Trends in Medical Device OEM Strategy and Implications for the Supply Chain

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Manning Advisors LLC

Merger and Acquisition, Advisory, and Financial Services

Manning Advisors

- Merger and acquisition advisor to middle-market specialty materials and precision engineering companies

- Strategic planning and value development services

- Market analysis and market entry planning

- Approximately 50% of our assignments are in the medical device supply chain
  - Buy-side
  - Sell-side

- www.manningadvisors.com for more information

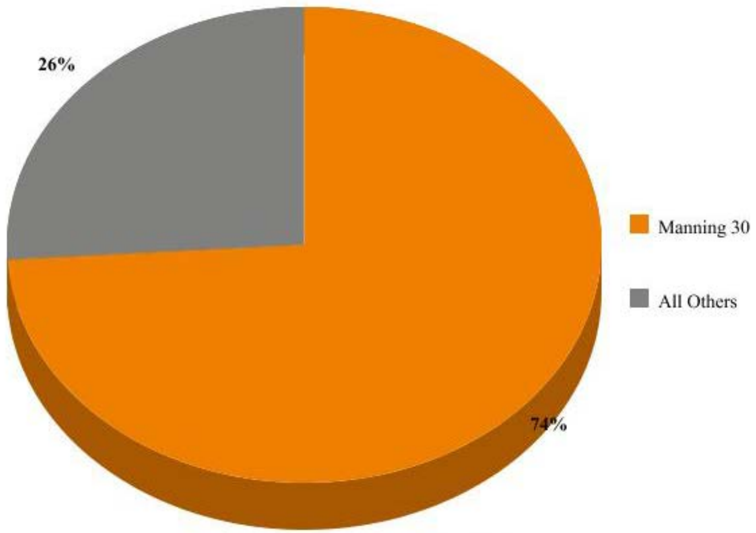
Executive Summary

- In 2015 medical device OEMs facing four business drivers
  - **Mega-acquisitions** for both market exposure and market share
  - **Focus on emerging markets** for future growth with “value” products
  - **Accountable care** changing product lines in North America
  - **Continued outsourcing** of manufacturing

- North American facing new issues as OEMs shift priorities
  - Changing definition of a preferred contract manufacturer
  - New manufacturing opportunities
  - LCC philosophy changing to lower-cost philosophy
  - The lure of branded product – two strategies

The Medical Device Industry

2014 Global Medical Device/Diagnostic Equipment Market



Source: Manning Advisors LLC

- Total market = US$330 billion in 2014
- The Manning 30
  - 30 largest global device and diagnostic equipment companies
  - All have sales over $2 billion and pushing $3 billion
  - 74% of 2014 medical device and capital diagnostic equipment market

Four Key Trends for OEMs in 2015

- Mega-acquisitions
- Growth markets
- Accountable care
- Outsourcing manufacturing

Mega-Acquisitions

- **Top 30 buying each other**
  - Always purchased smaller firms for growth and still do
  - What's new? A wave of large company acquisitions
    - Medtronic-Covidien
    - Becton Dickinson-CareFusion
    - Zimmer-Biomet
    - J&J - Synthes
    - S&N-ArthroCare
    - Stryker-S&N?

- **Drivers**
  - Coverage and penetration of growth markets
  - Market share strategy to deal with hospital consolidation in US, Europe
  - Product pipelines
  - Low interest rates

- **For the supply chain**
  - Limited impact today, one of the last items to consolidate is supply chain
  - Fewer large customers in the long run (2-5 years)

Growth Markets

Region	Growth Rate	2014 % of Market
US/Canada	4-6%	41%
W. Europe/Japan/AUS	4-6%	30%
Growth Markets	8-18%	29%
Global	5-8%	100%

- OEM sales focus moving to growth markets
  - BRICs
  - Other Asian and Latin American markets
- Different products for different markets
  - Emerging market focus on expanding healthcare, particularly infrastructure
  - Limited emerging market demand for developed country products
  - Development of “value” and “underserved” products for emerging countries vs. “premium” products in developed markets
  - Most manufacture is local for local consumption
- For the supply chain
  - Some opportunity on premium product exports as OEMs stress sales for affluent private-pay patients
  - Likely a focus on the NA/European markets for smaller players

Accountable Care

- ACO = Accountable Care Organization
- ACOs made up of payers and payees
  - Insurance companies and government organizations
  - Hospital groups and physicians associations
- Higher payments for superior outcomes, not fee-for-service
- Recommend reviewing Fresenius results scorecard in their financials:
  http://www.fmc-ag.com/files/20150112-13_FME_JPM_conf_SanFrancisco.pdf

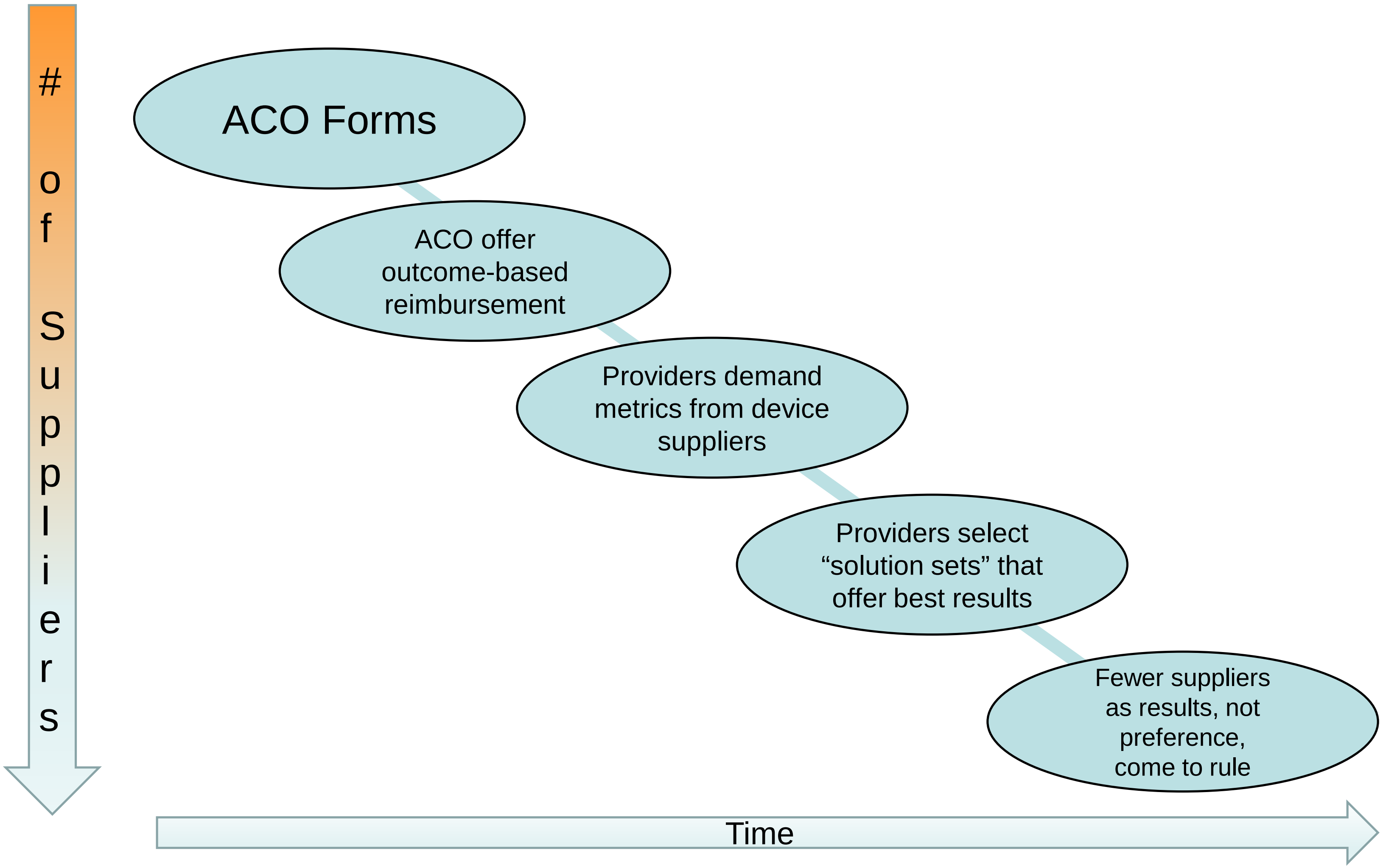
Accountable Care – Market Forces Arrive

- Rapid movement to accountable care model in US
  - Decline of fee for service
  - Rise of fee for superior results
  - 30 million Americans now covered under ACOs

- **→ Accountable care changes entire OEM product strategy, especially in North America ←**
  - No more "just sell the doc" model - Sell to the hospital group/ACO as where **metrics** are the driver
  - Fewer, more sophisticated, **more demanding buyers** as hospitals consolidate
    - Few independent hospitals and clinics
    - Over 70% now affiliated
  - OEMS will offer **complete product/service solutions** covering all aspects of care aimed at better results
    - Devices yes, but training/tracking/reporting as well
    - More electronics for management and reporting
    - More "outcome driving" features and services
  - Marginal players will be pushed out
  - Fewer, larger suppliers

- For the supply chain
  - Fewer OEMs per specialty. Greater market share to the remaining players. Pick your winners
  - Advantage to supplying more than just a product

Accountable Care – Fewer Suppliers



Outsourcing in Full Swing

- Every major OEM continues to outsource
  - Few new manufacturing facilities in developed countries
  - OEM cost of goods is steady to down over last five years
  - The outsource philosophy has worked
  - No sign the pendulum is swinging back
- Target numbers emerging
  - OEMs will consider outsourcing if they see a 10-30% savings
  - Translates to 3 to 5 gross margin points for the OEM
- For the supply chain - Expect growth
  - Estimated 12% global growth rate in outsourcing
  - Likely around 6-8% in United States

Summary

- Medical device industry is growing steadily
- Mega-mergers are creating fewer, larger players
- Sales focus shifting to growth markets
- Product lines are splitting into premium and value categories
- ACO rewards superior results
  - Likely rewards care systems rather than individual devices
  - Fewer brands in any given hospital department, pick your winners
  - Changing products to support demonstrated efficacy
- Outsourcing will continue

The Supply Chain

Definition of a Preferred Supplier Is Changing

- A new model of contract manufacturer emerged about 10 years ago
  - Broad portfolio of manufacturing capabilities
  - Modern medical quality standards
  - Demonstrated manufacturing expertise
  - Financially stable, over $40 million in sales

- New preferred CM model evolving – Even larger and broader companies

Design and manufacturing partner focused around medical practice areas
or
Manufacturing partner focused around areas of production expertise

  - Access to the new projects on which OEMs earn 80% of their profits
  - Supply chain dominance- displacing or subsuming smaller competitors
  - $100 million in sales – long term financial stability

- Timing of 3-5 years

CM Types and Examples

Design and Manufacturing CM	Manufacturing CM
Lake Region Medical (interventional)	Flextronics Medical (former Avail)
Vention (MIS devices)	Cadence (MIS devices)
Creganna/Tactx (MIS devices)	MICRO (tube-based devices)
Helix Medical (catheter systems)	Cretex (metals and plastics)
Tecomet (ortho)	Okay Industries (metals)

Changing Role of a Preferred Supplier

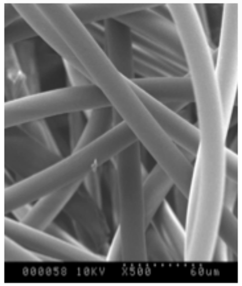
- Relationship with OEM will be longer and deeper
  - CMs formerly handled **projects**
  - Now need to handle **programs** for their multi-year lifecycle
  - Need program managers rather than project managers
    - “Ambassador” from CM to OEM
    - High level management skills
    - Proactive vs. reactive strategy
- Gaining responsibility for the supply chain
  - Selection/management of smaller suppliers passing to preferred CMs
  - Increasing sourcing and inventory management
- Expanding manufacturing portfolios
  - More capabilities, more opportunities
  - Greater lock on relationship with smaller number of large OEMs

Roles for the Future

- Contract manufacturer
  - Focuses on overall responsibility for the product
  - Increasingly expensive, difficult strategy
  - Near impossible without major capital and acquisitions
- Sub-contractor
  - Whatever the CM will share
  - OK for now, hard in the long-run
  - Will not be master of its own future, no matter how excellent the quality of their product
- Specialist
  - Profitable if the right niche is found
  - Valuable position for the long term

New Manufacturing Opportunities

- Electronics and informatics
  - Accountable care requires massive data collection
  - Wiring of hospitals, operating rooms, and devices
  - Most hospitals currently have modern IT equipment but little integration
  - New devices will contain electronics and digital IDs.
  - OEMs will seek CMs with relevant experience
- Powered devices
  - Not just a luxury, deliver consistent, optimal results
  - Requires specialized design/manufacturing/assembly capabilities
  - Watch for smaller electronics CMs to press in on this trend
- Union of biolgics and devices
  - Accelerating trend due to superior outcomes
  - Handling biologics a big step for most supply chain companies
  - Very profitable
- Additive manufacturing
  - Will be ubiquitous
  - Great opportunities today for prototypes and fixtures
  - Important to develop relevant expertise as will be disruptive technology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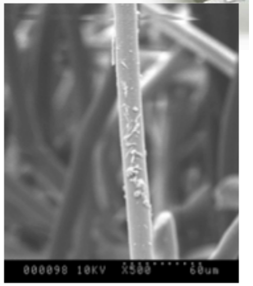
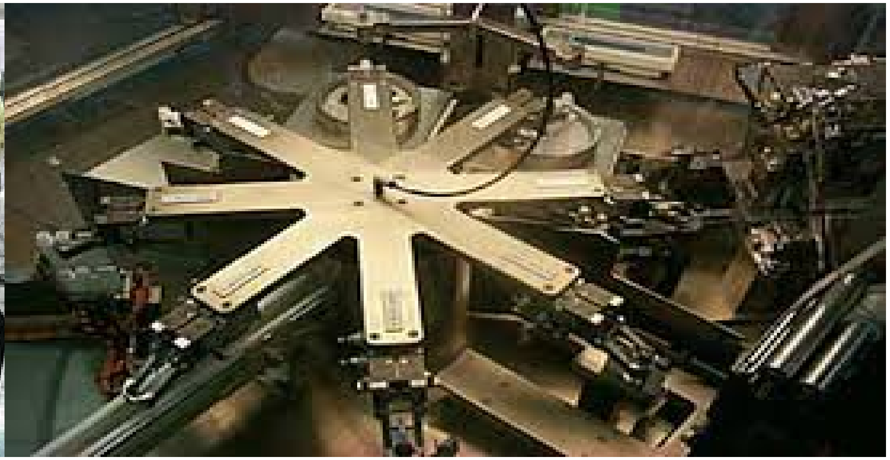

Drug Alone

LCC or Lower Cost?



- Pressure from OEMs to go offshore for lower costs – a mantra
- Makes sense for work with large labor component
- Automation increasingly may be more economically sensible
- Critical to **market** automation capabilities and results

The Lure of Branded Product

- Two models
  - Branded product sold to end-users
  - Branded product for private label sales
- To end-users
  - Challenging due to potential channel conflict
  - Gross margins of 60% or higher
  - High valuations, greater than 10X EBITDA, often much higher
  - Symmetry, Martech
- Private label
  - Evolving model
  - Can be full device or components/materials
  - Seems to add value but details are scarce
  - Lake Region, Creganna, Derringer-Ney

accellent
will be doing business as
Lake Region MEDICAL

POLEVAULT
THE GOLD STANDARD HYPOTUBE

PALINEY

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