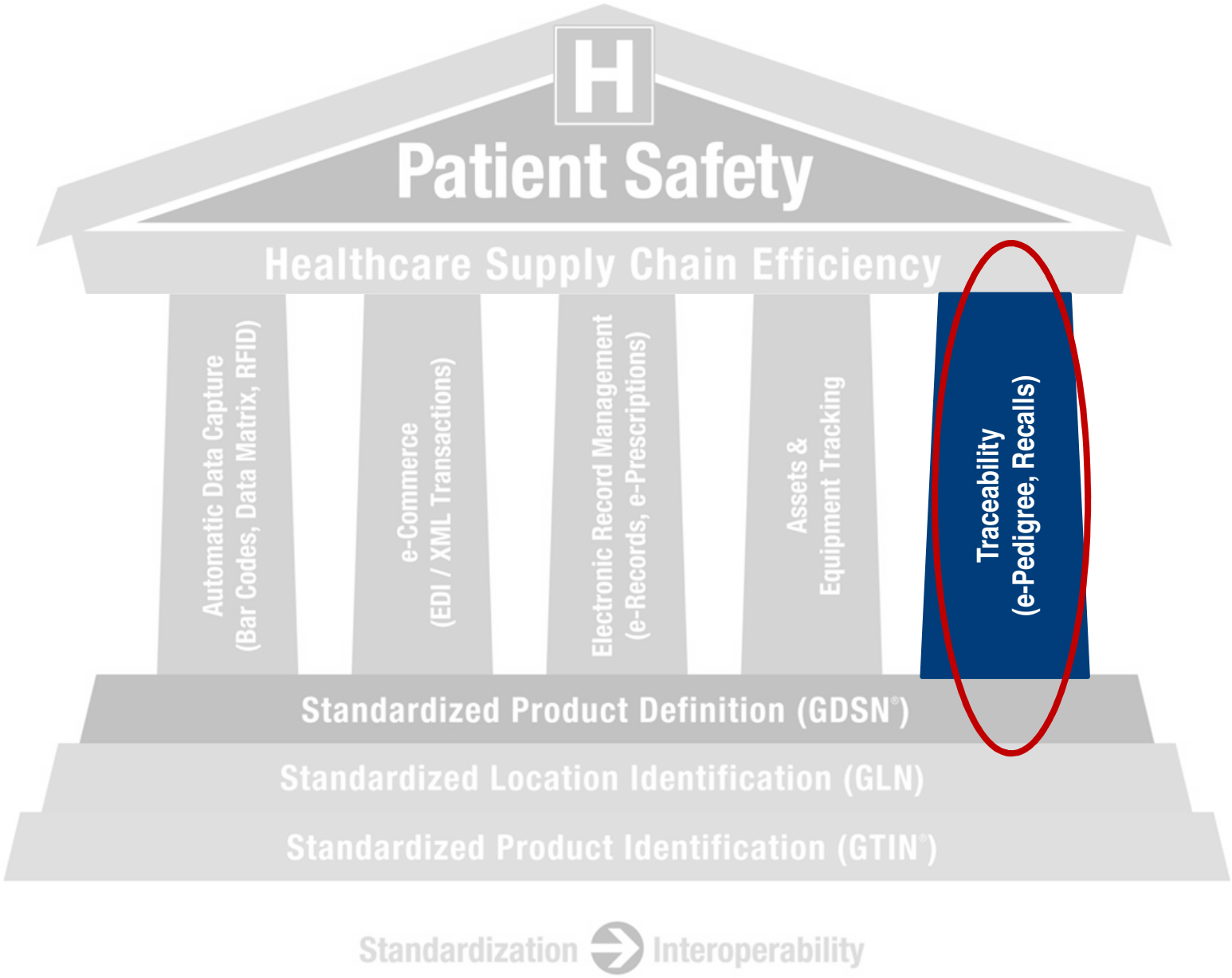
"Building Patient Safety"



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Tracking/Documenting Serialized Products & Achieving 2015 Compliance

Ronald Bone, SVP Distribution Support
McKesson Pharmaceutical Solutions

Supply Chain Integrity Is Critical

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- International legislative and regulatory agencies have concerns about the Pharmaceutical Supply Chain's ability to effectively protect products
  - Expiration Date Handling
  - Cold Chain Management
  - Returns Processing
  - Recall Management
  - Tainted Products (Counterfeit and Mislabeled)
- A single weak link in the supply chain means we ALL fail
- We need to be knowledgeable about the products we buy
- We need to have our electronic systems capture and validate the information, and provide actionable information to the staff
- As wholesalers, our greatest priority is the security of the supply chain

United States Federal ePedigree

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- U.S. Congressmen Buyer & Matheson introduced “Safeguarding America’s Pharmaceuticals Act,” to provide a uniform federal pedigree standard
- Key Provisions of the Bill:
  - Standard supply chain definitions across all states
  - Standard pedigree requirements
  - Standardized drug identifiers
  - High-risk drugs criteria
  - Report evaluating the feasibility and operational efficiencies of adopting security technologies
  - Preempts state laws on serialization and pedigree
- Outcome of this legislation is uncertain due to complexity of the bill and the timing; likely to be considered in 2009 or beyond

State of California ePedigree

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Implementation Dates

- From January 1, *2009*, to December 31, *2016*, inclusive, manufacturers, wholesalers, re-packagers and pharmacies shall initiate steps to accept and pass electronic pedigrees for all dangerous drugs, subject to the requirements

- All Manufacturers (branded and generic) must serialize 50% of their dangerous drugs by 2015, and the balance by 2016

- After July 1, 2016, wholesalers and re-packagers may not **sell**, **trade**, **transfer** or **receive** a dangerous drug without receiving and providing a pedigree

- After July 1, 2017, retailers may not **sell**, **trade** or **transfer** a dangerous drug at wholesale without providing a pedigree and may not **receive** a dangerous drug without a pedigree

Progress on Serialization / Pedigree

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- GS1 and EPCglobal developing the standard for serialization and pedigree
- FDA Amendments Act requires FDA to publish a serialization standard by March, 2010
- A small number of manufacturers in the US have moved forward with Serialization / Pedigree projects

Building Patient Safety

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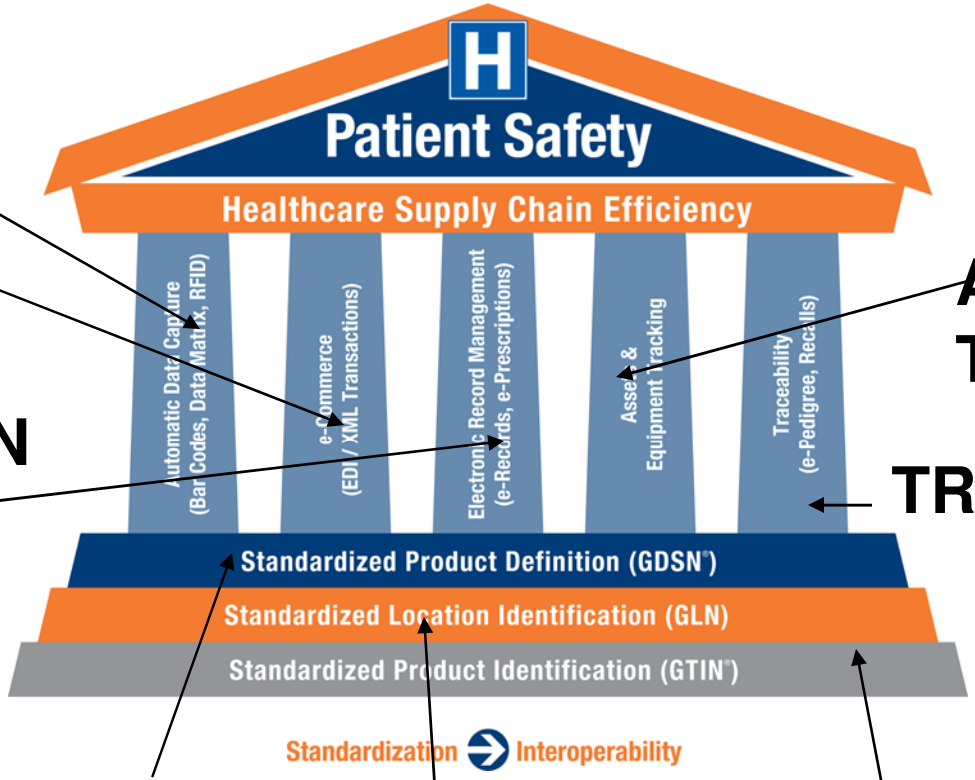
SCANNING

eCOMMERCE

ePRESCRIPTION

eRECORDS



ASSET TRACKING

TRACEABILITY

STANDARD DATA FORMAT

UNIQUE LOCATION ID

UNIQUE PRODUCT ID

The Wholesaler's Role

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- Gather the required data on the inbound shipment from the manufacturer
  - The critical new data element that we have not had before is a unique serial number at the lowest unit of sale.
- Verifying the electronic information received from the manufacturer against the physical product.
  - A new process of quarantining mismatching product is yet to be developed.
  - What are the ramifications to availability of drugs if 100% accuracy is not achieved?
- Picking units of products for the providers and retailers by serial number and commission a tote which connects the serialized units inside the tote with a serial number on the tote to enable quick check at the pharmacy.
  - What are the ramifications at the pharmacy site if this process has errors that need to be resolved before the product can be dispensed?