

#### **DSCSA Implementation**

Panel Discussion

Chaired by Mr. Scott Mooney, Vice President Distribution Operations - Supply Chain Assurance, McKesson Pharmaceutical

Mr. Christopher Reed, Global Operations Manager – GDSN, Johnson & Johnson Supply Chain

Mr. Thomas McHugh, Senior Strategeist Supply Chain & Technology, CVS Health

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# **DSCSA** Implementation

**Manufacturer Perspective** 

Christopher Reed Supply Chain Visibility October 2017

#### Johnson & Johnson

Global Presence

- Global Leader in Health Care
- More than 265 Operating Companies in 60 Countries
- Selling Products in More than 175 Countries



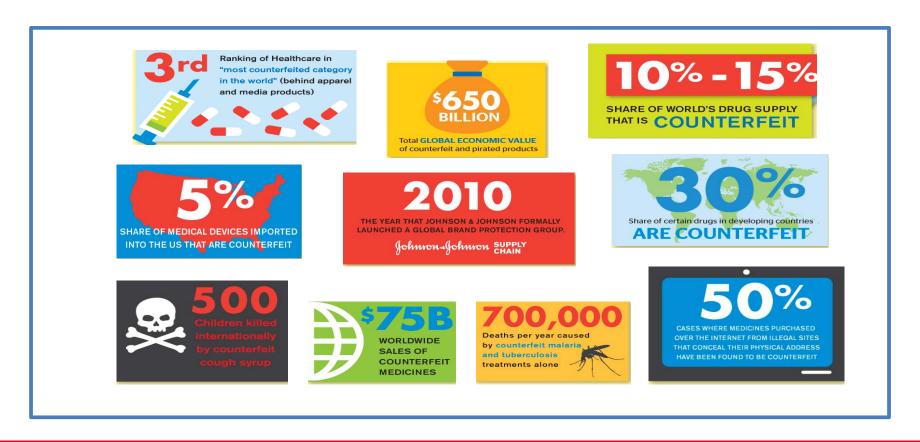
# Agenda

- Why Serialization?
- Effectively Operationalizing Your Serialization Program
- Challenges and Lessons Learned
- Next Steps and Interoperability

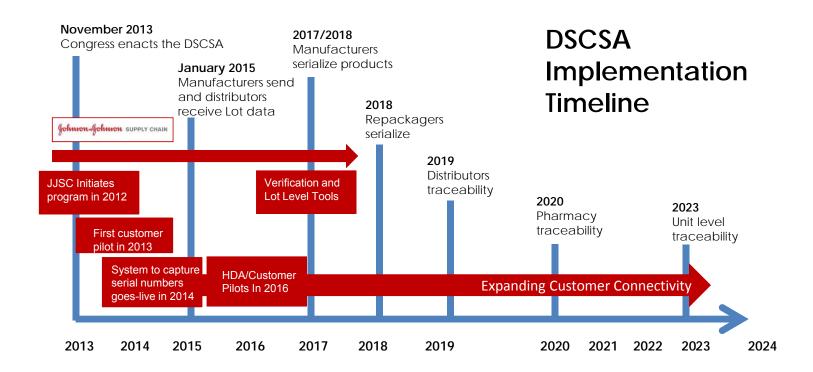


## Why Are We Serializing and Track & Tracing Our Products?

Counterfeit and diverted products are a global problem



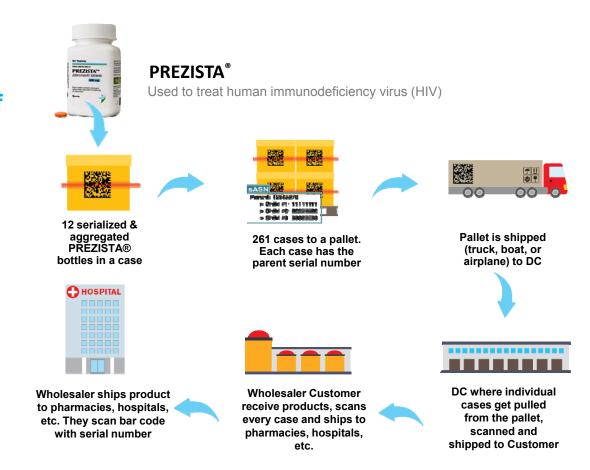
## **Timeline to Comply**



#### Supply Chain with Track & Trace

Regulatory mandates are demanding visibility of products from point of packaging to point of dispense

- Demand improved supply chain visibility
- What product?
- Where has it been?
- Where is it going?
- How long has it been there?
- What are the inventory levels?



### Effectively Operationalizing Your Serialization Program

The Johnson & Johnson Supply Chain Experience

#### Key Takeaways

- Regulations remain primary driver of serialization and traceability
- Interoperability relies on standards
- A multidisciplinary approach is a <u>must</u> have
- Workforce impact is significant
- Tremendous importance on master data and change management



### **Interoperability And Standards**

Development and adoption of standards are critical

#### Standards Must Enable These Capabilities



GTIN GLN SSCC



UPC / EAN
DATAMATRIX/BAR
EPC / RFID



GDSN EDI EPC / RFID

Source: GS1

### **Interoperability And Standards**

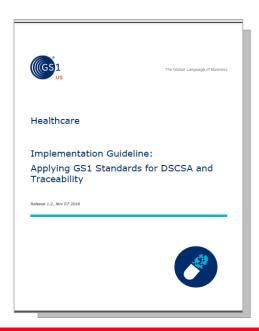
Development and adoption of standards are critical

# Internal/ External Standards and Guidelines are necessary to achieve and sustain end-to-end supply chain visibility









### Collaboration Identifies Additional Business Value Opportunities

- Strengthens supply chain integrity
- Higher fidelity visibility enables efficiency improvements
  - Reducing counts and checks
  - Reducing claims and credits
  - Enhancing returns verification
- Communal standardizing of "best practices"



#### CASE STUDY



AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings

#### CHALLENGE

The Food and Drug Administration (FDA) regulation requires that the pharmaceutical industry implement end-to-end tracability by 2023. Trading partners in the supply chain have chosen to implement and test GS1 Standards-based solutions in real-world pilots to meet the deadline for interoperability.

#### SOLUTION

While GSI Standards have created a hierarchy that reaches down to the product level for serialization, several industry entities have voluntarily chosen to use GSI EPCIS even as this standard evolves to fully meet the intent of the regulation. EPCIS allows trading partners to exchange data, in concert with the products as they move through the supply chain. An industry pilot between Johnson & Johnson Supply Chain (JISC) and AmeriscourceBergen Corporation (ABC) did ust that with actionable and repostable results.

#### BENEFITS

In addition to assuring compliance and continued product access for patients and customers, serialization can potentially enable the investigation of counterfeit and diverted products, affording brand owners additional supply chain integrity and security. End-to-end visibility means that recalls, where necessary, can be executed more efficiently. As the foundational standard, the Global Trade Item Number\* (GTIN\*) helps to automate all processes and minimize errors, ultimately increasing patient safety.

"The key to success in meeting any instance of regulatory compliance—really comes down to collaboration. It all rests on the willingness of our industry partners across the supply chain to work toward consensus and then drive to adoption. This pilot with JJSC has been a stunning example of true partnership as we move to establish a meaningful standard that serves our industry and protects patients."

- HEATHER ZENK, Vice President, Secure Supply Chain,

#### **Lessons Learned**

Organizing and sustaining a large, global initiative provides tremendous opportunities to learn and grow

- Agile
- Lead times
- Collaboration
- Communicate
- Utilization of partners
- Strategy and execution



#### 7 Billion Reasons to Care



Serialization and Traceability
Benefits Patients and Consumers Around the Globe



#### **Christopher Reed**

Supply Chain Visibility
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