Securing the pharmaceutical supply chain: U.S. FDA’s efforts and perspectives

ILISA B.G. BERNSTEIN, Pharm.D., J.D.
Director of Pharmacy Affairs
U.S. Food and Drug Administration
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Overview

• Globalization and international supply chain security
  – Challenges
  – Pilots/Guidances/Initiatives

• Domestic supply chain security
  – FDA Counterfeit Drug Initiative
  – Regulatory tools/approaches
  – Standards development for identification, track/trace & authentication
  – Technology

• What’s next?
Product integrity considerations

- Globalization has created unique challenges to supply chain security: private & public sector

- Need to consider the lifecycle of the product

  Starting materials  \rightarrow  Administration of finished dosage form

- Existing, new, and emerging technologies for track and trace hold promise
Challenges Presented by Globalization

- More foreign facilities supplying the U.S.
- Increasing volume of imported products
- More outsourcing of manufacturing
- Greater complexity in supply chains
- Imports coming from countries with less developed regulatory systems
- Greater opportunities for economic fraud
Regulatory Challenges: Supply Chain Safety

- Incomplete information about supply chains, including participants and vulnerabilities
- Gaps in regulatory standards needed to increase corporate responsibility/accountability to prevent risks
- Complex system of foreign, Federal, and State oversight of product safety
- Incomplete set of enforcement tools
- Resources not aligned with workload or public expectations
Good Importer Practices

  - Applies to USDA, DoC, HHS, DHS, DoT, CPSC, EPA, and USTR
  - Comment period closed April 13, 2009.
- Provides general recommendations for importers on practices/procedures to increase imported product compliance with U.S. safety and security requirements.
  - Prevent and detect problems at critical points in product life-cycle
Secure Supply Chain (SSC) Pilot Program

- Comment period closed March 16, 2009.
- SSC Pilot is part of FDA’s risk-based approach to regulating drug imports.
- Provides increased likelihood of “expedited entry” for participants.
- Finished dosage forms and APIs
Beyond Our Borders Initiative

- FDA in-country offices
  - Awareness
  - Capacity building
  - Standards/inspections
  - Collaboration
  - Leveraging opportunities
  - Locations:
    - China, India, EU, Latin America, Middle East

- Leveraging projects
  - Pilots/Info sharing
    - EMEA pilot
Framework—U.S. Action Plan

“Anti-counterfeiting strategy must be a multi-layered approach”

- Secure:
  - product and packaging
  - movement of drugs through the supply chain
  - business transactions
- Ensure appropriate regulatory oversight and enforcement
- Increase penalties
- Heighten vigilance and awareness
- Increase International collaboration
Secure the movement of drugs through the supply chain

- **Pedigree** – documenting each sale or transaction of the product
  - Knowledge of:
    » Who had the product
    » When they had the product
    » How long they had the product
    » Who they bought it from
    » Who they sold it to
    » Other information…..

- **Universal and Uniform Pedigree** -- *ideal*
  - Identical format for all 50 states
  - Passed by all supply chain stakeholders

- **Electronic Pedigree** -- *ideal*
Regulatory Tools

- **Pedigree laws**
  - Federal law – Prescription Drug Marketing Act
    - Challenges in the current pedigree law
    - Not all transactions
    - Need new law for universal and uniform pedigree
    - Litigation – *RxUSA v HHS*
  - State laws
    - Florida
    - California

- **Food and Drug Administration Amendments Act of 2007 (FDAAA)**
  - Authority to develop standards for Drugs
  - Authority to develop standards for Unique Identifier for Devices
FDA Standards Development
(New section 505D of the Act)

- Secretary shall prioritize and develop standards for
  - Identification
  - Validation
  - Authentication
  - Tracking and Tracing

- Serialization standard development deadline: March 2010
Guidance for Industry:
Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages
(DRAFT GUIDANCE)
Proposed Standardized Numerical Identifier (SNI)
Serialized NDC

Example of a serialized National Drug Code (sNDC)

<table>
<thead>
<tr>
<th>NDC</th>
<th>SERIAL NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>55555 666 77</td>
<td>+ 11111111</td>
</tr>
</tbody>
</table>

Labeler code + product code + package code + unique 8 digits

- Expiration date and/or lot or batch number – not included
- No recommendation for data carrier
- Machine and human readable
- Compatible with GS1 serialized GTIN
SNI Draft Guidance -- 44 comments submitted

Submitters by Type

- Trade Associations: 20%
- Industry (Pharmaceutical): 21%
- HC/HC-related Services: 11%
- HC Professional Organization: 11%
- HC Professional: 2%
- Consumer/Consumer Org.: 2%
- Academia: 2%
- Wholesaler: 5%
- Other Organizations: 7%
- Regulator: 5%
- Repackager: 5%
- Technology Vendors: 9%
Other Standards Development Efforts

- **505D**: Track and Trace - Authentication - Validation
- **GS1 standards**
  - Global Traceability Standard for Healthcare
  - GS1 Healthcare US efforts
- **Consortiums**
FDA International cooperation

- World Health Organization’s International Medical Products Anti-Counterfeiting Task Force (IMPACT)
- China Memorandum of Agreement (MOA)
- Permanent Forum on International Pharmaceutical Crime (PFIPC)
- Bilateral and multilateral agreements
Additional Activities

- Guidance for anti-counterfeiting technologies
- Pending legislation
  - Buyer/Matheson bill
- FDA/Commerce Anti-Counterfeiting Working Group
- Prioritizing Resources and Organization for Intellectual Property Act of 2008
What’s next?

• Borders are expanding – will only grow and become more complex
• Need to stay vigilant – private and public sector
• Need to continue aggressive enforcement strategies….risk-based
• Find ways to leverage resources and trusted partners
• Move forward on developing identification/track and trace/validation/authentication standards
  – Implementation…….
COMMENTS OR QUESTIONS???

THANK YOU!!!!

Ilisa Bernstein, PharmD, JD
ilisa.bernstein@fda.hhs.gov
U.S. Food and Drug Administration