Overview

• What are the challenges, threats, and risks?
• What’s needed?
• What’s FDA doing?
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

Threats throughout the drug supply chain

Fake raw materials contaminate heparin supply chain

Stolen Levemir sold to distributors

Counterfeit Lipitor

Raw material supplier

API producer

Finished form manufacturer

Distributors**

Retailers

Exciipient producer

Toxic fake glycerin

End users

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

Distributors may include any non-manufacturing intermediaries in the supply chain
What’s needed?

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

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
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

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
Title VII addresses supply chain threats

Fake raw materials contaminate heparin supply chain

Counterfeit Lipitor

API producer

Excipient producer

Finished form manufacturer

Nottingham, administrative destruction, detention

Counterfeit Lipitor

End users

Retailers

Raw material supplier

Excipient listing, notification, registration, delay/deny/limit/refuse; records for inspection

Stolen Levemir sold to distributors

Risk-based inspection, notification, records

Toxic fake glycerin

Distributors**

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Risk-based inspection, notification, records

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

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

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

Also: Recognition of foreign inspections; exchange of information, extraterritorial jurisdiction
Building on GxP’s & pharmacovigilance
“Filling in the supply chain holes”

- Manufacturer
- Distributor
- Pharmacy/Dispenser
- Patient

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

FDA’s changing operating model

- Increased presence overseas
- Reorganized
  - Global inspectorate
  - Program alignment
  - Quality focus
International collaboration efforts

- 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…
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)

Efforts in emerging markets

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

Thank you !!!

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