Health and Life Sciences (HLS) Industry Adoption Roadmap HLS and HUG Joint Meeting June 6, 2007

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Industry Adoption Communication Plan

Purpose of the Communication Plan

The EPCglobal Health and Life Sciences (HLS) Industry Adoption Task Force (IATF) is committed to sharing guidance from its "Industry Adoption Roadmap" with key stakeholders for the purpose of enhancing supply chain security and promoting common approaches to the unique identification of pharmaceutical products, data carrier selection and electronic pedigree deployment

Industry Adoption Communication Plan

Through a series of face-to-face meetings, Industry Adoption Task Force (IATF) members will share the Roadmap content with target audiences and solicit feedback

It is expected these face-to-face meetings will also help the Team to gauge receptivity and understand the broader industry perspective on the issues of serialization and electronic pedigree implementation. Feedback will be shared with the IATF

Industry Adoption Key Messages

- Serialization
  - Standard numbering schemas are essential to uniquely identify pharmaceutical products, maintain supply chain efficiency and promote widespread industry adoption/utilization
  - EPCglobal and GS1 are working to develop global standard numbering schemas
  - Outstanding issues remain regarding privacy and the inclusion of product identifying information in the Electronic Product Code (EPC)
- Data Carriers
  - Multiple data carriers (2D bar codes, RFID, etc) are likely to coexist for several years
  - Alignment around the type of data carriers to be used will facilitate channel security and encourage adoption

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Industry Adoption Key Messages

- Pedigree
  - Regulatory requirements exist today
  - The Pedigree Messaging Standard has been ratified by EPCglobal
  - Other standards are in development
  - It is important for individual companies to begin now to develop plans to comply with current and emerging regulatory requirements
- Standards, Industry Alignment and Collaboration
  - All are essential to promote widespread adoption of serialization, common data carriers and interoperable pedigree solutions while maintaining supply chain efficiency

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Industry Adoption
Sample of 80+ Task Force Members

- **Manufacturers**
  - Abbott Labs, Alcon, Allergan, AstraZeneca, Bristol Meyers Squibb, Dow, Genzyme, GSK, J&J, Merck & Co, Pfizer, Proctor & Gamble, Wyeth
- **Wholesale Distributors**
  - AmerisourceBergen, Cardinal, McKesson
- **Retailers**
  - Albertson's, CVS, Target, Walgreen Co, Ahold
- **Regulators, Trade Associations, and Others**
  - FDA, EPCglobal, GS1 Global and MO's, HDMA, NACDS, NCPA, MIT Auto-ID Labs

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Many thanks to Peggy Staver (Pfizer) and Laura Osburnsen (Unisys) for their work in crafting this communications outreach presentation

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HLS Industry Adoption Roadmap

HLS / HUG Joint Meeting
June 6, 2007

Communication Deck V2

(based on Interim Draft v9.0

[changes and new material for discussion in green text]

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Disclaimer

- Supply chain participants should rely upon their companies' legal interpretations of regulatory requirements.
  - The Industry Adoption Task Force does not interpret legislation nor recommend compliance postures.
  - Guidance presented in the Roadmap and associated documents is designed to provide a starting point for industry collaboration to drive towards common solutions.
  - Guidance and/or other team deliverables are not to be considered as legal advice and are not intended to substitute for competent legal counsel.

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Outline

- Purpose of the Roadmap
- Scope of the Roadmap
- Capabilities, Guidance and Rationale
  a. Unique Identification
  b. Pedigree
- Standards Progress and Other Resources
- Action Steps
- Summary and Recommendations
- Appendices

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Purpose of the Roadmap

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Purpose of The Roadmap

- The Roadmap provides guidance in meeting current and emerging regulatory expectations, including the direction outlined by the FDA's *"Counterfeit Drug Task Force Report: 2006 Update"*, the California Pedigree Law (SB1476), and Federal PDMA law.
  - Pedigree and Unique Identification, deployed in a coordinated manner, are two Key Capabilities which can advance the industry towards improvements in the safety and security of the supply chain.
- Serves as a starting point for broader discussions within the context of industry trade associations.
- Documents the best ideas from the Industry Adoption Task Force, composed of a cross-section of knowledgeable industry representatives.
- Describes the thought process and rationale of the Industry Adoption Task Force in arriving at the various guidance elements.

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Purpose of The Roadmap

- The Health and Life Sciences (HLS) industry shares the vision of a ‘safe and secure drug supply chain’ premised on transparency and accountability by all persons who handle the prescription drug, starting with the manufacturer and ending with the pharmacy or other healthcare points of dispense, including both forward- and reverse-logistics transactions.
  - Simply issuing a Pedigree or Uniquely Identifying a product alone does not improve safety nor security. The “coordinated exchange” of uniquely identified products using the concept of pedigree transactions can result in improved supply chain safety and security.
  - The Roadmap is constructed to balance the perceived risks and benefits. This balancing is needed to lessen the impact of incremental costs on the continued availability of affordable healthcare while still achieving the goal of ‘a safe and secure supply chain’.

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Scope of the Roadmap

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Scope of The Roadmap

- Addresses two Key Capabilities:
  - Unique Identification, including,
    - Serialization
    - Data Carriers for Serialization
      - RFID
      - Barcodes
  - Pedigree, which includes the secure exchange of product transactional information between trading partners using an interoperable electronic system.

- Presents Guidance, Action Steps, and Issues/Barriers and Assumptions as a starting point for industry trade associations.

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Scope of The Roadmap

- Applies to HLS supply chains and participants.
  - Focus on US Rx drug supply chains and products:
    - Most urgent compliance requirements and dates.
    - California represents the most stringent set of requirements.
  - Designed with flexibility to address other HLS products and geographic regions as future requirements arise.
  - Adapts and leverages existing GS1 and EPCglobal standards and guidance from HDMA publications.
  - A comprehensive list of key sources is included in the Appendix.

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Capabilities, Guidance and Rationale: Unique Identification

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Capability: Unique Identification
(excerpted from SB1476)

Note: California law defines 'dangerous drug' as a "drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006". [Section 4022]

- [Section 4034(d)] "A pedigree shall track each dangerous drug at the **smallest package or immediate container** distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug."
  - Capability needed: identify the prescription drug at the Item level as defined in California law.
- [Section 4034(i)] "…uses a ***unique identification number,*** *e*stablished at the ***point of manufacture****…that is* ***uniformly used*** by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug."
  - Capabilities needed: assign a unique identification number at point of manufacture; uniformly use that unique identification number throughout the supply chain.

Ref: http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_1451-1500/sb_1476_bill_20060929_chaptered.pdf or http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

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Guidance: Unique Identification
Serialization

- Uniquely Identify – Pallets, Totes, Cases, Items.
- Unique Identification should be based on Serialization.
  - Use current GS1 and EPCglobal serialization schemes for the chosen data carrier.
  - Synchronize serial numbers used on Primary and Backup data carriers:
    - SSCC: serial number ranges are the same for both Barcode and RFID.
    - SGTIN: serial number range for AI(21) when used as backup for SGTIN-96 should be limited to same range as SGTIN-96.
  - Avoid encoding of Lot Code and/or Expiry Date as an integral part of the serial number; instead, encode this data into RFID User Memory and/or into barcode Application Identifiers designed for this purpose.
- Include backup human-readable text per GS1 standards.
- Continue to partner with GS1 Serialization Team to define global solutions to meet varying serialization challenges.

Draft: Pending GS1 Serialization Team Recommendation

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Guidance: Unique Identification
Serialization

- Use EPCglobal, GS1, HDMA standards and guidelines as primary guidance.
  - Follow current GS1 and EPCglobal standards for use and/or re-use of serial numbers (standards for SSCC, SGTIN, AI(21) Serial Numbers).
  - Companies choosing to use other standards should be prepared to work with their trading partners to assure interoperability.
- See Appendices for additional guidance on special-interest serialization topics:
  - Serialized Inference

    Guidance for inferring reads when less than 100% of data carriers are read.
  - NDC Masking

    Guidance for omitting the Item Reference portion of the NDC from RFID tags to avoid divulging product number for products with patient privacy concerns.
  - Barcode and RFID Co-Existence

    Guidance for ensuring synchronization of serial numbers for primary and backup data carriers when using RFID and Barcodes.

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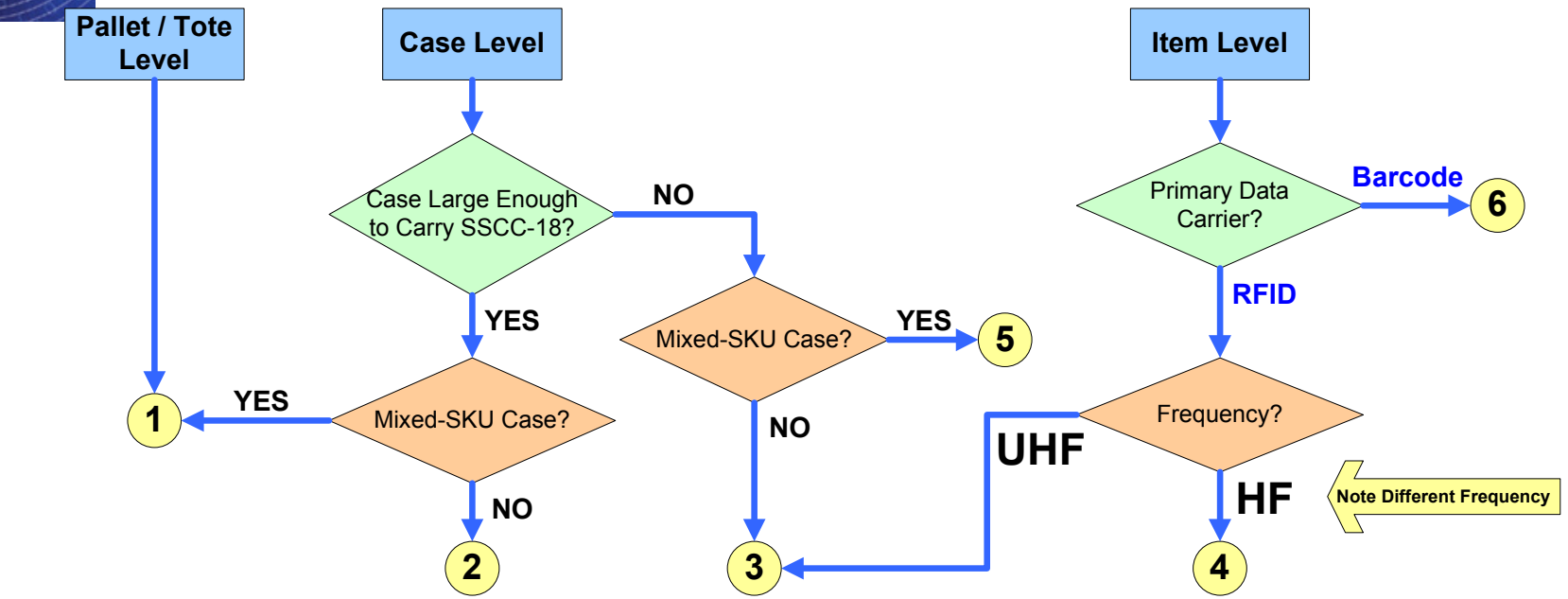
Guidance: Unique Identification
Data Carriers for Serialization



Use Cases: Data Carriers for Serialization

	1	2	3	4	5	6
Primary Data Carrier	**RFID UHF Gen2** -SSCC-96 data encoded	**RFID UHF Gen2** -SGTIN-96 data encoded	**RFID UHF Gen2** -SGTIN-96 data encoded -NDC Present or Masked (Item)	**RFID HF Version2** -SGTIN-96 data encoded -NDC Present or Masked (Item)	**RFID UHF Gen2** -SSCC-96 data encoded	**2-D Data Matrix** -ECC200 format -AI(01) + AI(21) data encoded
Backup Data Carrier	**GS1 Code 128** -AI(00)SSCC-18 data encoded -Human-Readable AI(00) text	**GS1 Code 128** -AI(01) + AI(21) data encoded -Human-Readable AI(01) + AI(21)	**2-D Data Matrix** -ECC200 format -AI(01) + AI(21) data encoded -Human-Readable AI(01) + AI(21)	**2-D Data Matrix** -ECC200 format -AI(01) + AI(21) data encoded -Human-Readable AI(01) + AI(21)	**2-D Data Matrix** -ECC200 format -AI(00)SSCC-18 data encoded -Human-Readable AI(00) text	**Text Backup** -Human-Readable AI(01) + AI(21)

Draft: Pending GS1 Serialization Team Recommendation

Capabilities, Guidance and Rationale: Pedigree

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Capability: Pedigree
(paraphrased from SB1476)

Summary of key language; NOT to be used as a substitute for the actual legislation.

- Means a Record, in Electronic Form,
  - Containing information regarding each transaction
  - Resulting in a change in ownership
  - From sale by manufacturer until final sale to a pharmacy or other dispense point.
  - Includes all information required by law
- Created / Maintained in an Interoperable Electronic System
  - Contained within a standardized non-proprietary data format and architecture
  - Uniformly used by manufacturers, wholesalers, pharmacies for the pedigree
  - Ensuring compatibility throughout all stages of distribution
- Tracked at the Smallest Packaging Level *(see Serialization Guidance)*
- Certifying that the Pedigree Information is True and Correct
  - From a Responsible Party of the source
  - Under penalty of perjury
- Returns documented on same Pedigree as the receipt transaction

Ref: http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_1451-1500/sb_1476_bill_20060929_chaptered.pdf
or http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf

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Guidance: Pedigree

- Currently there are two Options to provide a Pedigree:
  - **Option 1 – *Drug Pedigree Standard***
  - **Option 2 –*Track and Trace***
- Option 1: Drug Pedigree Standard is available now.
- Option 2: Track and Trace in Requirements phase now. Standards will follow at a later date.
- Further guidance for choosing an Option cannot be provided until the following is completed for Option 2:
  - Requirements
  - Standards
  - Software designed and available which meets Standards

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Rationale: Pedigree

At this time, the California Board of Pharmacy has no preference for either Option presented below, and the use of the terms 'track and trace' in the California SB1476 legislation is not intended to emphasize or endorse any particular option or technology.
[Feedback from EPCglobal Pedigree Meeting with California Board of Pharmacy, Mar. 8, 2007]

- Option 1 (Drug Pedigree Standard)
  - The California Board of Pharmacy believes the standard meets California's electronic pedigree requirements.
  - However, additional work and amplification need to be done by the California BOP and Industry.
  - In some cases, California regulations may be necessary to provide the necessary amplification.
- Option 2 (Track and Trace)
  - Being designed with flexibility to accommodate known requirements from California and other jurisdictions.
  - As with Option 1, additional work and amplification may need to be done by the California BOP, other jurisdictions, and Industry. In some cases regulations may be necessary to provide the necessary amplification.

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Rationale: Pedigree

- Interoperability between systems based on Option 1 or Option 2 must be addressed to prevent supply chain and pedigree disruptions.
  - It is likely that both Options 1 and 2 will co-exist within the supply chain.
  - Therefore, any pedigree initiated under either Option must be interoperable with both Options for forward- and reverse-logistics.
  - The EPCglobal Track and Trace Interest Group and the Supply Chain Integrity Joint Requirements Group are tasked with documenting these requirements for inclusion into:
    - A future revision of the Drug Pedigree Standard, and
    - The current requirements documents for the HLS Track and Trace Interest Group, and
    - Future standards developed for Track and Trace

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Action Steps

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Action Steps

Typical Activities For All Trading Partners

- Engage with your Industry Trade Associations to ensure you have the most current information regarding policy and positions.
- Work with EPCglobal and GS1 groups to obtain standards, education, and to learn from others.
- Choose Serialization data carriers for every packaging level. (see Slide 27)
- Choose Pedigree Option and software. (see Slide 35)
- Develop scale-up and rollout-plans for Serialization and Pedigree (e.g., based on SKU counts or geographical rollout).
- Work with all affected trading partners with sufficient leadtime on Serialization and Pedigree choices and options to facilitate efficient supply chain operations.
  - See EPCglobal Public Policy Guidelines for Healthcare Industry.
- Convert operations to apply and aggregate serial numbers.

Action Steps

Typical Activities For All Trading Partners

- Develop, implement, and adhere to effective Privacy standards to ensure appropriate use of these technologies.
- Install capability to transact serial numbers and serialized pedigrees—based on specific local regulatory requirements.
- Test serialized pedigree + serialized product final configurations with trading partners.
- Start shipping serialized and pedigreed products.
  - Pallet, Tote, Case, Item Serialization.
  - Transact a manufacturer-initiated pedigree.
  - With sufficient lead time to load the supply chain with serialized products supported by a pedigree.
- Execute your Scale-Up / Rollout Plans.
- Retain Pedigree data according to regulatory data retention requirements.
- Respond to requests for verification of Pedigree data.

Summary and Recommendations

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Summary

- The Industry Adoption Task Force has taken the lead in synthesizing available material into a coherent, forward-looking Roadmap which can be used by industry trade associations as a starting point in their discussions with their members.
- The Roadmap describes Guidance to meet the two Key Capabilities in a balanced yet effective manner.
  - Pedigree
  - Unique Identification
- The Roadmap provides direction to help reconcile the varied interests of the diverse set of stakeholders toward common solutions.
- Providing trading partners with agreed-upon standards and guidance reduces complexity, barriers to adoption, and lowers overall costs for all participants.

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