# Outsourcing in the Age of Healthcare Reform

## “The Tale of 4 Lens”

ACT/Lens 1: Chris Oleksy – President, ATEK Medical
ACT/Lens 2: Denise Odenkirk – VP, 3PL Programs OM Healthcare Logistics
ACT/Lens 3: Roger Brink – VP,  Chief Quality /Regulatory Officer, ATEK Medical
ACT/Lens 4: YOU!  Be Ready to be Asked for Your Opinion ☺

***Medical Device Supply Chain Council May 2010***

# OLEKSY FULL DISCLOSURE… RAISED IN A 'HOUSE DIVIDED'

- Mother's Uncle 'Dale Bumpers' (D), Former Governor and Long Time Senator from Arkansas
- Father Served In Multiple Campaign Leadership Roles for Prominent Democrats in Indiana
- Internship in Washington 1982 with Elwood (Bud) Hillis (R), U.S. Rep. from Indiana; Chairman of the Armed Services Committee
- Served as Gov. Bob Orr's (R) State Youth Chairman in 1983
- Grew Up With Experience on 'Both Sides of the Political Spectrum'

# ATEK Medical Fast Facts

- Manufacturer of FDA class I, II, and MDD Class III devices.
- Private / Woman Owned
- $70M in Sales
- 375+ Employees
- Domestic and Off-Shore Operations
  - Grand Rapids, Michigan
  - Heredia, Costa Rica
- Regulatory Certifications
  - ISO 13485:2003 certified ,
  - Scope: Design Controls & Pneumatic/Electro Mechanical Active Devices including Bio Resorbable Implants.
  - FDA registered Contract Manufacturer #1419629

# High Mix, Low to High Volume Finished Goods

**6 Million Units Manufactured Per Year / 1,200 Different FG Product Codes / 5.4 Sigma Quality**

- High Mix, Low to High Volume
- Annual quantities per code vary from 25 – 400K per year

**Materials Managed**

- Machined Components and Implants
- Titanium parts
- Metal injection molded parts (MIM)
- Bio-resorbable polymers
- Plastic molded parts
- Silicone molded parts
- Electrical Components
- Printed Circuit Boards
- Braids
- Extrusions

# Healthcare Reform "Process"

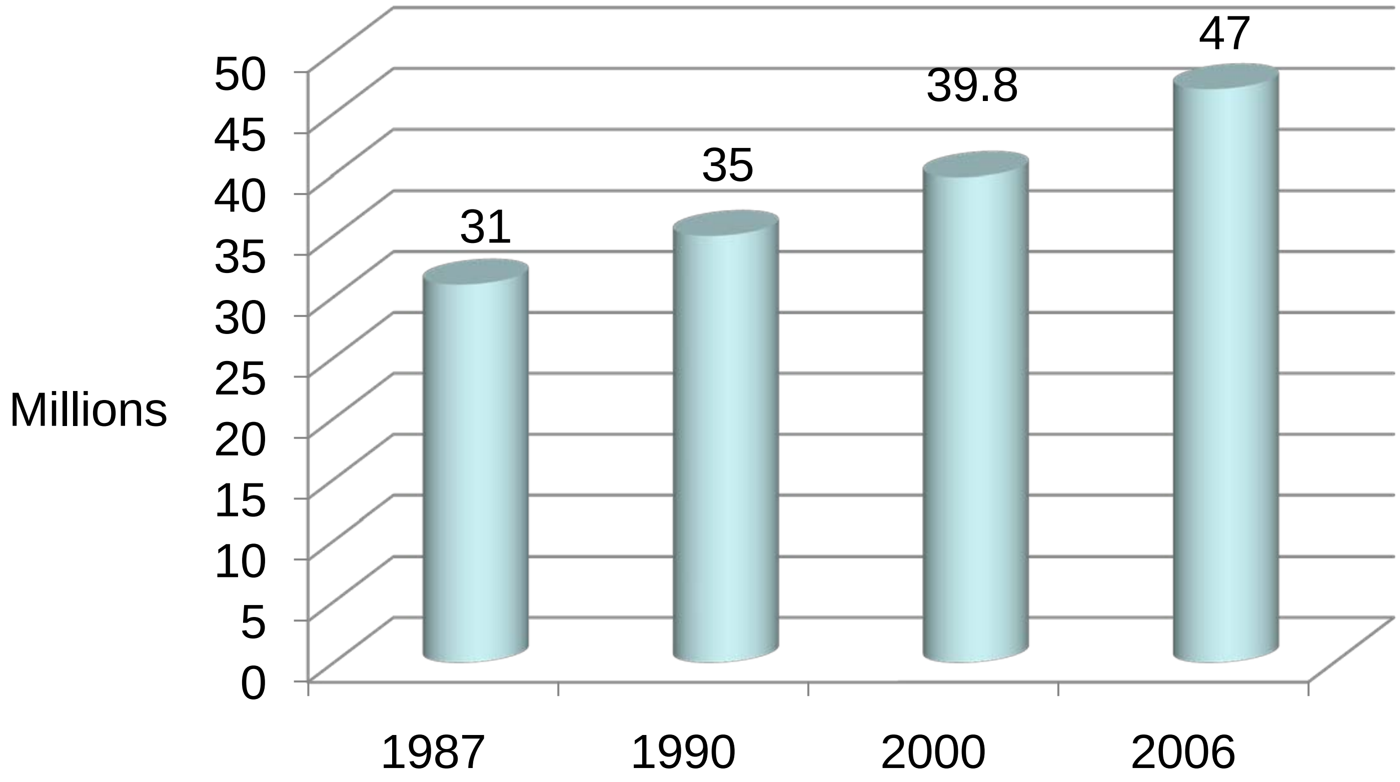
**Current State** → **Transition State** → **Future State**

"We Simply Cannot Configure Our Supply/Value Chains (Or COMPANIES), Without Understanding" :

1) How we Got to the Current State?
2) Where We Are Heading (Future State)?
3) What Transition We Need to Go Through

A Guarantee = ***CHANGE***!

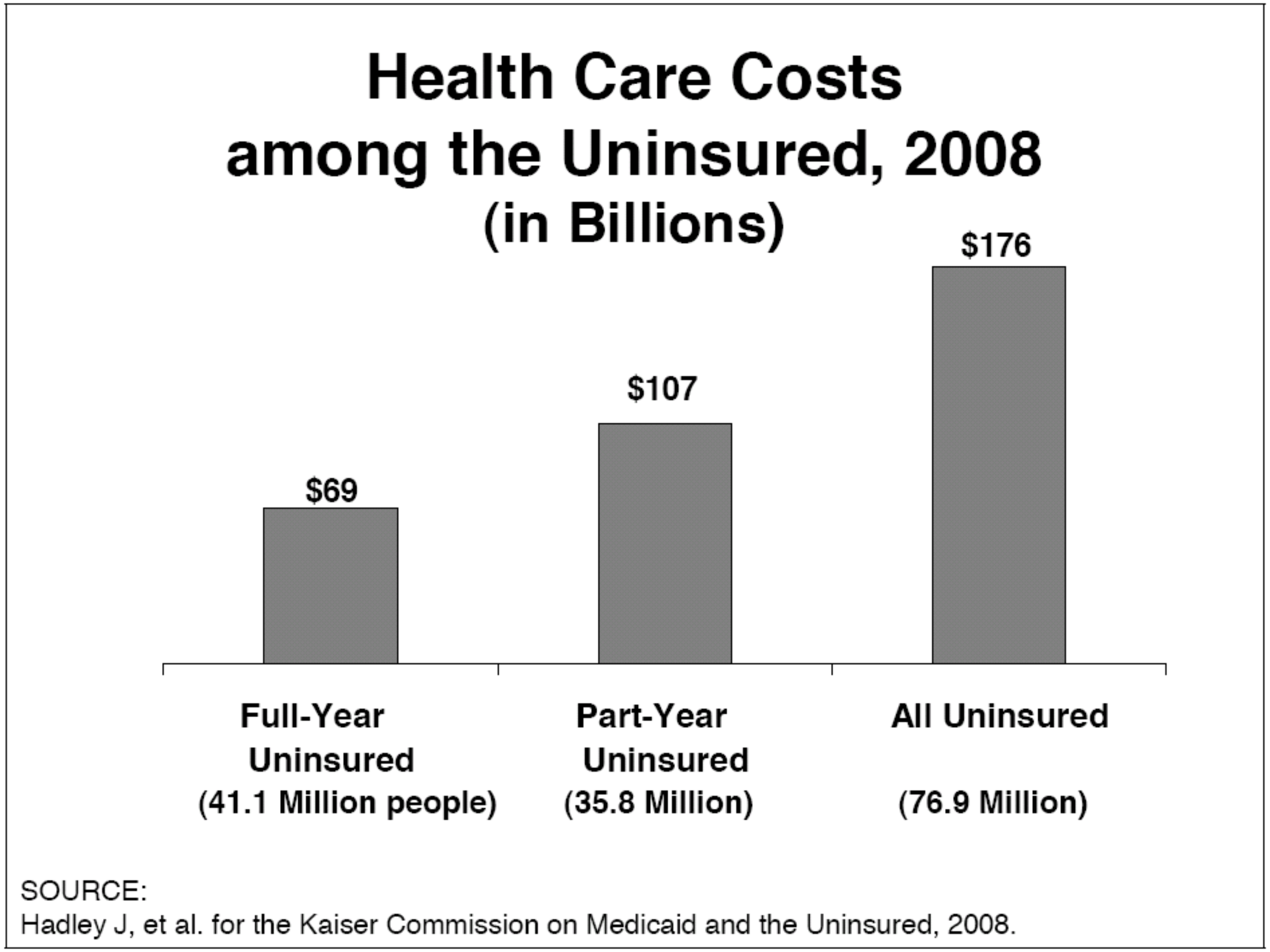
# UNINSURED IN THE U.S.




***51% Increase in 20 Years!!!***

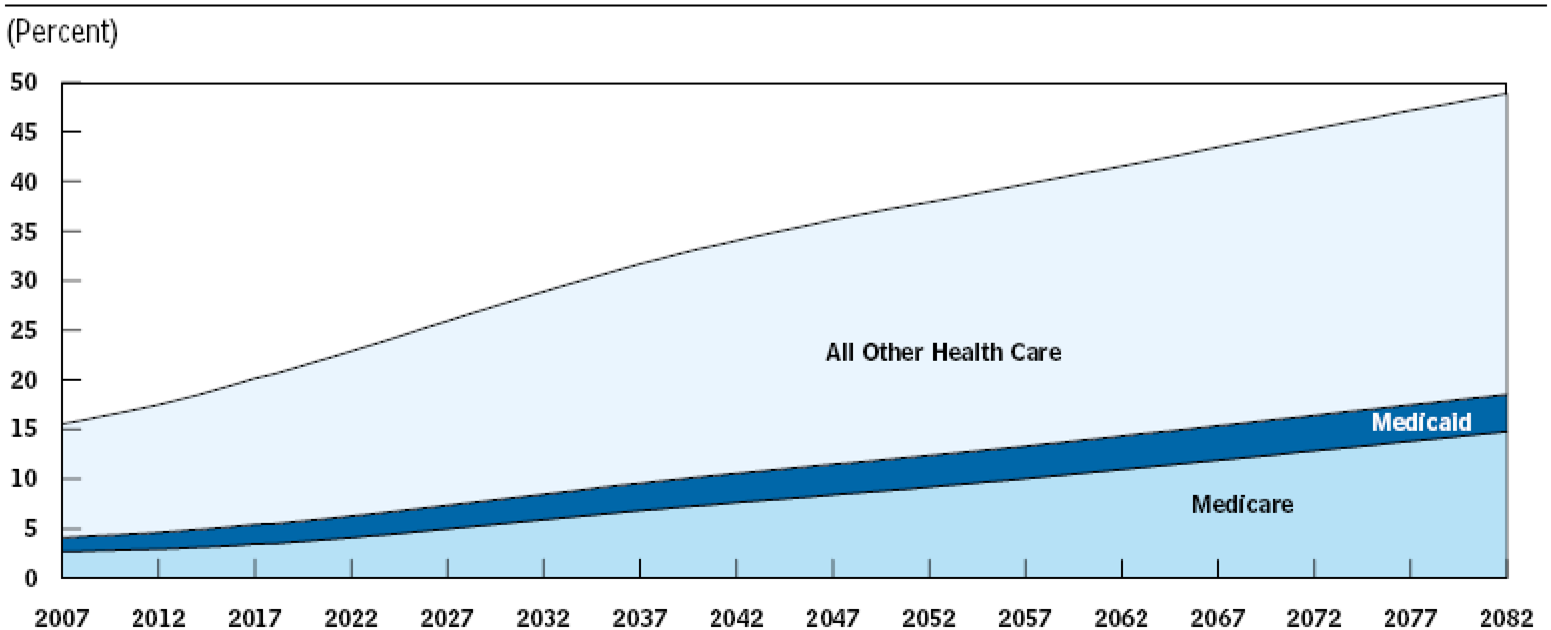
***Source = U.S. Census Bureau***

# Current State
## Cost of Uninsured




- *Approx. $56B (2.3% of total spend) uncompensated cost is incurred when people are uninsured*
- *The Federal and State governments pay roughly 75% of this cost ($43B) with charity care covering the rest (little evidence suggests private sector premiums are impacted)*

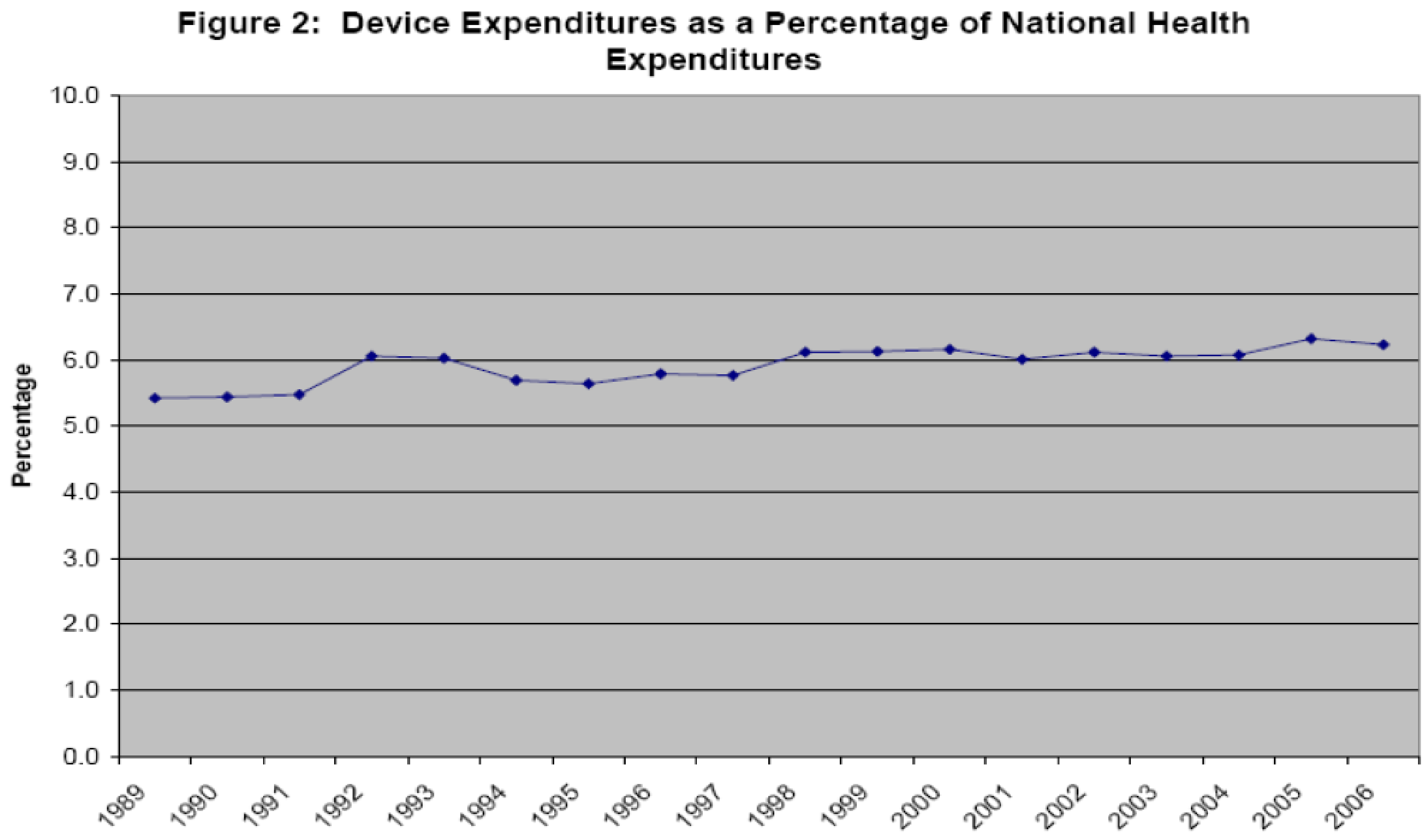
# PROJECTED HEALTHCARE SPEND AS % OF GDP



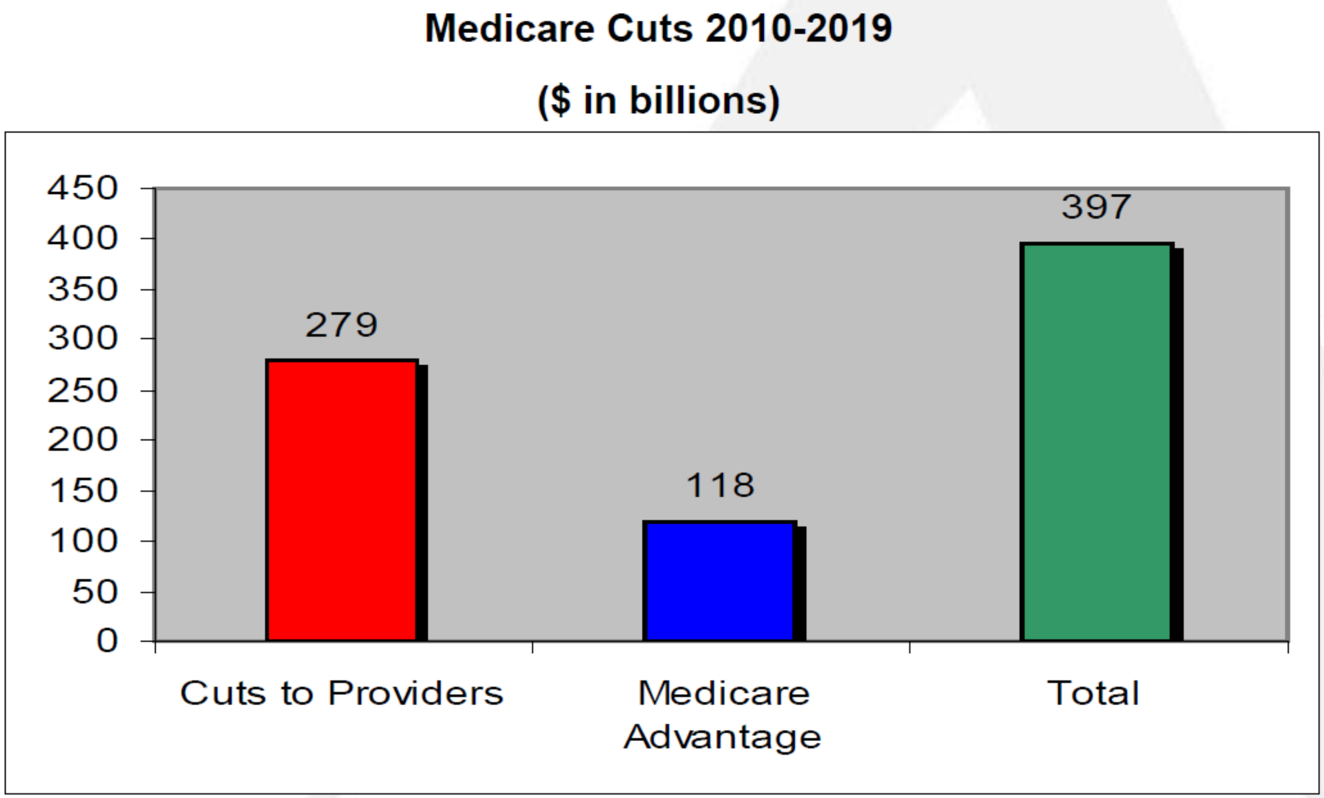

Source: Congressional Budget Office.

Note: Amounts for Medicare are net of beneficiaries' premiums. Amounts for Medicaid are federal spending only.

# As a Percentage of National Health Spend, Device Costs Have NOT Been Escalating Out of Proportion



# Proposed Cuts to Medicare / Providers




Source: Congressional Budget Office, Senate leadership bill, 11/18/2009, Table 2

# “Reform Alignment”

***What is Healthcare ’s Business Direction? (Uninsured/Costs)***

***Configure The Direction! (Operations Configuration) (Insurance)***

***Actions! (Who Does What?) (Insurance, Tax on Device Cos, Medicare / Provider Cuts)***

***OUTCOME = Unprecedented Focus on Costs***

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# "The Changing Face of Innovation Has a Dramatic Impact on Your Value/Supply Chain Configuration"

***(25 Years Ago )***
***Many Unmet Needs***

Unmet Patient Medical Needs

↓

Invent The Solution

↓

Price The Solution

Market Would Allow A Premium To the Inventor(s) for R&D, Risk, Scale etc.

***(Today)***
***Less Unmet Needs***

Understanding Price Point to Compete

↓

Apply the "Stacked Bar" Supply Chain Configuration

↓

Price The Solution

Too Great a Focus on Cost Could Result in a Sub-Optimum Solution if Not Managed Correctly

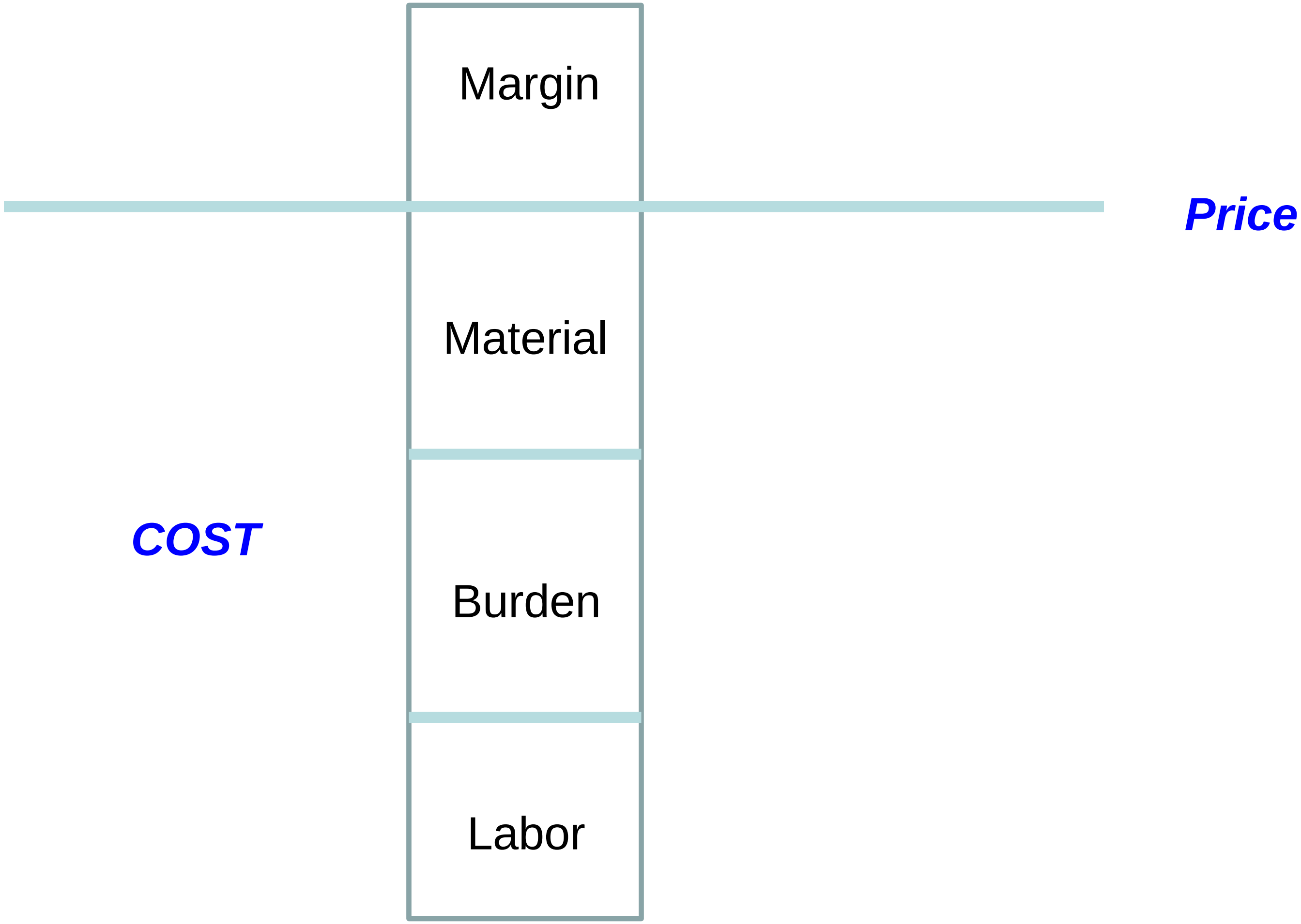
# The Call to “**RE-Invent**” or “RE-Engineer”

In Simple Terms, The Way To Support and in Some Cases, Survive Healthcare Reform, is to ***Re-Invent*** Supply/Value Chains and Companies, To Improve Value While Decreasing Costs

Configuring (**RE-INVENTING**) the Value / Supply Chain Correctly Is Mission Critical More Now than Ever Before!

**Re-Inventing** Could Be The PRODUCT Itself; The Delivery Mechanism; Or Any Component of the Supply/Value Chain. Don’t Presume that Re-Invent Only Focuses on the Product!

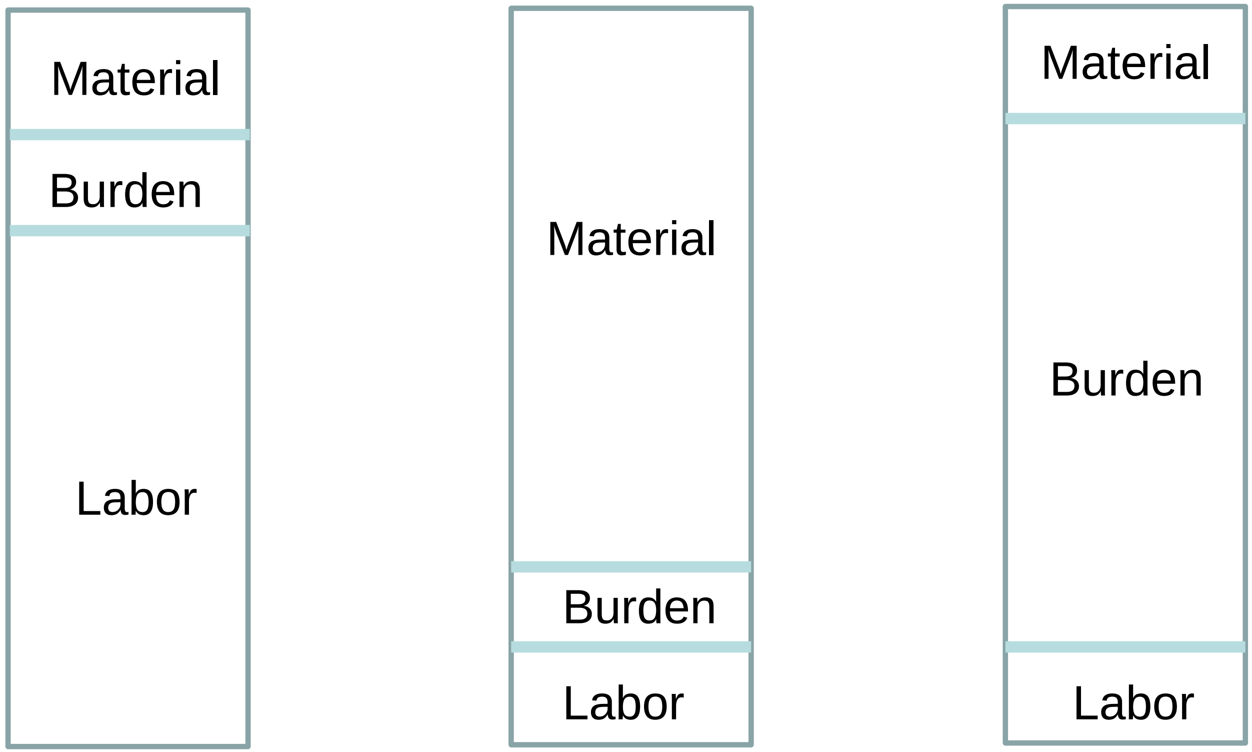
# "The Supply Chain "Stacked Bar" Configuration




**(Components of a Product Used for Explanatory Purposes Only.
Components are Not Meant To be 'In Proportion" for This Example. )

# "Be Careful Not to Chase the Wrong Configuration'

**Scenario A** | **Scenario B** | **Scenario C** | **Scenario XYZ+**

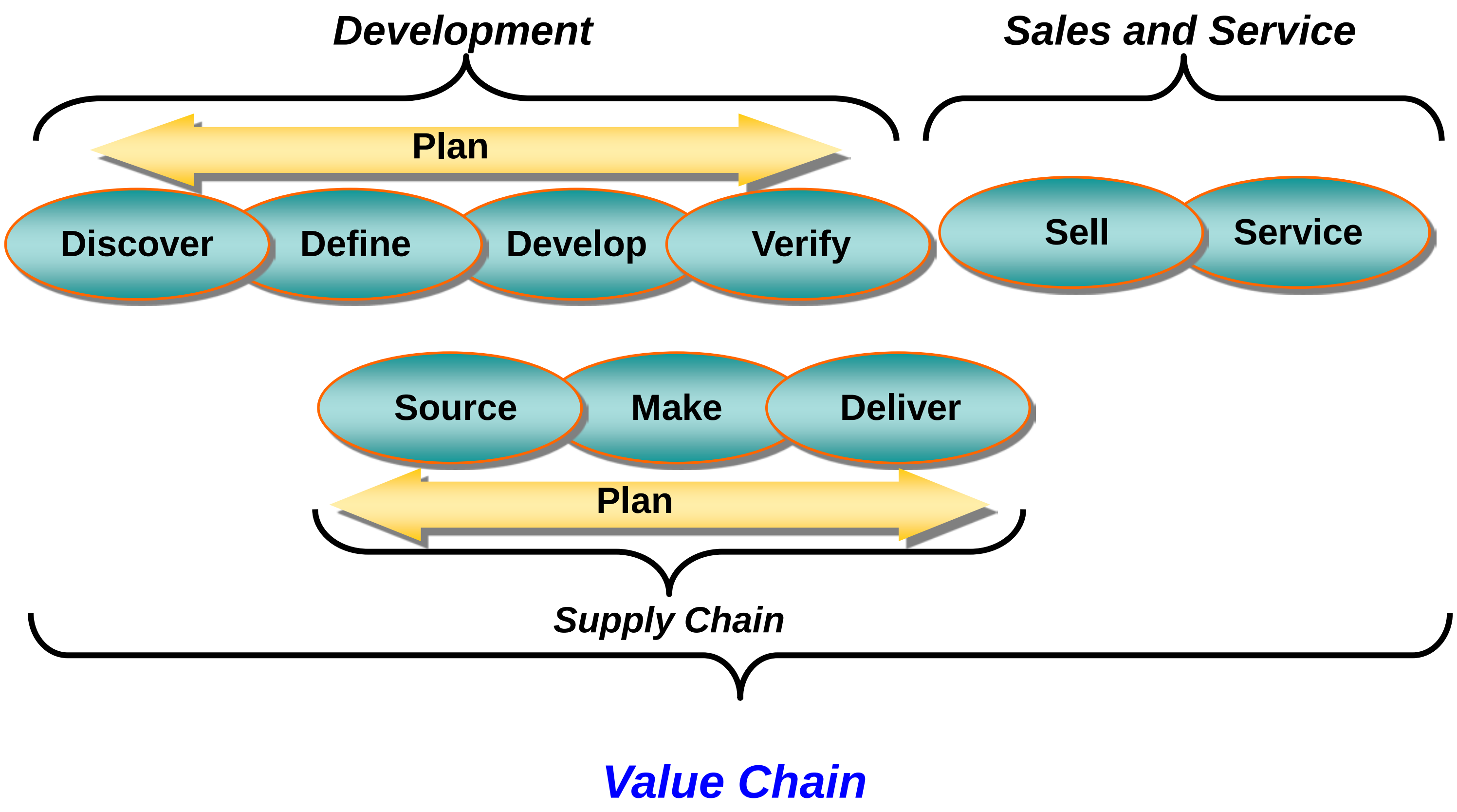



***Prime Candidate for Off Shore Mfg.; Automation; "RE-Invention"***

***Likely NOT a Candidate for Off Shore Mfg. or Automation But Strong Candidate for "RE-Invention"***

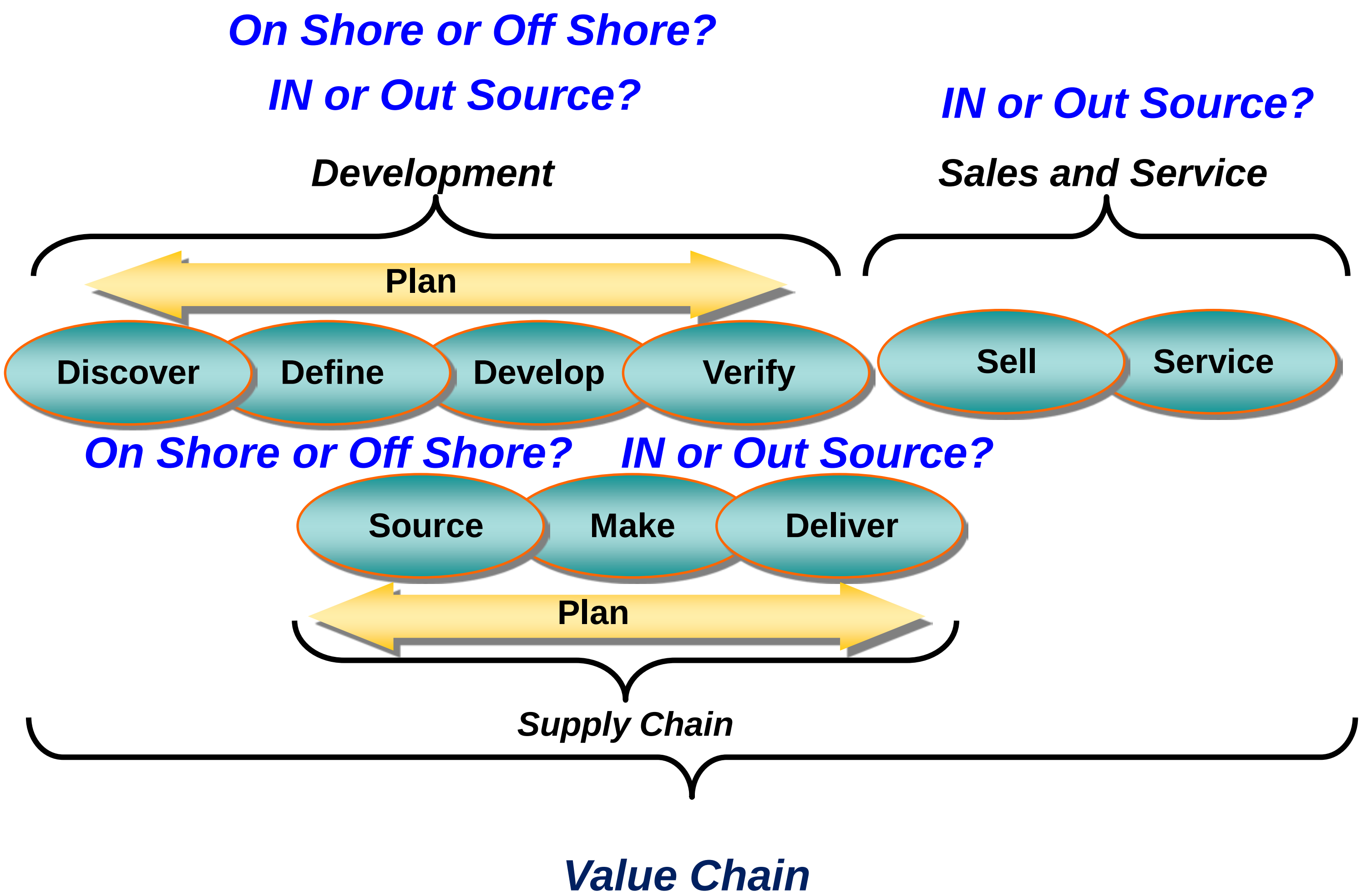
***"Could" Be a Candidate for Off Shore Mfg. (vs. Capital); Variabalize the Burden by XYZ; Strong Candidate For "RE-Invention"***

# RE-Inventing The Configuration of ALL Elements is Key!
# "Simulate Blowing UP The Value Chain"



# Delineate Labor/Burden/Material Across The Value Chain!

*Example*



# OM HCL Fast Facts



- Outsourced warehousing, transportation and value added services
- Full order to cash processes
- cGMP compliant for medical device and pharmaceuticals
- End-to-end supply chain control and visibility

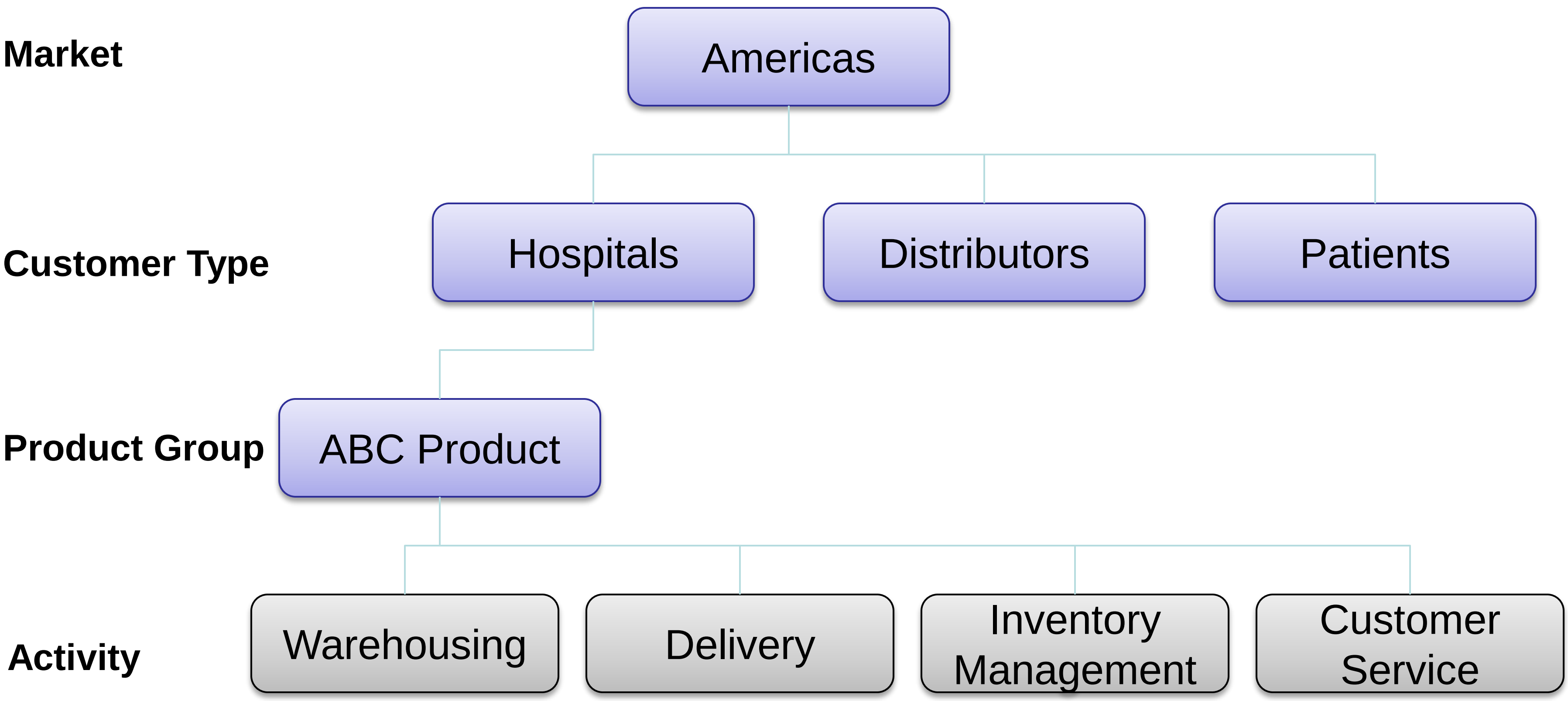
# Truly Re-inventing Your Operating Costs





- Improved productivity
- Lower infrastructure costs
- Transportation mode shifting
- Sku rationalization
- Modify packaging and delivery model
- Fewer expedited shipments
- Reduced inventory levels
- Improve DSO
- Lower inventory write offs
- Reduced asset depreciation and interest expense
- Hard to manage processes (samples, kitting, etc.)

# Evaluating Cost Reduction Opportunities




***Identify opportunities to reduce operating costs by looking at segments of products, marketing and customer types that have a higher cost to serve***

Example

# Supply Chain Costs Status Quo

| | |
|---|---|
| **Average Selling Price -** | **$100** |
| **COGS -** | **$ 50** |
| **Selling Expense -** | **$ 10** |
| **Supply Chain Expense -** | **$ 30** |
| **Profit -** | **$ 10** |

| Warehousing | Delivery | Inventory Management | Customer Service |
|---|---|---|---|
| **$ 4.5** 15% | **$ 12** 40% | **$ 9** 30% | **$ 4.5** 15% |

Example

# Cost Improvement Initiatives Identified

| | |
|---|---|
| **Average Selling Price -** | **$100** |
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| Warehousing | Delivery | Inventory Management | Customer Service |
|---|---|---|---|
| **$ 4.5** 15% | **$ 12** 40% | **$ 9** 30% | **$ 4.5** 15% |
| • Outsource Warehouse<br>• Improve Productivity | • Implement TMS<br>• Shift Mode | • Expiry Date Mgmt | • Improve Productivity<br>• Reduce DSO |

Example

# Supply Chain Savings Realized

Average Selling Price - $100

COGS - $ 50

Selling Expense - $ 10

Supply Chain Expense - $ 24.50

**Profit - $ 15.5 less incremental 2.3% tax = $13.2**

| Warehousing | Delivery | Inventory Management | Customer Service |
|---|---|---|---|
| **$ 4.0** 15% | **$ 8** 40% | **$ 8.5** 30% | **$ 4.0** 15% |
| • Outsource Warehouse<br>• Improve Productivity | • Implement TMS<br>• Shift Mode | • Expiry Date Mgmt | • Outsource CS/AR<br>• Improve Productivity<br>• Reduce DSO |

# *New Era for Medical Companies – Unprecedented Pressures*

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- Cost Pressures
  - Hospital and GPO pressure to lower product cost
  - Decreased government reimbursement
  - New healthcare program taxes
- Supply Chain Pressures
  - Mergers, acquisitions, and consolidations by suppliers resulting in material changes and eliminations
  - Global Supply Chain Management requirements
  - Economic downturn requiring evaluation of financial health and even survival of key suppliers
- FDA Enforcement/Regulatory – Increased Pressures

# What NOT To Do…

**CRASH COURSE** – The American Automobile Industry's road from glory to disaster…Paul Ingrassia

Excerpts:

*"Cost became the paramount priority – quality & customer were distant second"*

*"No amount of cost cutting that GM conducted – host of layoffs, plant closings, outsourcing – provided the ability to achieve the company's product & quality objectives"*

*"The price beating that has gone on in the US auto industry between Ford, GM, Chrysler and their respective suppliers is legendary and has resulted in ongoing series of bad outcomes for both parties"*

# FDA Enforcement Pressures

- New FDA Era and Leadership
  - Dr. Margaret Hamburg, Commissioner
  - Dr. Jeff Shuren, CDRH
  - Dr. Janet Woodcock, CDER

- New Congressional Expectations

  "Commissioner Hamburg is expected to be more aggressive about drug and medical device regulation"

  -Rep Henry Waxman

# FDA More Aggressive

- FDA Orders Baxter to Recall and Destroy All Colleague Infusion Pumps (May 2010)
  - New Pre and Post-market requirements for manufacturers of infusion pumps planned
- FDA Orders Boston Scientific to Halt Domestic Defibrillator Sales (March 2010)
  - Company neglected to get FDA clearance on two manufacturing changes
- FDA Warning Letters Double Between 2005 – 2009 on Supply Chain Controls…
  - 35 new FDA inspectors to be added
  - Downstream supplier surveillance also

# FDA New Initiatives

- Corrective Fix “Pilot”
  - Device makers to recall older devices when improvements approved by CDRH
- E-Medical Device Reporting

  “Industry too cozy with FDA and lax in tracking malfunction devices”

  -American Assn for Justice
- “Address” Class III Device Types that Currently Allowed to Enter Market thru 510(k) Process (Dec 2010)
- Unique Device Identifier (UDI) System Implementation
  - Sept 2010 Complete pilot
  - Sept 2013 CDRH to implement a UDI System

# FDA New Initiatives – 510(k) Process

- ReGen Menaflex® FDA Product Review and Approval Process were Compromised and were a Clear Deviation from Principles of Integrity

  -GAO Office

- Questionable Rigor of the 510(k) Process and Effectiveness of the Regulation of the Industry

  -Institute of Medicine

- Mass Medical Survey (April 2010)
  - Two-thirds of medical industry respondents believe 510(k) approval process is adequate to protect and promote public health
  - High concern for the impact of reform

    --Approval Times

    --Development costs

    --Regulatory submission requirements

    --Medical device innovation

# FDA New Initiative – 510(k) Process

- Expectations
  - Revised 510(k) approval process that will require more testing including patient testing
- Next steps
  - External review conducted with results due March 2011

# FDA New Initiative Supply Chain

- Increased FDA and EU Required Quality Controls as Result of Heparin Contamination Health Scare (China plant falsified ingredient)
  - Global Harmonization Task Force GHTF SG3:2008
    - "Guidance on the Control of Products & Services obtained from Suppliers" www.ghtf.org
    - FDA expects medical manufacturers to follow this guidance
- Supplier Quality Agreements Required
  - Globalization & product passing through many different hands; Suppler Quality Agreements need to be iron clad
  - Products and processes cannot be changed without approval
- Supplier Selection and Evaluation Procedures in Place Including Primary and Secondary Suppliers

# What To Do…

- Establish robust effective and efficient supplier evaluation programs within your organization – defined process with disciplined approach.
- Establish performance metrics for each strategic supplier; rigorously manage suppliers.
- With globalization and materials passing through many different hands, assure your Supplier Quality Agreements are iron clad documents.  Change control is critical!
- Take time to know your Strategic Outsource Partners… MDMs that develop partnerships of greater depth use those partners to reduce cost and enhance quality.

# What To Look for In Supplier Selection …

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- Take time to know your Strategic Outsource Partners… MDMs that develop partnerships of greater depth use those partners to reduce cost and enhance quality.

# What to Look For…

- Best outsource partners have a demonstrated commitment to lean manufacturing and quality, providing a wealth of expertise that streamline projects and processes.

- Identify best value suppliers, not the lowest price supplier. Cost savings, service and innovative methods all add value.

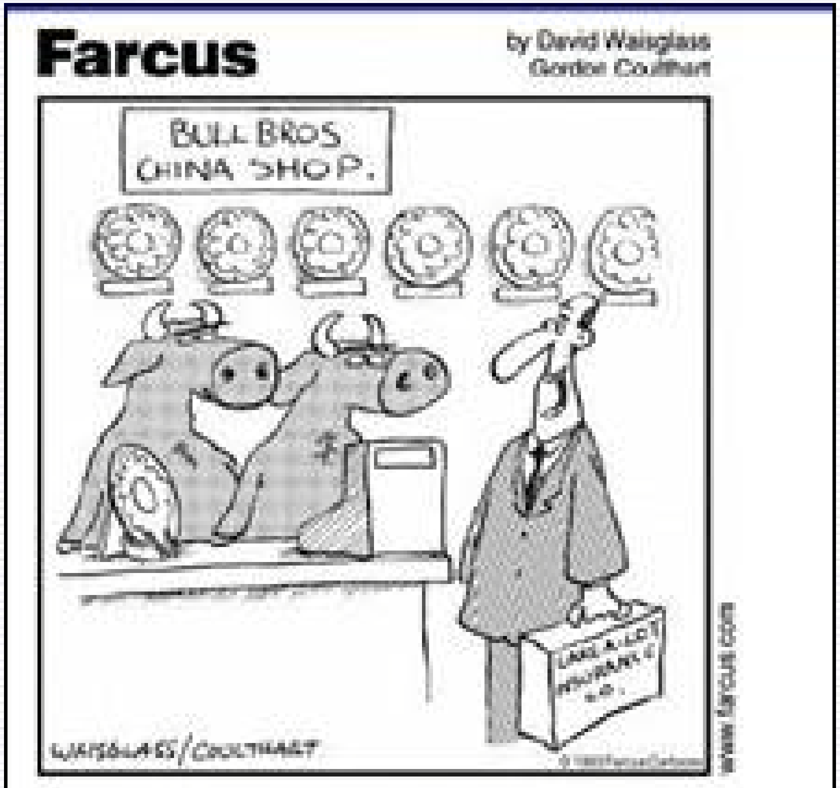
- Identify experienced medical suppliers. Value is enhanced when outsource provider has same level (or higher) expertise.

- Top notch outsourcing partners make quality compliance an integral and important part of their business – a strong internal audit program.

# What to Look For…Overseas Quality

- Suppliers that have demonstrated Quality System Compliance by one of the GHTF Member Regulatory Systems:
  - Canadian (CMDCAS)
  - European Union Notified Body (ISO13485)
  - Japanese Medical Device Ministry – MLW
  - Australian Therapeutics goods Administration

# Yet Many Companies Are Blind to Supplier Risks




"I'm sure it won't be a problem ... you fellas look like a good risk to me."