Health Care Logistics: an Enabler of Change

BioLogistics in a Changing Healthcare World
Northwestern University Transportation Center

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April 20, 2016
Health Care is Transforming

Tremendous growth in medical innovation

Health Care costs based on quality, not quantity

FDA focus on traceability and expanded compliance

Expanding points of care: driven by cost, innovation, and consumerism

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## The Basics

### Specialty Drugs
- Treatment of complex, chronic, and/or rare conditions, e.g. cancer, Hep C, HIV
- High cost, $10,000- $100,000 annually
- Mostly injected, but oral is on the rise
- Biologics are Specialty drugs
- Available through exclusive, restricted, or limited distribution
- Ongoing monitoring and patient management for safety and/or efficacy
- Specialty drugs generated $150B in ‘15; projected at 50% of total scripts by ‘18
- Advertised Brands: Avastin (Cancer), Harvoni (Hep C), Abilify (Depression)

### Biologics
- Protein-based biologics include vaccines, blood and blood derivatives, allergens, gene therapy, living cells and tissues, and more
- Biologics require cold-chain
- Many lose their efficacy within hours if removed from conditioned space
- In 2018, biologics will account for nearly 50% of the 100 top-selling medications
- Advertised Brands: Humira (RA), Enbrel, (RA, Psoriasis), Neupogen (Cancer)

Sources: IMS Health and American Pharmacist Association
Biologistics is the management of the safe flow of high value, temperature sensitive and time-critical biological materials as they are:

- delivered for patient care
- analyzed for diagnostic purposes
- processed to higher value products
- stored to meet physical and data archival needs

Their composition makes it necessary to:

- use aseptic manufacturing principles
- have source-to-dispensing control over the measurement, monitoring and reporting of temperature, humidity, and vibration

...any deviations may put drug consumers at risk for adverse consequences
2,320 Novel products in late stage reviews, many with superior clinical trial efficacies

The supply chain plays a critical role in supporting in large, multi-month clinical trials

Sources: IMS Health
### Biologics Driving M&A

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Cost Reduction

- Capped reimbursement reinforces quality focus, and penalizes waste, redundancy, and errors
- While biologics are expensive compared to conventional drugs, they also hold promise of lower total patient cost due to better efficacy
- When choosing Cold Chain Partners, look for:
  - Strategic-minded partners - solution focus vs. product focus
  - Compliance-savvy, understand tolerances, risk and quality plans
  - Full Service - can handle the breadth of a manufacturer’s temperature, humidity, vibration, and shock requirements
  - Network locations and partners in key markets who can service patients 24 X 7
Currently, Specialty Distributors, Pharmacies, and Clinics are used for the distribution, and administration of biologics.

Requires full service, “white glove” handling and last mile delivery within small delivery windows.
Industry coalition formed in 2013 (PDSA) to advocate for uniform state licensing and better security for products in the US supply chain.

DSCSA was enacted (Nov ‘14) to accomplish the above as part of a total program to minimize fraud, adulteration, theft and diversion of pharmaceuticals...and biologics... in the US.

- Lot/batch level tracking; serial # provided on labels, but not tracked
- Information exchanged upon change of ownership
- Uniform Federal licensing for all stakeholders in the Supply Chain
- Third Party Logistics companies are now licensed independent of drug distributors.

Notable Exclusions in the law: stakeholders do not include carriers
PDSA

PDSA’s mission is to develop and help enact a federal policy proposal that enhances the security and integrity of the domestic pharmaceutical distribution system for patients. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.
The New World

- Lot/Batch level information shared between trading partners for transaction history
- Chain of Custody
- Validation of warehouse system (distribution system of record)
- Regular QA testing of Active Pharmaceutical Ingredients
- Good Distribution Practices for wholesale distributors & 3PLs
- Contingency planning
- Serial #, and real time temp, humidity, vibration data shared for transaction history
- Chain of Integrity
- FDA Transportation Audits
- Validation of all distribution systems: WMS, Environmental
- Intense quality testing of Bioequivalent sources
- Expanded GDPs to include in transit SOPs for product integrity
- Multi-levels of contingency plans that focus on handoffs, highest risks
Thank You!