Ghada Askhar, PharmD and Ben Taylor have no real or apparent conflicts of interest to report.
TRADING PARTNER AUTHENTICATION AND DRUG VERIFICATION IN THE PHARMACEUTICAL SUPPLY CHAIN

Agenda

• Introductions
• Challenges for pharmacists
• DSCSA & GS1
• FDA BRUINchain Pilot
• XATP Identity Pilot
Learning Objectives

• Identify the challenges for pharmaceutical supply chain stakeholders in ensuring their trading partners' authorized status for transactions and mandated information disclosures

• Evaluate the study team's methodology, results, and conclusions in testing enhanced verification workflows

• Discuss standards and workflow requirements for interoperability between ATPs
Meet Our Speakers
Meet Our Speakers

Ghada Ashkar, PharmD
Interstitial Chief Pharmacy Officer / Director of Ambulatory Pharmacy

Ben Taylor
CEO
UCLA Health

- More than 670,000 unique patients per year
- 2.8 million outpatient clinic visits
- More than 73,000 emergency department visits
- 36,000 hospital stays
- 3,200 total faculty
  - 3,050 clinical faculty
  - 150 basic science faculty
- 1,300 residents and fellows
- 3,800 registered nurses
- 32,200 employees
LedgerDomain

- Founded in 2016 to create content-rich collaborative healthcare applications backed by secure decentralized technologies.
UCLA Health & LedgerDomain Partnership

2018
Clinical Supply Blockchain Working Group

2019
FDA DSCSA pilot project BRUINchain (real-time tracking and drug verification)

2020
XATP production (dispensers and manufacturers together defining compliance)

2021
Clinical Supply Blockchain Working Group

2022
XATP pilot study (KYC authentication & interoperability)

2023
Exploring opportunities for UCLA Health to reduce waste, enhance patient outcomes, and work directly with manufacturers.
How can we ensure that pharmacists are not pulled away from important clinical work to complete technical processes?
Challenges for Pharmacists

**Human factors**
- Lack of consistent staffing guidelines for health system pharmacies in the industry
- Unforeseen staffing issues/ sick calls, LOAs, FMLAs, etc.
- Human error
- Communication issues

**Technical & EMR limitations**
- Rx transcribing errors / dosing errors / DUR errors
- Filling station – Wrong drug in vial error
- Verification – Last step before dispensing
- Dispensing / distribution to patient – accurate and timely delivery

**Distribution issues**
- Wrong patient
- Wrong address
- Shipping carrier reliability
- Cold chain maintenance
- Timing of deliveries
- Cost per package

**Supply chain issues/Formulary issues**
- Inventory management (lack of automation/340B)
- Supply and demand
- Price variations and reimbursement
- Formulary limitations
- Substitution errors
- Short dated inventory
- Recall pulls
What is DSCSA?

- Drug Supply Chain Security Act (2013) imposes requirements for an interoperable system that will track the vast majority of prescription drugs through the US by 2023.

- Requirements include:
  - Packages serialized with barcodes
  - Enhanced verification
  - “Know your customer” for all Authorized Trading Partners (ATPs)
  - FDA encouraged LedgerDomain & UCLA to help dispense community meet this challenge

**DSCSA Timeline**

<table>
<thead>
<tr>
<th>Year</th>
<th>Key Event</th>
</tr>
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<tbody>
<tr>
<td>2013</td>
<td>DSCSA Enacted</td>
</tr>
<tr>
<td>2014</td>
<td>Repackers associate &amp; verify SAs</td>
</tr>
<tr>
<td>2015</td>
<td>FDA to issue; Licensing standards for 3PLs; Guidelines on processes for warnings, exceptions &amp; exemptions; Final guidance on grandfathering product</td>
</tr>
<tr>
<td>2016</td>
<td>Repackers associate &amp; verify SAs</td>
</tr>
<tr>
<td>2017</td>
<td>Manufacturers verify SAs; DSCSA requirements effective</td>
</tr>
<tr>
<td>2018</td>
<td>Repackers associate &amp; verify SAs</td>
</tr>
<tr>
<td>2019</td>
<td>Repackers associate &amp; verify SAs</td>
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<tr>
<td>2020</td>
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<td>Repackers associate &amp; verify SAs</td>
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<tr>
<td>2023</td>
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</tr>
</tbody>
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Image courtesy of SlideCraft
Common Data Model

- DSCSA: prescription drugs required to have **standardized unique identifiers in the form of 2D barcodes**
- GS1 leading standard
- Barcodes serve as the foundational information building block for a **common data model**

```
NDC: 64406-058-01
SN: 10000000000001
EXP: JAN 31 2021
Lot: 123456
```
Last Mile DSCSA “Sad Paths”
FDA Pilot Learnings & Outcomes (2019)

- GS1 barcode scanning nearly 100% effective with commercial off-the-shelf iPhone
- Drugs can be tracked to the “refrigerator” level within a dispensing pharmacy (not just ownership, but physical custody)
- Tracked expiration dates, verified barcodes, inspected for problems
- Tracing and verifying by interoperating with upstream relational databases
- Automatic removal of double-counts and flagging suspect transactions
- Notify colleagues about availability and verification in real-time
The Missing Piece: Identity

Authorized Trading Partners (ATPs)

Under DSCSA, tens of thousands of ATPs are responsible for authenticating each other’s identities before they can transact with one another. To address this challenge, we developed and tested XATP, a framework for ATP authentication, verification routing, and saleable returns documentation.
Trading Partner Authentication and Drug Verification in the Pharmaceutical Supply Chain

XATP Working Group & Pilot

Working Group (Fall 2020)

- **Amgen**: Natalie Helms, Alina Grigorian, Nikhil Vinnakota
- **Genentech**: Nirmal Annamreddy, Kathy Daniusis, Mark Karhoff, Vid Rajaram
- **IQVIA**: Greg Plante
- **LedgerDomain**: William Chien, PharmD, Will Jack, Ben Taylor
- **Providence Health**: Todd Barrett, RPh
- **Sanofi**: Arthi Nagaraj, Josenor de Jesus, PharmD, Ghada Ashkar, PharmD, Kalpan Patel, PharmD

Pilot Group (Jan 2021)

- **Amgen**: Natalie Helms, Alina Grigorian, Nikhil Vinnakota
- **Genentech**: Nirmal Annamreddy, Kathy Daniusis, Mark Karhoff, Vid Rajaram
- **Sanofi**: Arthi Nagaraj
- **UCLA Health**: Josenor de Jesus, PharmD, Ghada Ashkar, PharmD, Kalpan Patel, PharmD

Acknowledgements: Jose Arieta (formerly HHS); Paul Hackett (Accenture); Alan Lodder, RPh (formerly Intermountain); Mike Karhoff (Ten Count Consulting); Mike Marchant (UC Davis); and Jen Colon, PharmD (Yale). Participation implies no obligation nor endorsement. All intellectual property remains the property of respective owners.
Verifiable Credentialing for ATPs

TRADING PARTNER AUTHENTICATION AND DRUG VERIFICATION IN THE PHARMACEUTICAL SUPPLY CHAIN
The Dispenser View

- **Recalled and expired drug packages intercepted** with iPhone barcode scans
- **Rapid scanning mode** for bulk processing
- **Fast and secure verification** for any drug in the US, preventing counterfeit drugs from reaching patients
The Manufacturer View

- **Interoperability on day zero** - human-in-the-loop supported by verifiable credentials and secure web endpoints

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You've received a drug verification request from Chadha Ankar at UCLA Health.

This is an official request for drug verification under the DACsIA from an authorized trading partner to possession or control of the drug package below. Please respond within 24 hours if you’re a manufacturer or repacker and want to know more about this email, please contact us at info@dtg vendors.org.

**Request from:**
Chadha Ankar
UCLA Health

**License No:** PHE 40971
**Verifiable credentials:** verifyxatp.org
**Purposes of Request:** Pre-Agreement for Stable Bonan
**Tuesday, 16 May 2023 16:34-43 UTC**

**Drug:** Oseltamivir Phosphate
**NDC:** 0999-8180-66
**GTIN:** 10500000305843
**SN:** 052209847272
**Lot:** FLH24X
**Expiration:** 10/30/2023

This document was produced by an Authorized Trading Partner (ATP) under the US Drug Supply Chain Security Act (DSCSA) using the XATP system powered by LedgerDomain, which makes drug verification under the DSCSA faster, easier, and more secure. This is not an advertisement. If you are not an ATP recognized under US federal law, please discard this email and report to info@dtg vendors.org. By clicking the first button, you verify that the drug information is valid. By clicking the second button, you will send the pharmacist a notification to quarantine the drug, pending further action. Learn more at xatp.org.

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Please confirm your selection by clicking the button below:

**YES, this drug is VERIFIED**

If you feel you reached this page in error, or you want to change to NOT VERIFIED, please return to the email and adjust your selection.

By clicking the button above, you verify that the drug information indicated in the email is valid in compliance with DCSA requirements. Learn more at xatp.org. If you have any questions, please contact admin@xatp.org.
Third Party View

- **Product verification certificates** support saleable returns and custody transfers
- Originating ATP generates verification certificate, receiving ATP only needs paper/web
TRADING PARTNER AUTHENTICATION AND DRUG VERIFICATION IN THE PHARMACEUTICAL SUPPLY CHAIN

Architecture

- **KEY GENERATION**
  - on User Device

- **SYS ADMIN**
  - DevOps / Monitor

- **GOVERNANCE**
  - Root-of-Trust

- **XATP**

- **SELVEDGE APP SERVER**
  - KitChain Server
  - DocuSeal SDK
  - OracleDK Configuration
  - Selvedge SDK
  - goHFC SDK

- **FABRIC CA**
  - Certificate
  - Trusted Triangle
  - Revocation
  - Management

- **XATP Smart Contracts**
  - Membership
  - Transactions
  - Consensus
  - Blockchain

- **MASTER DATA**
  - 240,000 Packages
  - Recalls / Med Guides

- **DOCUSEAL OFF-CHAIN**
  - PRIVATE DATA

- **3RD PARTY**
  - ACCREDITATION
TRADING PARTNER AUTHENTICATION AND DRUG VERIFICATION IN THE PHARMACEUTICAL SUPPLY CHAIN

**XATP 2020 Pilot → 2021 Test → Controlled Release**

- Pharmacist-in-Charge can register their pharmacy as ATP & form workgroup
- Tested genuine drugs and synthetic recalls at UCLA Health
- Coalition of stakeholders including Genentech, Amgen and Sanofi
- Synthetic recalls and expired drug packages flagged by barcode scanning
- Rapid scanning mode for inventorying multiple totes
- Fast and secure verification routing with verifiable credentials
- Master data: recalls, extended expirations & med guides for >200,000 packages
- >100 transactions/second on a single server
- “Day zero” interoperability for most drug packages
Peer Review Study

- Published in the peer review journal Blockchain in Healthcare Today
  https://doi.org/10.30953/bhty.v4.168
TRADING PARTNER AUTHENTICATION AND DRUG VERIFICATION IN THE PHARMACEUTICAL SUPPLY CHAIN

Future Implications

- Better patient outcomes
- Workflow and efficiency enhancements
- Drug shortage mitigation
- Recalled and expired drugs removed from supply
- Supply chain transparency
- DSCSA compliance
- Identity management for personalized medicine and cell & gene therapies

With collaborative technologies and common standards, pharmacists can focus on clinical activities and delivering better patient outcomes
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Questions?

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UCLA Health
LedgerDomain