### FDA Counterfeit Drug Task Force Public Workshop

#### Unisys Perspective on the Track & Trace Adoption Curve

Presented by: Laura Osburnsen February 8<sup>th</sup> & 9<sup>th</sup>, 2006



# Topics

- Overview
- Our Take
  - The Healthcare & Life Sciences (HLS) Industry Adoption Curve
- Variables Impacting Adoption
  - Policy Decisions
  - Trade Relations
  - Process Impact
  - Technology Performance
- "What If?"
- "So What?": Key Takeaways

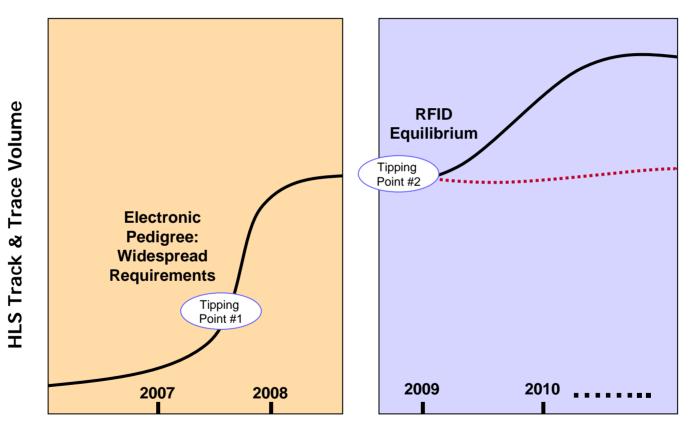


## **Some Good News**

- Unisys has seen significant progress in the adoption of track & trace technology since FDA's 2004 report
- In 2005, Unisys saw spending 2x to 3x the level it was in 2004 in the HLS industry
- In 2006, we anticipate an increase of 3x to 4x as piloting continues to gain momentum
- But...at that rate of adoption, it will take well beyond 2007 before the majority of the HLS supply chain is track & trace enabled

#### **UNISYS**

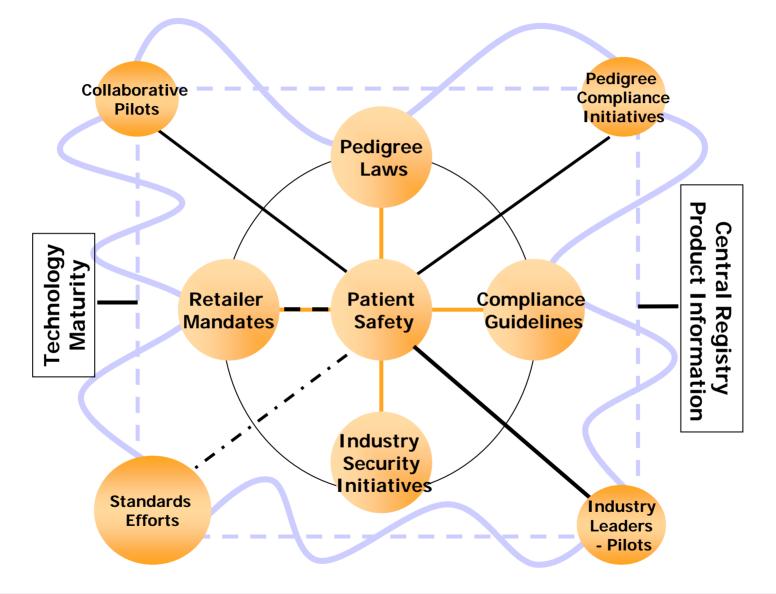
## **HLS Industry Adoption Curve**



Inside the Planning Horizon

**Outside the Planning Horizon** 

#### The Current "DNA" of HLS Industry Adoption



## **Variables Impacting Current Rate of Adoption**

Category	Supply Chain Actors	Regulators
Policy Decisions	•Agreement Around the "Form Factor" for Track & Trace (Trade Associations)	•Status of PDMA Pedigree Requirements •State Mandates Continue
Trade Relations	<ul> <li>Retailer Mandates</li> <li>Collaborative Pilots – Industry Pioneers</li> <li>Pedigree Data – Share the Burden</li> <li>Data Sharing</li> </ul>	•Interdependencies – Jurisdiction & Trade Agreement
Process Impact	<ul> <li>Item Serialization – Cost of Quality</li> <li>Distributor Pedigree – Paper vs. Electronic</li> <li>Diversity of the Inbound – Distributor "How To"</li> <li>Authentication – Time, Place &amp; Procedures</li> <li>Speed of Consensus – Standards, Schema</li> </ul>	•Interdependencies - Pre-Existing Policies (e.g. GMPs, 21 CFR Part 11)
Technology Performance	<ul> <li>Approach to Security &amp; Privacy</li> <li>Frequency Debate - Outcome</li> <li>Alignment - Cost / Performance</li> </ul>	•Laissez Faire or

## What If?

### 1) FDA removes stay of PDMA Pedigree...

-All trading partners invest in pedigree infrastructure

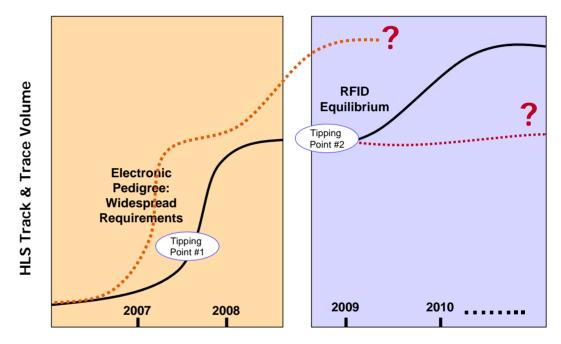
2) Standards widely adopted in 12-18 months...

-Helping to resolve the issues of frequency, schema, security, and other obstacles

–Further facilitating trading partner collaboration

3) A Jump to the 2<sup>nd</sup> Curve: Value chain incentives align driving increased data sharing...

> -Opening up process efficiencies and greater incentives across the chain



**Inside the Planning Horizon** 

**Outside the Planning Horizon** 

## Key Takeaways

- Track & Trace is a complex domain with many interdependencies but it's not a "science project"
- The variables with the greatest potential to impact the pace of Track & Trace adoption are in the areas of trade relations and collaborative process change
- A key success area for policy makers is to minimize unintended consequences that impact quality and/or cost of business operations

