



# Health Care Logistics: an Enabler of Change

**BioLogistics in a Changing Healthcare World**  
**Northwestern University Transportation Center**

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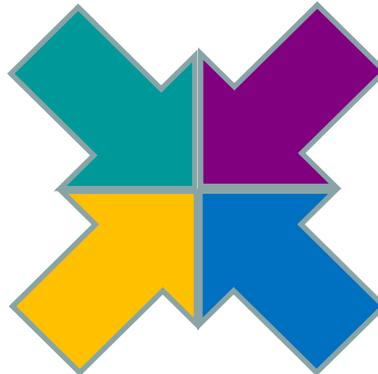
April 20, 2016

# Health Care is Transforming

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Tremendous growth in medical innovation

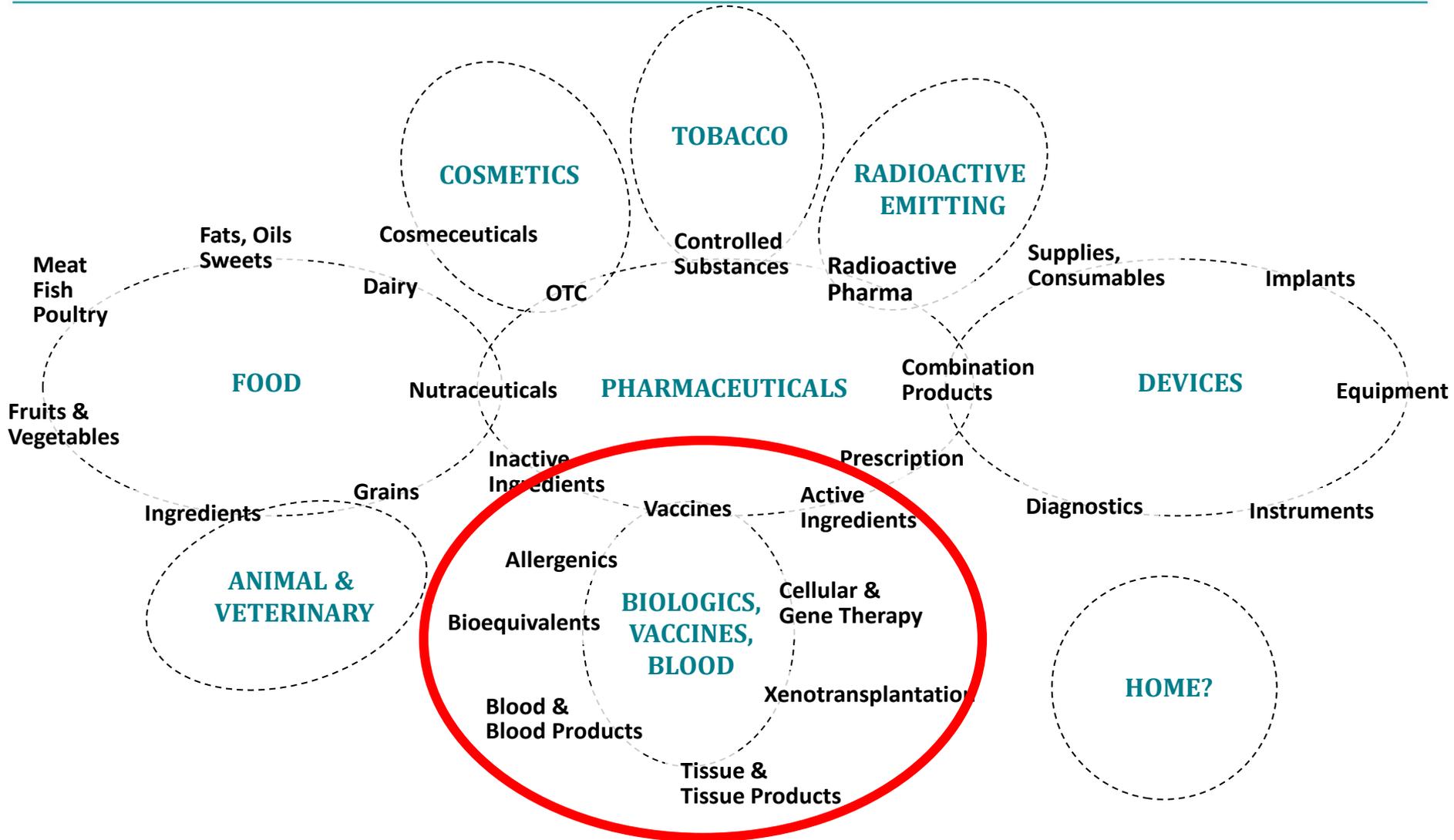
Health Care costs based on quality, not quantity



FDA focus on traceability and expanded compliance

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

# Where Do Specialty / Biologic Drugs Fit?



# The Basics

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## 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

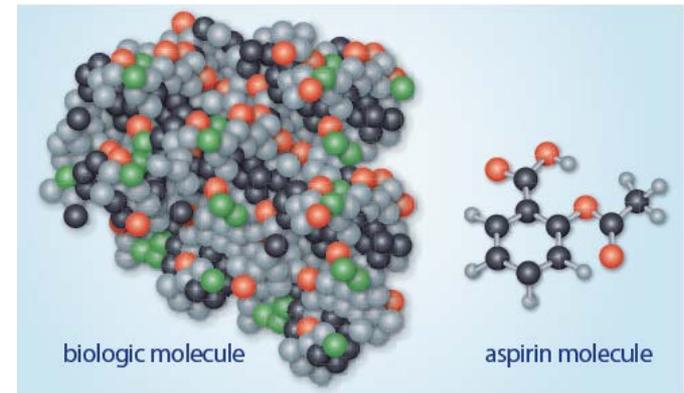
- Protein-based biologics include vaccines, blood and blood derivatives, allergenics, gene therapy, living cells and tissues, and more
- Biologics require cold-chain
- Many lose their efficacy within hours if removed from conditioned space
- In 2018, biologics will account for nearly 50% of the 100 top-selling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

# Biologistics

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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***

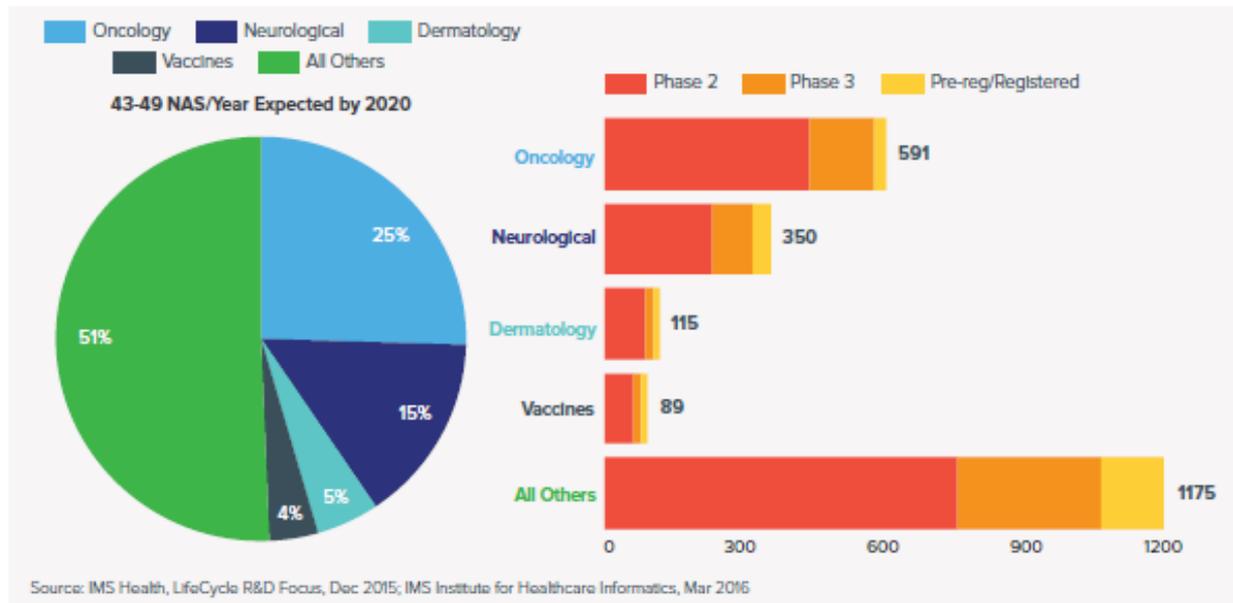
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# Biologics Driving Medical Innovation



2,320 Novel products in late stage reviews, many with superior clinical trial efficacies

Chart 32: Late Phase R&D Pipeline by Top Therapy Areas



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

Sources: IMS Health

# Biologics Driving M&A



## 122 Articles about M&A Activity in Biotech/Pharma

### Acquirees include:

- Retail Pharma
- Generic Pharma
- Pharma Distributors
- Universities
- Equity Investors

The Supply Chain is critical to integrating acquirees to achieve desired synergies and benefits without disrupting service

#### Biotech/Pharma - Mergers and Acquisitions

**Allergan** (AGN)'s Potential Shopping List Expands 4/19/2016

Covered in \$30 Billion Debt, Embattled **Valeant** (VRX) Mulls Over Which Assets to Sell 4/19/2016

A Week After **Medivation** (MDVN) Rumored to Snub **Sanofi** (SNY) Bid, **AstraZeneca PLC** (AZN) in Talks to Make Its Own \$10 Billion Offer 4/18/2016

**PROMETHERA Biosciences S.A./N.V.** Acquires Key Assets Of **Cytonet LLC** To Create The Global Leader In Regenerative Medicine And Cell Therapy For Liver Diseases 4/18/2016

**Recipharm AB** Creates A Global CDMO Leader Through SEK 1.7 Billion Strategic Acquisitions In The US, Sweden And India 4/18/2016

China's **Venus Medtech** Snaps Up **Transcatheter Technologies** 4/18/2016

**InfuSystem, Inc.** (IFLO) Agrees To Acquire Infusion Pump Assets From **InfusAID, LLC** 4/18/2016

**Tricol International Group Limited** Completes Asset Acquisition Of **HemCon Medical** 4/18/2016

Bay Area's **Carbylan** to Suspend Clinical Development of Hydros-TA and Slash Jobs to Conserve Cash 4/15/2016

Promising Hep B Drug Makes SoCal's **Arrowhead Pharma** (ARWR) a Pretty Target for **Gilead** (GILD) and Other Big Companies 4/15/2016

3 Biotechs Might Have M&A Targets On Their Backs 4/15/2016

**Advent, Baxter International** (BAX) Preparing Bids for Private Indian Drugmaker **Gland Pharma** 4/15/2016

If **Pfizer** (PFE) Wants to Buy, Here's a Shopping List 4/15/2016

Embattled **Valeant** (VRX) Working with Banks to Review Options Amid Interest from Buyout Firms 4/15/2016

**WuXi AppTec** Acquires **CRELUX GmbH** 4/15/2016

**OSE Pharma** And **Effimune** Announce The Signing Of The Merger Treaty 4/15/2016

**Elorac, Inc.** Acquires **Gideon Pharma** 4/15/2016

New Jersey's **Catalent** (CTLT) Jumps on Rumors of **Lonza Group** (LZAGY)

After Exploring Strategic Alternatives, **Synta** (SNTA) Agrees to Merge with **Madrigal** Metabolic Diseases and NASH Company 4/14/2016

Bay Area's **Medivation** (MDVN) Stock Pops 11% After Rumors It Rejected A **Sanofi** (SNY) Acquisition Bid 4/14/2016

**Novogene** Establishes First U.S. Genomic Sequencing Center Located At **UC Davis**; Acquires Second



# Cost Reduction

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- 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



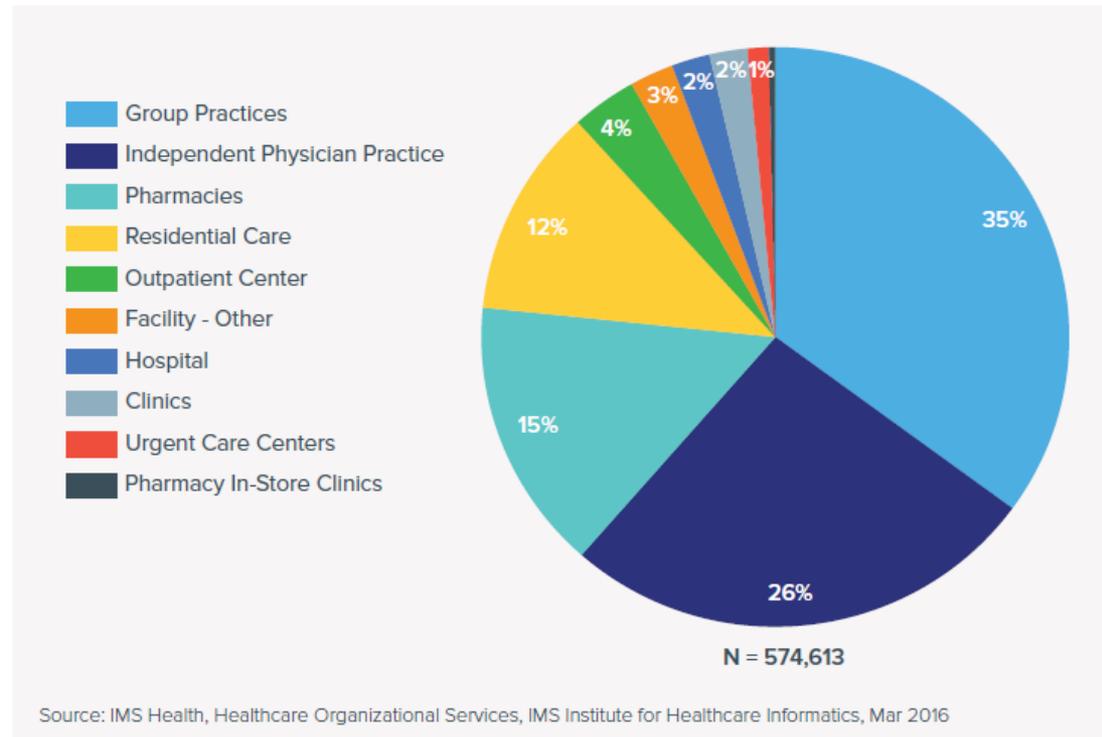
# Growth and Diversification of Points of Care



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

Chart 27: Healthcare Facility by Type for 2015



# Regulatory and Legal Compliance

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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

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# 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

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- 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
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**Thank You!**

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