U.S. Food and Drug Administration
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Securing the pharmaceutical supply chain: U.S. FDA's efforts and perspectives

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FDA's New Campus

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 → 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

- Draft Guidance for Industry on Good Importer Practices published on January 13, 2009.
  - 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

- "Secure Supply Chain Pilot Program; Notice of Pilot" published in the Federal Register on January 15, 2009.
- 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

  Rx drugs
- 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)

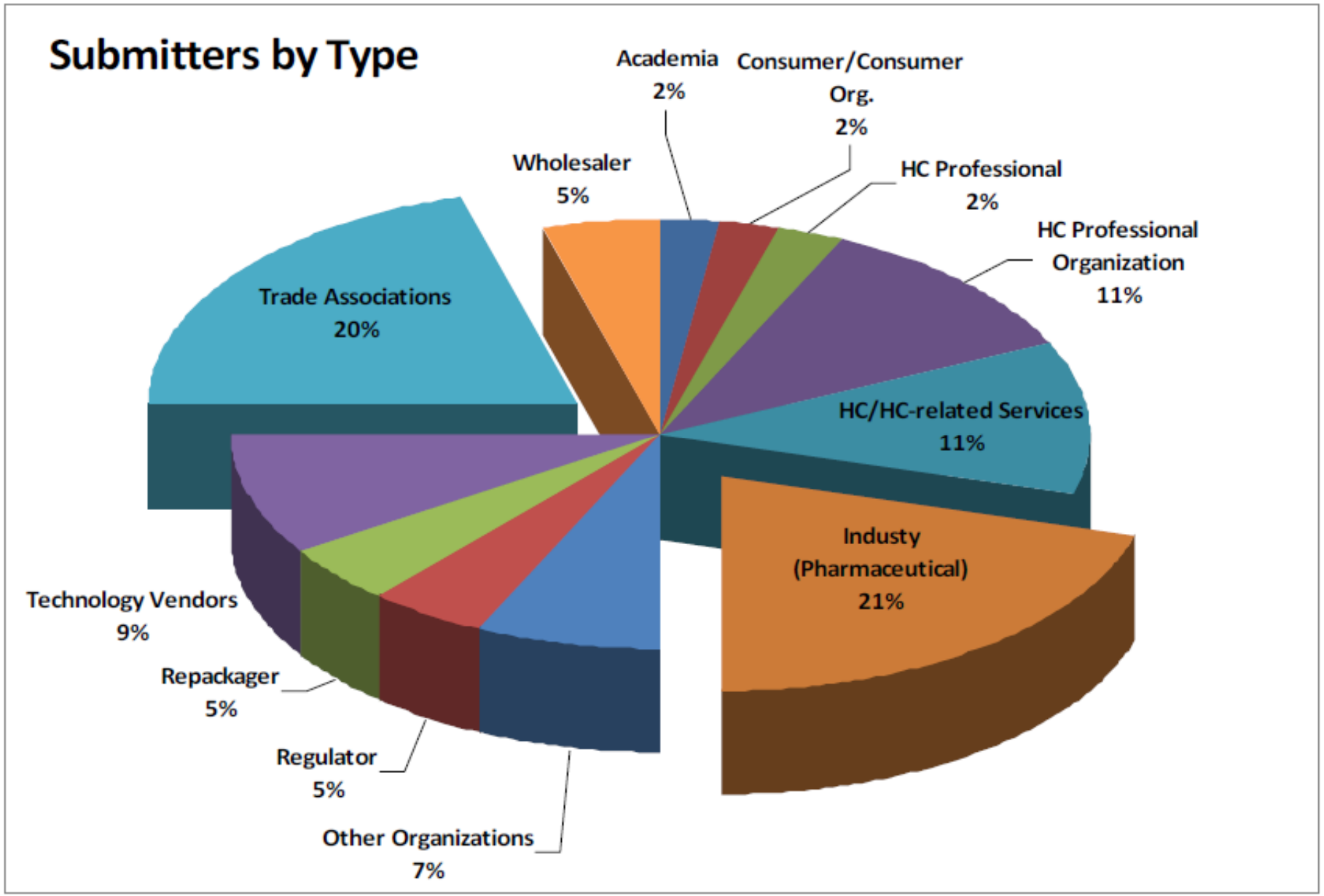
Serialized NDC

Example of a serialized National Drug Code (sNDC)

NDC		SERIAL NUMBER
55555 666 77	+	11111111
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



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!!!!

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