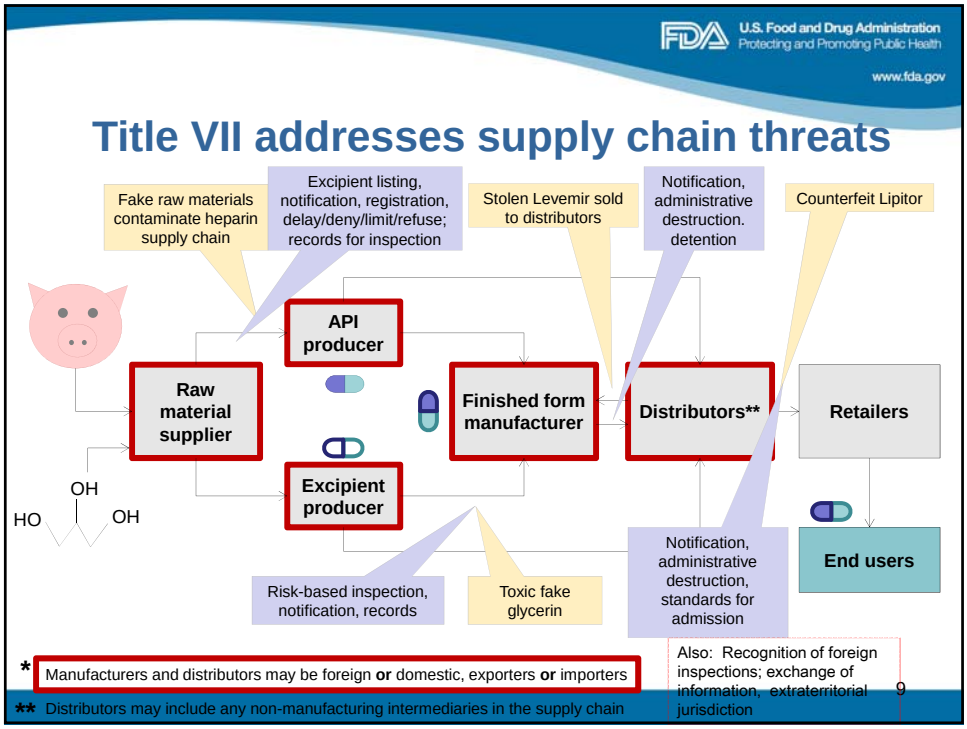
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Title VII addresses supply chain threats
Fake raw materials contaminate heparin supply chain
Excipient listing, notification, registration, delay/deny/limit/refuse; records for inspection
Stolen Levemir sold to distributors
Notification, administrative destruction. detention
Counterfeit Lipitor
API producer
Raw material supplier
Finished form manufacturer
Distributors**
Retailers
Excipient producer
End users
OH
HO
OH
Risk-based inspection, notification, records
Toxic fake glycerin
Notification, administrative destruction, standards for admission
* Manufacturers and distributors may be foreign or domestic, exporters or importers
** Distributors may include any non-manufacturing intermediaries in the supply chain
Also: Recognition of foreign inspections; exchange of information, extraterritorial jurisdiction
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New Drug Supply Chain Security Act (Track and Trace)
• Outlines steps to build an electronic, interoperable system to identify and trace certain Rx drugs as they are distributed in the U.S.
– Product identification
– Product tracing
– Product verification
– Detection and response
– Notification
– Wholesaler (WDD) licensing/standards
– Third-party logistics provider licensing/standards
– Enhanced system – 10 years
– Penalties
– National uniform policy
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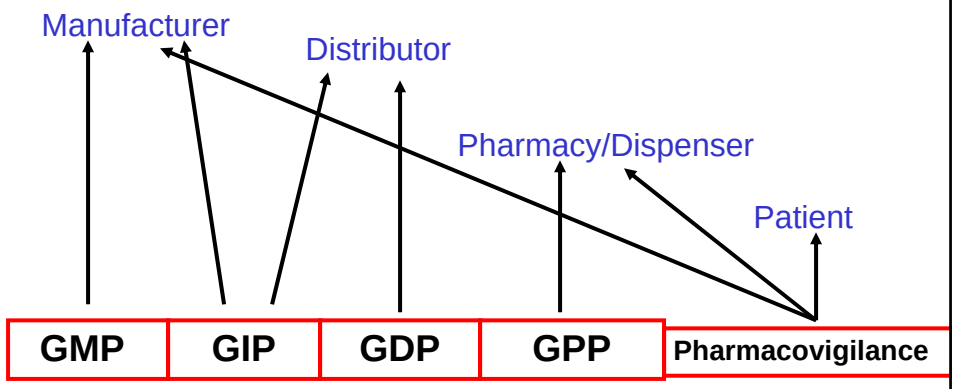
Building on GxP's & pharmacovigilance

"Filling in the supply chain holes"



GMP=Good Manufacturing Practice, GIP=Good Importer Practices, GDP=Good Distribution Practice, GPP=Good Pharmacy Practice

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FDA's changing operating model

- Increased presence overseas
- Reorganized
  - Global inspectorate
  - Program alignment
  - Quality focus

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FDA's Foreign Offices

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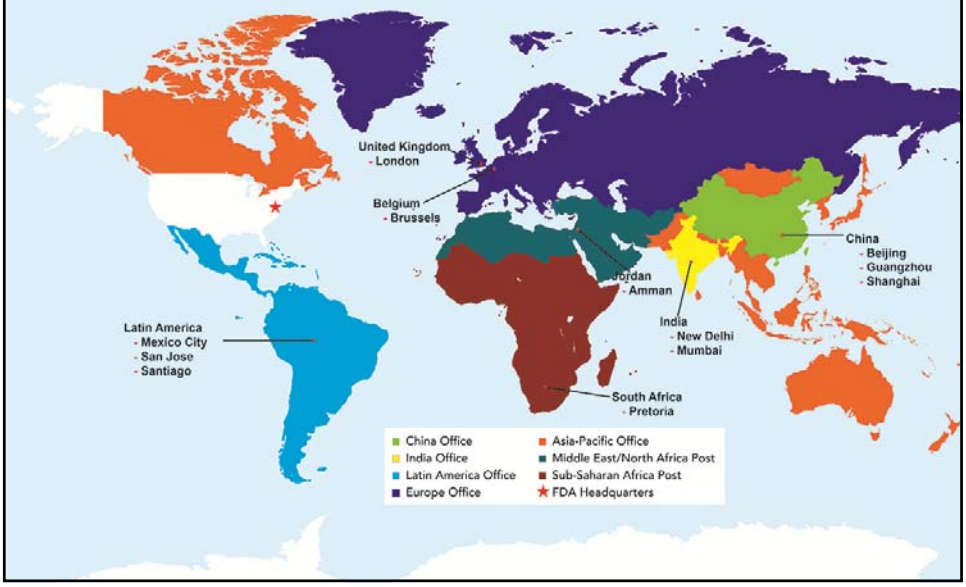

International collaboration efforts

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- Observational/Joint inspections – GMP, GCP, BE
- Enhance inspection strategy (FDA/EMA)
- RCC – Regulatory Cooperation Council (FDA/Health Canada)
- PIC/S – Pharmaceutical Inspection Cooperation Scheme
- ICMRA – International Coalition of Medical Regulatory Authorities
- ICH – International Conference on Harmonization
- APEC– Asia Pacific Economic Cooperation
  - Supply chain integrity roadmap
- WHO – World Health Organization
- FDA country office collaborations
- More…

INTERPOL

APEC Asia-Pacific Economic Cooperation

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Regulatory system strengthening

- A strong regulatory system is key for each country's public health, national security, and economic viability
  - Promote access to safe, effective, quality medicine
- IOM Report: Strengthening Regulatory Capacity
  - IOM identified gaps and strategies
  - IOM identifies several core elements of a regulatory system: responsive, outcome-oriented, predictable, risk-based or proportionate, and independent
- World Health Assembly resolution (2014)

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Efforts in emerging markets

- Recognition of special concerns
  - Data integrity
  - Substandard/counterfeits
- Inspections
- Capacity building and technical assistance
- Outreach

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Final thoughts….

- Significant challenges, threats, and risks to the global drug supply
- Supply chain vigilance and due diligence is essential
- Global coordination and cooperation is imperative
- We (FDA, industry, other regulators) must continue to evolve to meet new demands and challenges

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Thank you !!!

ILISA B.G. BERNSTEIN, Pharm.D., J.D.
FDA/CDER/Office of Compliance
ilisa.bernstein@fda.hhs.gov

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