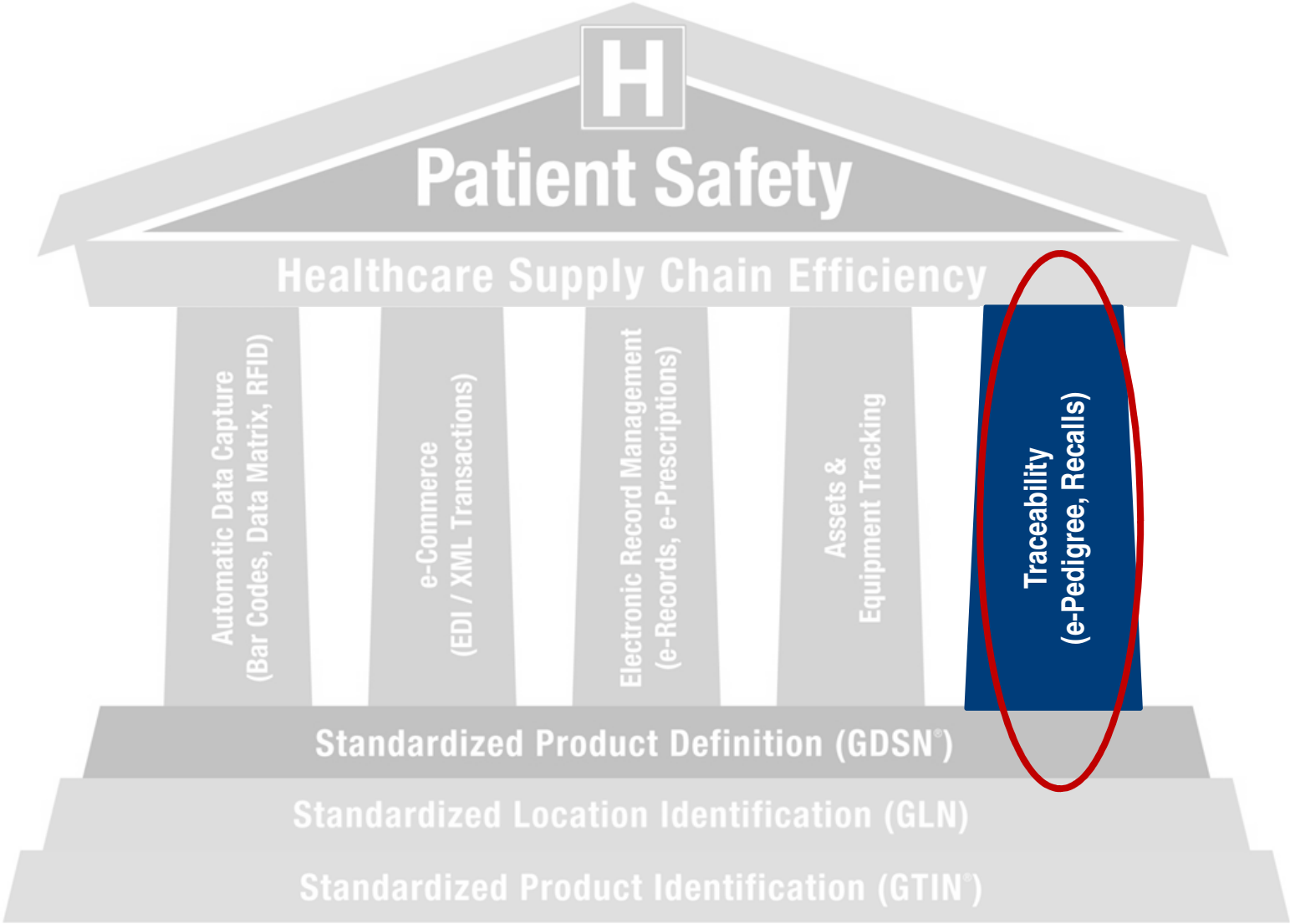


**“Building Patient Safety”**



Standardization → Interoperability

# Serializing and Tracking Products – 2015/2016 Manufacturer Perspective

*Johnson & Johnson*



**Mike Rose**  
**Vice President, Supply Chain Visibility**  
**Worldwide Supply Chain Group**

# Johnson & Johnson Anti-Counterfeiting Position

- **Our Credo responsibility**
- **Patients should receive genuine products**
- **Taking tangible steps**
- **Monitor markets**
- **Work with regulators to strengthen laws**

## Counterfeit Health Care Products . . . The Johnson & Johnson Position

At Johnson & Johnson we believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products. In today's global economy, where patients and consumers may be exposed to counterfeit products of all kinds, we must take tangible steps to ensure they receive the genuine products of the Johnson & Johnson family of companies.

Counterfeiting of health care products is a serious and growing concern because it can undermine confidence in product safety and effectiveness while putting people's health and lives at risk. Counterfeiting is a global problem and while difficult to quantify, the World Health Organization reports the incidence of counterfeiting is growing. Additionally, the United States based Center for Medicines in the Public Interest predicts that counterfeit drug sales alone will reach \$75 billion globally in 2010, an increase of more than 90% from 2005.

Johnson & Johnson companies take a variety of approaches to identify and mitigate the risks of counterfeit health care products. They include a range of product and packaging security measures that help distinguish the authentic product from a counterfeit, and aid in minimizing the potential for tampering. We are working to make improvements in the supply chain -- from sourcing of ingredients and manufacturing through distribution -- to help minimize the risk of counterfeit products entering the system.

We monitor markets and investigate counterfeiting activities. We collaborate with regulatory and law enforcement authorities, as well as our business partners, to locate and remove counterfeits from the market, seize and destroy the manufacturing equipment, and prosecute or take civil action against the perpetrators.

We work with governments and regulators to identify opportunities to strengthen laws and enforcement efforts in order to ensure the integrity of distribution channels. And, we are working to raise awareness of the dangers of counterfeit health care products and to educate stakeholders on the role they can play in helping to eliminate this illicit trade.

# Manufacturer Role 2015/2016 Compliance

- **Serialize product**
- **Ensure accuracy of serial number**
- **100% Readability of 2D data matrix, bar code, or RFID**
- **Retain database of valid serial numbers**
- **Initiate first step in tracking product**
- **Prepared to verify initial transaction**

# Key Considerations

- **Broad operational impact**
- **Evolving technology**
- **Limited practical experience**
- **Diverse products = complex manufacturing environments**
- **GMP compliance**
- **Coordination with external manufacturers as well as downstream supply chain stakeholders**
- **Defining industry wide interoperability**

# Regulatory Diversity

- **Italy**
- **California**
- **France**
- **Turkey**
- **Brazil**

# Other Potential Ancillary Benefit Areas

- **Returns**
- **Chargeback/Rebates**
- **Cold Chain Integrity**
- **Demand Signals**



*Johnson+Johnson*

# Worldwide Supply Chain

