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](http://www.manningadvisors.com) for more information
The Medical Device Industry

2015 Global Medical Device/Diagnostic Equipment Market

- Total market = US$345 billion in 2015, up 4% over 2014
- The Manning 30
  - 30 largest global device and diagnostic equipment companies
  - All have sales over $2 billion and pushing $3 billion
  - 75% of 2014 medical device and capital diagnostic equipment market
Four Key Trends for OEMs in 2016

- Integration of major acquisitions
- Focus on growth markets
- Embracing accountable care with new products and services
- Rationalization of manufacturing continues
Acquisition Moves To Integration

- **Top 30 were buying each other from 2013 and 2015**
  - Always purchased smaller firms for growth and still do
  - A wave of large company acquisitions
    - Medtronic-Covidien
    - Becton Dickinson-CareFusion
    - Zimmer-Biomet
    - S&N-ArthroCare
    - Pfizer-Hospira
  - Drivers:
    - Coverage and penetration of growth markets
      - By geography
      - By medical specialty → Moving to clearly defined dominance
    - Product pipelines
    - Low interest rates

- **For 2016 the focus is execution**
OEM Integration and Execution

- Acquirers are focused on successful integration of their purchases
  - Large promises made and to be kept
  - Great risks associated with premiums paid

- Key metrics of acquisition
  - Example - Medtronic has promised $875 million in savings by 2017

- Pressure to execute is on non-acquiring peers as the acquirers improve their market share and performance
  - Danaher, Bard, Boston Scientific, Baxter all mention their focus in 2016 is execution of existing plans

- For the supply chain
  - OEMs are digesting
  - Adjust to new geography of market leaders
  - Likely a two to three year hiatus from the commercial earthquakes of past two years
Growth Markets

<table>
<thead>
<tr>
<th>Region</th>
<th>Growth Rate</th>
<th>2014 % of Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>US/Canada</td>
<td>4-6%</td>
<td>40%</td>
</tr>
<tr>
<td>W. Europe/Japan/AUS</td>
<td>4-6%</td>
<td>29%</td>
</tr>
<tr>
<td>Growth Markets</td>
<td>8-18%</td>
<td>29%</td>
</tr>
<tr>
<td>Global</td>
<td>5-8%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- OEM sales focus moving to growth markets
  - China and India, in particular
  - Other Asian and Latin American markets
  - Smaller growth markets in Poland, Turkey, Persian Gulf

- 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 North American supply chain
  - Some opportunity on premium product exports as OEMs stress sales for affluent private-pay patients
  - Few opportunities without presence in growth economies
Accountable Care Expands

- Medicare trending away from fee-for-service
- 90% Category 2-4 by 2018 \(\Rightarrow\) Quality of Care based reimbursement
- Drives rest of US healthcare reimbursement model
OEMs Embrace Accountable Care

- OEMs are tailoring their products to fee for value instead of fee for service.

- Selling on the basis of:
  - Lower overall costs of treatment
  - Superior patient results

- Creation of care systems – families of products intended for use together

- The result is a smaller number of winning OEMs in the operating room.
Examples of New, Quality of Care Products

- St. Jude CardioMEMS for advanced warning of heart failure
- Cardinal Health congestive heart failure system
- Medtronic Operating Room Management Services
St. Jude CardioMEMs HF System

- Internal wireless sensor detects rise in vascular pressure, an early warning sign of heart failure

New standard of care
- Warns healthcare team in advance of need to change medications
- Automated alerts to providers, pharmacy, and patient
- Saves an average of $10,640 in hospitalization costs over three years vs. traditional methods
- Medicare approved due to superior results
Cardinal Health CHF Program

Cardinal Health is both a device company and large distributor of other OEMs products

Studied “Top 50” hospitals for congestive heart failure (CHF)

Found Tufts Medical Center’s combination of products and procedures:

- Reduced hospital stay time, cut costs $33K per case
- Reduced Rx costs $25K per case
- Survival rates over national average
- Would save 8,000 lives and $1.3 billion per year if adopted on a national basis

Cardinal Health promotes the Tufts results to the medical profession

Not surprisingly, Tufts uses Cardinal Health products for CHF treatment
Medtronic ORMS

- Medtronic ORMS = Operating Room Management Services
- Core from 2014 acquisition of NGC, an Italian operating room and cath lab management company
- Medtronic currently has contracts for $140 million annually, exclusive of MITG products used in the facility
- The company projects service revenue of $650 million by FY2020
- Moving beyond cath labs to hospital-wide consulting
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
  - Every aspect of device design, approval, manufacture, and distribution process has been successfully outsourced

- 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 have created fewer, larger players who are concentrating on integrating their acquisitions

- Sales focus shifting to growth markets

- New products being sold on results, creating fewer winners
  - Likely rewards care systems rather than an individual device
  - Early sign of OEMs using product and services to dominate hospital departments
  - OEMs taking on the burden of demonstrating superior outcomes

- Outsourcing will continue
The Supply Chain
Supplier Consolidation Underway

- We are in the era of the $100 million plus CM

- Primarily created by acquisitions
  - Greatbatch – Lake Region/Accellent
  - Tecomet – Symmetry ortho assets, et. al.
  - Freudenberg Medical – Medventure, VistaMed, Cambus, Hemoteq
  - Creganna – Precision Wire
  - Cadence – Plainfield Precision (three units)

- Why buy? It fits the preferred supplier profile
  - Broad portfolio of manufacturing and logistics capabilities
  - Financial size is equated with stability
  - Can afford quality systems

- Less business for also-rans
  - In the “charmed circle” or not
  - Don’t have to be over $100 million but it helps
Critical Factors for Success as a Preferred CM from the OEM Perspective

- The “Show Me” Requirements
  - Show me your company will be there five years from now
  - Show me I have less quality risk than any other source, including internal manufacture
  - Show me you can make the product for less than internal costs

- Prefer “One Neck To Choke” but the dream is not yet a common reality
  - Single point of communication, service, and responsibility for as much of the supply chain as possible
  - Many CMs still working out the details of consistent delivery, not used to managing so many activities
  - The reality of a single supplier is still not up to the promise but seems to be improving – weak execution

- Have a Unique Selling Proposition (USP)
  - No USP permits an uneducated buyer to define you
  - Having one challenges competitors
Is Device Design Necessary?

- No…but alliances may be wise
- CMs that can design generally win production on over 80% of projects
- Design is often self-limiting to specific classes of devices. Critical to synch design skills and manufacturing capabilities

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Proactive Planning Necessary for Preferred Status

- If accept
  - Most devices can be 100% outsourced and
  - The “Show Me” criteria hold true

- It is critical for the CM to focus ahead of the customer
  - Program management is essential for success
  - Ongoing expansion of service spectrum, cost management initiatives, and quality requirements

- Live in the future
  - Challenging in a largely reactive manufacturing setting
  - Primarily demonstrated risk reduction
New Manufacturing Opportunities

- Electronics and informatics
  - Accountable care requires massive data collection
  - Wiring of hospitals, operating rooms, and devices
  - Creating opportunities for non-traditional CMs
    - Google working with J&J on data analysis for OR products
    - Oracle focused on hospital/device integration
  - OEMs will seek CMs with relevant experience

- Powered devices
  - On the rise as they deliver consistent results
  - Requires specialized design/manufacturing/assembly capabilities
  - Watch for smaller electronics CMs to press in on this trend

- Union of biologics and devices
  - Accelerating trend due to superior outcomes
  - Handling biologics a big step for most supply chain companies
  - Very profitable

- Personalized medicine?
  - The promise of additive manufacturing
  - Compelling economics? The jury is out
For More Information

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