

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

March, 2017

Manning Advisors LLC

Merger and Acquisition, Advisory, and Financial Services



Executive Summary

- **Medical Device OEMs focusing on improved organic growth**
 - 2016 saw major OEMs relying heavily on acquisitions to improve revenues
 - OEMs see the eventual end of needle-moving acquisitions and are focusing on how to accelerate organic growth
 - Fee-for-value reimbursement and growing use of informatics are leading to redesign of product suites

- **The Supply Chain is consolidating around fewer, larger players**
 - The supply chain is also consolidating via acquisitions
 - OEMs are embracing risk reduction by working with larger supply chain partners
 - The new threat to existing supply chain companies is the penetration of the market by giant global contract manufacturers like Flextronics and Celestica
 - Opportunity exists for smaller, nimble players who can assist OEMs in bringing product to market more quickly
 - Opportunities also exist for specialized manufacturers



About Manning Advisors

- Merger and acquisition advisor to middle-market specialty materials and precision engineering companies
- Broad experience in advising the medical device supply chain
- Strategic planning and value development services
- Market analysis and market entry planning
- Offer both buy- and sell-side services
- Please visit www.manningadvisors.com for more information



The Origins of this Presentation

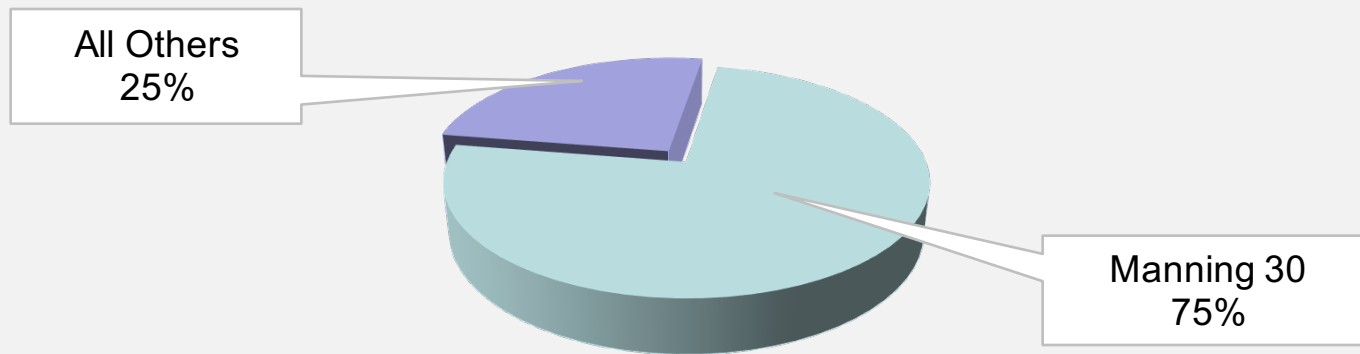
- Annual analysis of trends in the the medical device industry and implications for its supply chain. Past years at www.manningadvisors.com/manning-reports
- Grew out of a presentation to mdmX, an industry organization of medical supply chain companies
- The objectives –
 - Identify themes driving medical OEM market and product strategies
 - Link OEM actions to impacts on contract manufacturers
- Sources include public OEM presentations to the analyst community, SEC filings, news reports, and third-party analysis



The Medical Device Industry

2016 Global Medical Device/Diagnostic Equipment Market

REVENUE %



- Total market = Estimated US\$352 billion in 2016, up \$12 billion over \$340 billion in 2015 ¹.
- The Manning 30
 - 30 largest global device and diagnostic equipment companies
 - All companies on the list have sales over \$2 billion
 - The Manning 30 in aggregate control 75% of the global 2016 medical device and capital diagnostic equipment markets

¹. Please see Appendix 1 of this presentation, *The Manning 30*, for detail.

Conflicting Trends Have Constricted Revenue Growth



■ **Drivers** of revenue growth

• **Consolidation**

- **Big deals** by Medtronic, Danaher, others, grew top lines
- **Reorganization** of business units uncovered additional medical/diagnostic revenue, for example Philips and Siemens
- **Acquisitions** of smaller OEMs also drove revenues
- While small firms remain, few “needle-mover” targets remain
- Low interest rates fueled acquisitions

■ **Drags** on revenue growth

- **Weak**, and sometimes negative, **organic growth**. Average organic growth for Manning 30 under 5%¹.
- **A strong US dollar** suppressed 2016 revenues in an industry dominated by US-based companies

■ Major OEMs require accelerated organic growth as acquisition has its limits

¹. Organic growth estimated by Manning Advisors from public filings of Manning 30 companies. Reorganization of business units within a given company impacts growth estimates

Three Sets of Trends are Steering OEMs in 2017



1. **Long-term trends** of favorable demographics and expanding healthcare in developing countries
2. **Medium-term trend** of push towards consolidation
3. **Newer, evolving trends**
 - Accelerated product commercialization efforts
 - Fee-for-value reimbursement continues to grow in US
 - Move to early detection and improved disease management increases the use of electronics in devices and linkage into “big data” informatics systems

Long Term Trends Favor the Global Medical Device Industry

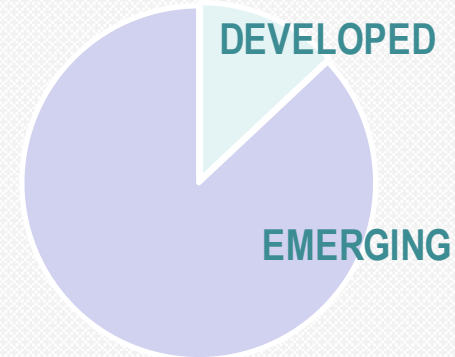


- **Continuing favorable demographics** for device consumption
 - North America, Europe, Japan hitting peak device consumption as post-WWII generation crosses 65
 - Middle classes of the developing world starting to consume product in volume
- **Expanding health coverage in developing countries**
- **The device industry can expect organic revenue growth in the low- to mid-single digits for years to come**

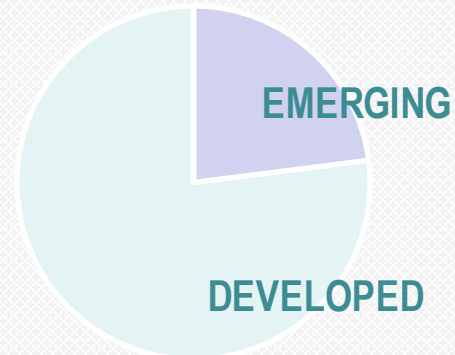
Significant Opportunity to Improve Patient Care in Emerging Markets ^{1, 2}.

2015

GLOBAL POPULATION
7.3 Billion



MEDTECH SPENDING
\$370 Billion



Developed –
(US, Western Europe,
Other Developed)

Emerging –
(China, India,
Other Emerging)

Source: MedTech market size per EvaluateMedTech; MedTech emerging vs. developed per BMI; Population per U.S. Census Bureau, International Database

1. From 2016 Johnson & Johnson Analyst Day Presentation, Gary Pruden, Executive Vice President, Hospital Medical Devices.
2. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Medium Term – Top 30 OEM Consolidation Continues



Acquirer	Target	Year
Smith & Nephew	Arthrocare	2014
Medtronic	Covidien	2015
Zimmer	Biomet	“
Becton Dickinson	CareFusion	“
Pfizer	Hospira	“
Cardinal	Cordis (J&J)	“
Dentsply	Sirona	2016
Abbott	St. Jude	“

- Major OEMs growing by acquiring other majors (plus smaller firms)
- Integration efforts well along. Promised savings are materializing
 - Medtronic are well along investors \$875 million annual savings by end of 2017 and is on track to deliver
 - Zimmer/Biomet plans \$270 million in annual savings by 2018
 - Abbott/St. Jude plans \$500 million in savings by 2020
- Threat to supply chains
 - Fewer major customers to approach
 - Evolving expectations of OEMs that supply chain partners should accept cost cuts and additional project risk

Evolving Trends – New Focus on Getting to Market More Quickly



- In **2015**, as companies digested large acquisitions and improved operations, buzzwords were **“integration”** and **“execution”**
- In **2016** the focus began to change. Leaders discussed **“increased innovation”** and **“need to innovate more rapidly”**
- Stated another way: **“Given our low organic growth rate we need to get new products to market more quickly”**
- Forming new partnerships
 - Non-standard medical players like J&J/Alphabet (Verb Surgical), Medtronic/IBM Watson, Boston Scientific/Accenture
 - Major OEMs stress the need to work with their own supply chains (J&J, Medtronic, Zimmer Biomet, S&N)
- Opportunity for supply chain if a supplier has something to bring:
 - Accelerate time-to-market via nimble manufacturing
 - Unique product development expertise/capability

Evolving Trends – New Focus on Getting to Market More Quickly



Priority: accelerate growth through innovation and transform our go-to-market models

— from Johnson & Johnson May, 2016 Analyst Presentation
Alex Gorsky
Chairman and CEO

“Our primary focus is growing our market share through what we are calling ‘Speed to Scale’ product launches. Speed to Scale involves coming to market with a steady cadence of new products as a result of faster innovation cycles...”

— Omar Ishrak
Chairman and CEO
Medtronic
Q3 FY16 Earnings Call

Focused On High-Value, High-Potential R&D

- *Shifting an increasing proportion of R&D investment to new product development*
- *Increasing R&D operational efficiency*
- *Enhancing internal capabilities*
- *Advancing strategic partnerships*
- *Pursuing the most compelling opportunities*

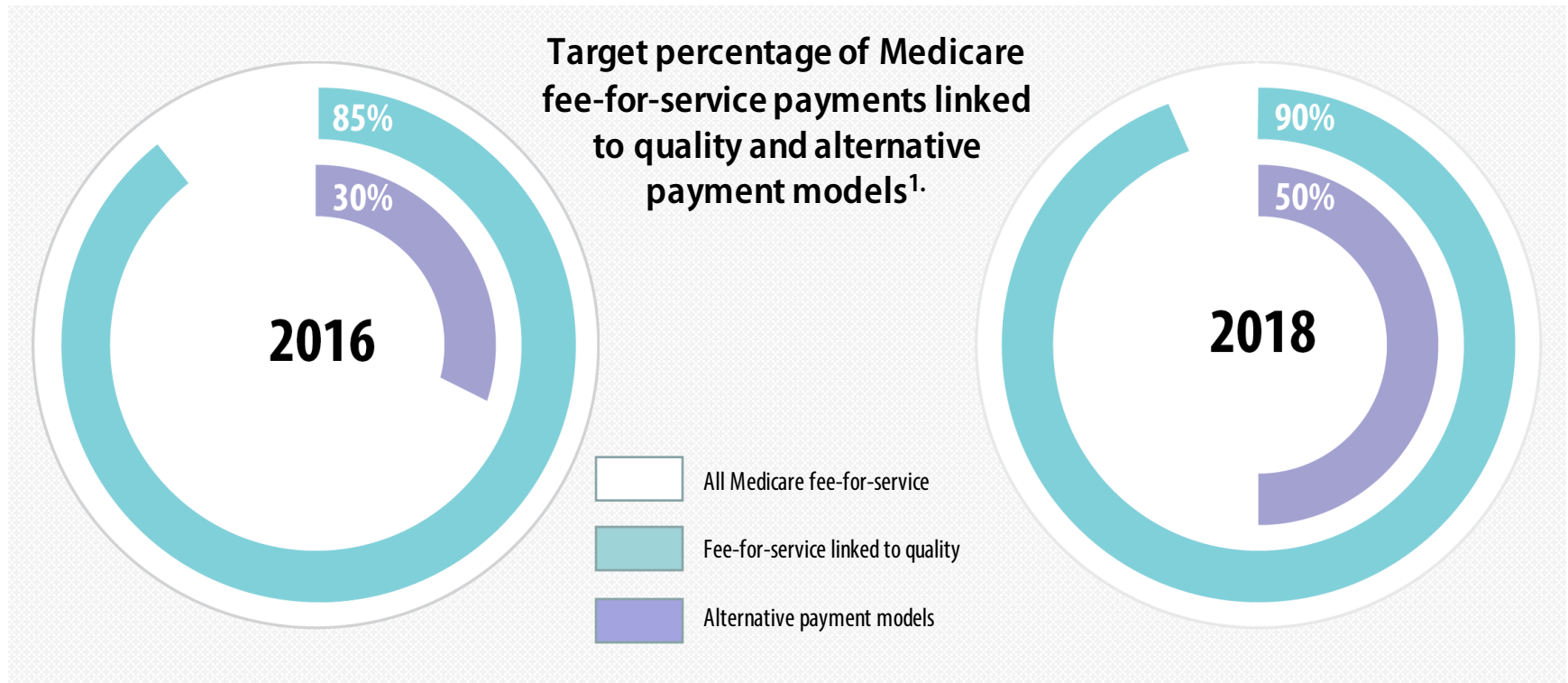
— from January, 2017 JP Morgan Healthcare Conference
José Almeida
Chairman and CEO
Baxter International

Evolving Trends – Fee-for-Value Creates New Device Opportunities



■ Fee-for-service being replaced by fee for value

- Fee-for-service rewards healthcare givers for activity, not results
- Fee-for-value rewards superior outcome, for example is higher reimbursement for fewer re-admittances or post-surgical infections



¹. Data from B.E. Smith "Healthcare Trends 2016". <https://www.besmith.com/thought-leadership/white-papers/healthcare-trends-2016>

Evolving Trends – Fee-for-Value Creates New Device Opportunities



- In 2015 Medicare and Medicaid represented 37% of US healthcare spending¹.
- In 2016 20% of Medicare reimbursements were fee-for-value based².
- US Centers for Medicare & Medicaid services target 75-80% of Medicare reimbursements by 2020¹. Private insurers also pressing ahead with fee-for-value through their own efforts and accountable care organizations
- A key motivation for OEM consolidation is offering a broader, more holistic product line with better guarantee of results
- OEMs see requirement/opportunity to re-design product lines
 - Moving to superior outcomes from use of new products
 - For existing product lines, making them demonstrably better for patients, providers, and reimbursement organizations
 - Devices for earlier detection/treatment of diseases, management of chronic diseases to reduce costs which in turn pushes medicine out of traditional settings
 - Smartphones and tablets becoming a key link in managing and operating devices
- Opportunity for supply chain to assist in the new generation of devices called for by fee-for-value payment model

¹. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

². Data from B.E. Smith "Healthcare Trends 2016".

Evolving Trends – Fee for Value Devices



St. Jude CardioMEMs



- 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

Boston Scientific WATCHMAN



- Left atrial appendage closure (LAAC) device protects against stroke from blood clots
- Addresses reality that 40% of patients prescribed blood thinners do not consistently take their medication
- Direct and indirect costs of strokes over \$65 billion annually in the US ¹.

■ New products designed for superior medical and financial outcomes

1. *Human and Economic Cost of Stroke*, Anthony Di Carlo, *Age and Ageing*, January, 2009. <https://doi.org/10.1093/ageing/afn282>

Evolving Trends – Electronics and Informatics



- Major OEMs recognize that medical devices are often some of the most sophisticated yet least connected products in the world
- Effort to improve outcomes, lower costs by networking devices and tracking data
- Every major player is involved in adding electronics to improve results
- For OEMs, electronics and informatics opportunities are not just standalone products
 - Increase revenue by selling suites of products, not just a standalone product
 - Product suites raise barriers for competitors
- Opportunity for supply chain to incorporate electronics and software in service offerings

Evolving Trends – New Electronic Devices



Boston Scientific ADVANTICS



- Integrated hardware/software systems linking patients, providers, business systems
- Offers
 - Remote monitoring of devices and disease states
 - Integration with medical records
 - Pooled results data to share with all providers

Stryker Mako Total Knee



- Robot used to assist in knee replacement surgeries
- Offers
 - Consistent, repeatable results
 - Less soft tissue damage than manual surgeries
 - Reduced re-admissions, lower costs

- Devices are increasingly incorporating electronic or electromechanical components to improve results

Summary



- OEM consolidation continues but at a slower pace
- Focus moving to accelerate organic growth. Partnership opportunities exist
- New product lines influenced by reimbursement trends and expanded technology are coming to market

The Supply Chain





Supplier Consolidation Continues

Target	Acquirer	Area
Ci Medical	Technimark	Design, molding, assembly
Creganna Medical	TE Connectivity	Minimally invasive devices
Phillips-Medisize	Molex	Design and manufacturing of complete devices
Laserage	AMETEK	Laser component fabrication
Forum Plastics	Squadron Capital	Precision injection and insert molding of surgical device components
CEA Medical Manufacturing	Graphic Controls	Critical care and powered devices
Cartika Medical	Teleflex	Cardiovascular components and assemblies
NorMedix	Surmodics	Catheters
Specialty Silicone Fabricators	Trelleborg	Silicone components
Remmele Medical/Alcoa	LISI Medical	Machined components and assemblies
Tegra	SFS Group	Precision machining and assemblies
Vention Medical	Nordson, MedPlast	MIS devices, design services, and components/assemblies

- Sampling of deals above demonstrates consolidation at all levels of the supply chain
- \$2 billion plus in deal activity

Rise of the \$100 Million Contract Manufacturer (CM) Continues – What Drives the Relentless Pace of Acquisitions?



■ OEM drive for **risk reduction**

- OEMs are now convinced they can outsource any portion of design, manufacturing, supply chain management, or logistics
- Prefer larger contract manufacturers as these partners allow them to transfer the risks of manufacture more efficiently to supply chain
- “Risk reduction” should be understood in its broadest sense. Given a range of outcomes, which approach offers the highest probability of increased income? Includes many factors including price, quality, timely delivery, absence of defects, transference of liability
- Looking for suppliers with broad capacities, global reach, up-to-date quality systems, and financial stability
- “One neck to choke” strategy

■ CMs doing acquisitions to **buy customers**

- OEM consolidation means fewer large customers for CMs
- For CMs, cracking into the next major OEM may be accomplished more rapidly by purchasing a desired customer’s supplier



No Lack of Suppliers but Right Suppliers?

■ Number of \$100 million plus CMs rising. Has the “risk reduction” theory played out?

✓ Yes

- Increasingly, only the larger CMs are awarded contracts for manufacturing new products
- Smaller suppliers are overlooked or disintermediated with associated margin pressures

✗ No

- While offering a broad portfolio of design, manufacturing, and logistical support services, the large CMs have struggled with consistent performance across projects
- Often formed from many acquisitions, large CMs are still working out their own internal integration
- Agile smaller suppliers can assist OEMs in rapidly getting product to market

The 800-Pound Gorillas are Coming



- **Global contract manufacturers are entering the medical supply chain at the top of the pyramid as prime contractors**

- **Flextronics International/Flex Medical**

- \$1.7 billion revenues, 65 medical products designed, ~60 medical transfer projects
- Opened 530,000 ft² medical manufacturing in Tijuana, Mexico in 2015 with 2,400 employees
- In 2015 acquired Farm, a medical device design company
- In 2016 hired John Carlson of J&J to run Flex Medical Solutions



- **Celestica HealthTech**

- Eight plants with ISO13485 certification
- Moving from an electronics focus to include manufacturing of MIS devices



- **Plexus Corp.**

- \$780 million in sales in healthcare/life sciences in in 2016
- Primarily electronics but moving into surgical instruments



Will the Global CMs Succeed in Med Device Manufacturing?



- Likely yes

- Highly motivated to enter medical markets
 - Historic electronics markets are mature and low margin
 - Medical and diagnostic devices are higher margin and growing rapidly
 - Have already made significant investments in medical manufacturing facilities and services

- Already have been accepted by major OEMs
 - Have significant medical revenues
 - Increasingly becoming prime contractors
 - Match the risk reduction profile
 - One neck to choke
 - Financial strength and longevity
 - Global sourcing mastery
 - Expert at cost reduction
 - Expert at electronics and systems integration

Will the Global CMs Succeed in Med Device Manufacturing?



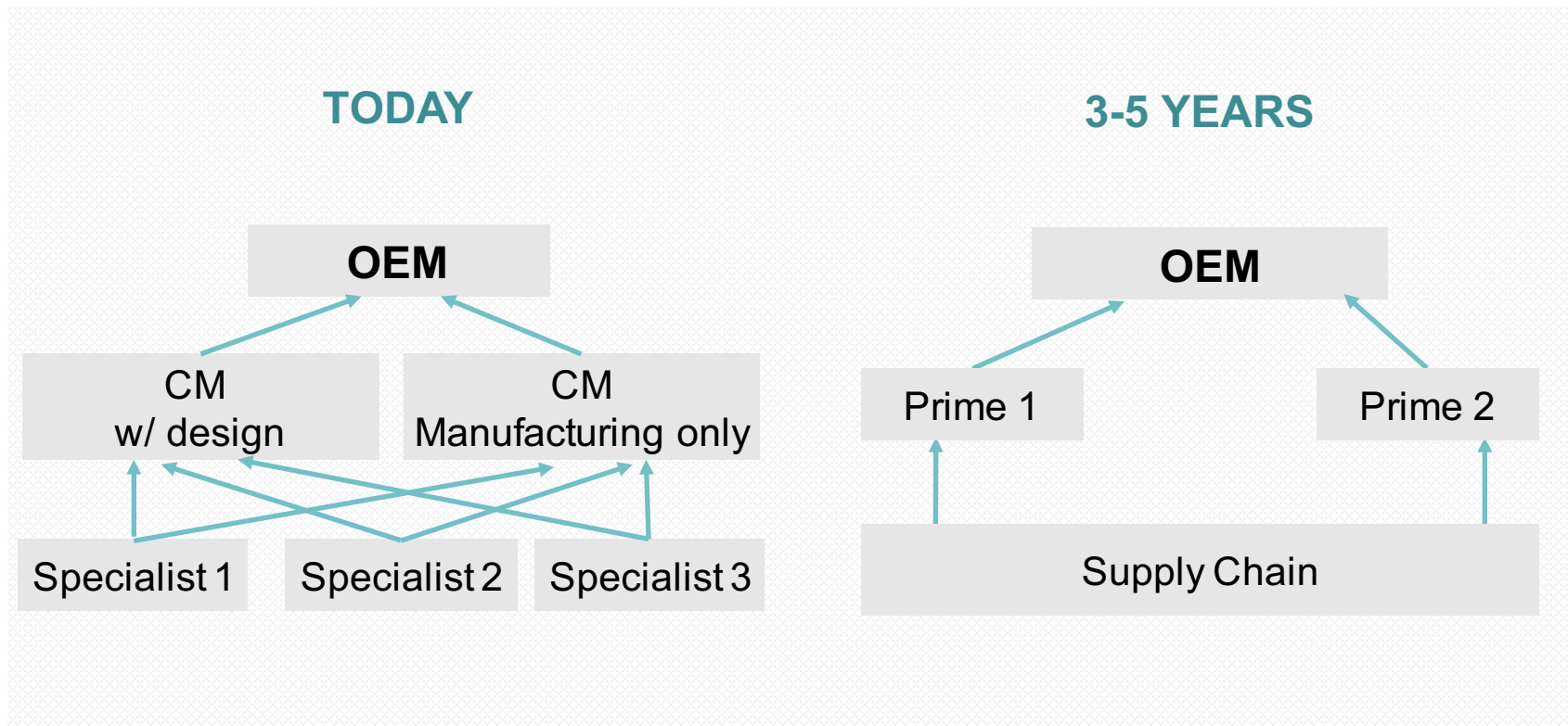
- Will they stumble in a demanding, regulated industry?
 - They may stumble but are likely to learn and recover
 - They are rapidly building a track record
 - Global CMs are angling to be prime contractors – may take three to five years to become “go to” players

- Threat to specialized medical CMs?
 - Yes, the global CMs will pull business and eventually press margins of sub-contractors
 - Specialized medical device expertise and agility are key to survival



The Evolving Supply Chain Structure

■ New tier structure evolving





The Evolving Supply Chain Structure

- Prime – Responsible for complete products and product lines
 - \$100 million or greater in revenues
 - Broad portfolio of manufacturing capabilities
 - Excel at program management
 - Excel at supply chain management
 - Often provide design services
 - Modern facilities, regular addition of new capabilities
 - Subcontractor – Providing components and assemblies to primes
 - Will face radical pressure on costs and quality
 - Maintaining profitability will be tough over the next five years
 - Requires continuous improvement to remain profitable
 - Specialist – Unique component or service
 - Do one thing well
 - Identify your company's place in the supply chain
-

Critical Factors for Success in the New Supply Chain



■ Risk reduction

- Financial stability
- Quality
- Time to market/agility
- Cost reduction

■ Partnership capabilities

- Design/development excellence in a niche/niches
- Supply chain
- Logistics
- Electronics and informatics

For All CMs — Canaries In the Coalmine



✓ Success

- Growth in revenues with slight increases in profit margins from year to year
- Expanding offering of design, manufacturing, or supply chain services
- Gain in new product launch projects from year to year
- Most challenging: increasing number of major OEMs customers with \$1 million plus projects

✗ Stagnation

- No expansion of new capabilities to customers
- Declining number of new product projects, stuck on legacy work
- Disintermediation from OEMs
- Weakening revenue and profitability growth rates

Appendix 1 – The Manning 30



TOP MEDICAL DEVICE MANUFACTURERS	RANK	2016E REVENUES (US\$ Billions)
Medtronic	1	29.0
Johnson & Johnson	2	24.9
Philips Healthcare	3	18.6
GE Healthcare	4	17.6
Siemens Healthineers	5	15.2
Danaher	6	12.8
Becton Dickinson	7	12.5
Cardinal Health	8	12.4
Stryker	9	10.9
Baxter International	10	10.0
Abbott Labs	11	10.0
Boston Scientific	12	8.3
Zimmer Biomet	13	7.7
Essilor	14	7.5
B. Braun	15	7.0
St. Jude Medical	16	6.0
Alcon/Novartis	17	5.8
3M Healthcare	18	5.5
Olympus Medical	19	5.4
Smith & Nephew	20	4.6
Terumo	21	4.5
Dentsply Sirona	22	3.7
CR Bard	23	3.7
Fresenius	24	3.3
Varian Medical	25	3.2
Getinge Group	26	3.2
Edwards Lifesciences	27	3.0
Hologic	28	2.8
Intuitive Surgical	29	2.6
Sonova Holding	30	2.3

For More Information



- Please contact:

Tony Freeman

Managing Director

Manning Advisors LLC

www.manningadvisors.com

(917) 868-0772

tfreeman@manningadvisors.com