

Medical Market Segmentation

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CCI Business Analytics

What We Do

- Business Analytics is a dedicated CCI unit that functions as a shared resource
- Purpose: provide key stakeholders with knowledge and tools to optimize strategic decision making and mitigate investment risk
- Key functions
 - Quantification of commercial potential
 - Evaluation of competitive technologies, approaches, companies
 - Identification of potential licensees/commercial partners



Risk Mitigation: Multifacteted

Sources of Risk Along the Commercialization Continuum



Market Opportunity

Everything is a Multibillion Dollar Opportunity

- Market opportunity can be defined in many ways – some lacking value
- Sensational headlines are ubiquitous, but often bereft of context, rationale
- Sophisticated customers will see through “fluff”
- Be prepared to defend your claims with thoughtful, relevant data

“Peripheral Vascular Stents Present Billion-Dollar Opportunity”

“Multi-Billion-Dollar Opportunity – Disc Replacements Will Soon Surpass Fusions as Surgical Solution”

“Global Obesity – The Ballooning Billion Dollar Opportunity for Controlling the Bulge”

“Multi-Billion Dollar Opportunity in Hypertension is Progressing Well”

Market Opportunity

Patients

- Real-world examples of disease states with significant patient populations
- All valid, useful starting points
- However, topline data are insufficient to truly define most opportunities

An estimated 5.7M Americans ≥ 20 years of age have Heart Failure

The 2010 worldwide prevalence of AF was estimated at 33.5M

PAD affects ~8.5M Americans

Source: AHA Heart Disease and Stroke Stats, 2015



Market Segmentation

The Importance of Good Market Segmentation

- Indicates your understanding of an addressable target market
- Establishes your credibility
 - Presentation
 - Data sourcing
- Establishes a baseline for forecasts and scenario analysis
- Determines basis for marketing and sales plan
- Contributes to valuation for financings
- A critical first step in building a business plan; requires continuous refinement
- Triangulate from multiple data sources (no data are perfect!)

Market Segmentation

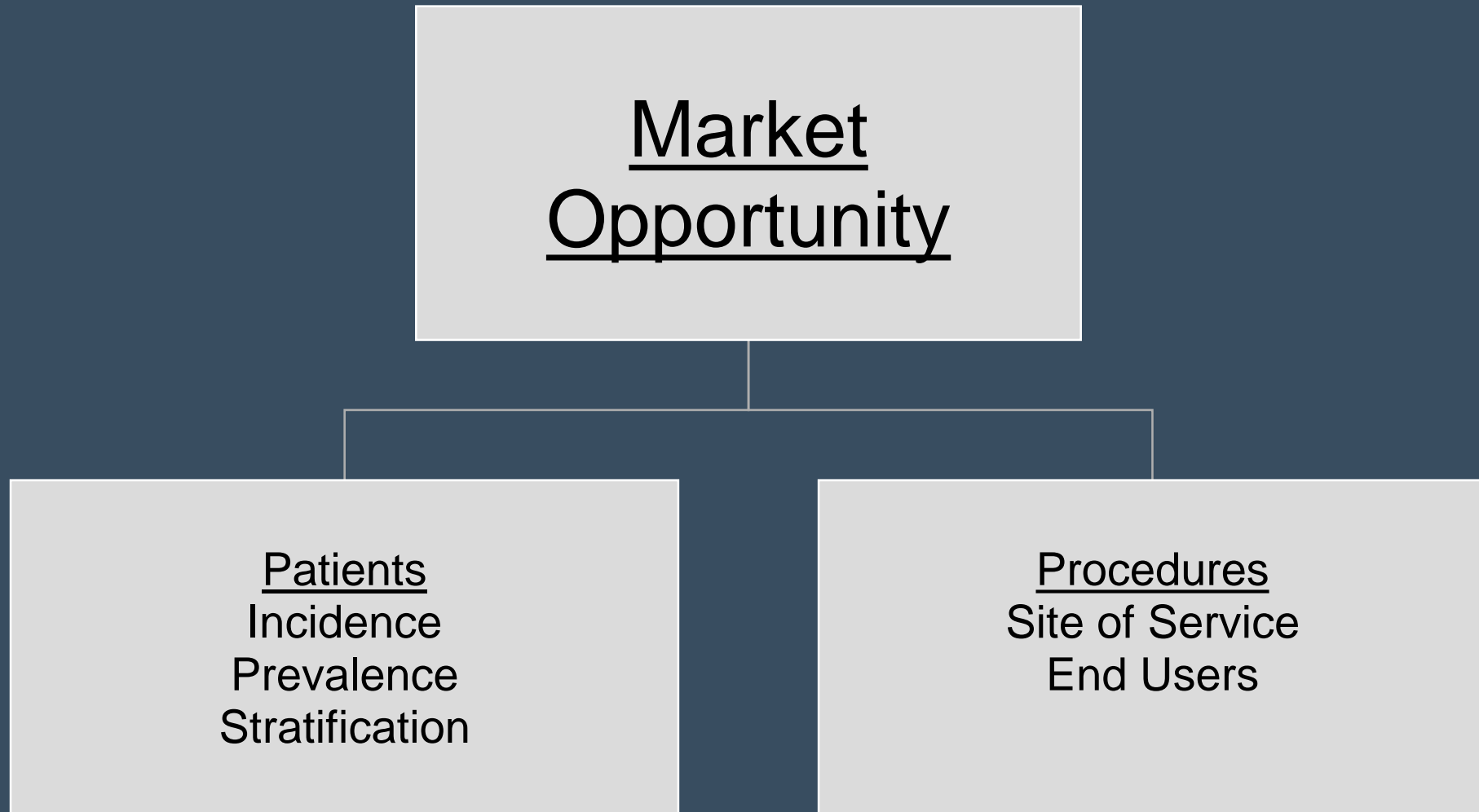
Dimensions

Market
Opportunity

Patients
Incidence
Prevalence
Stratification

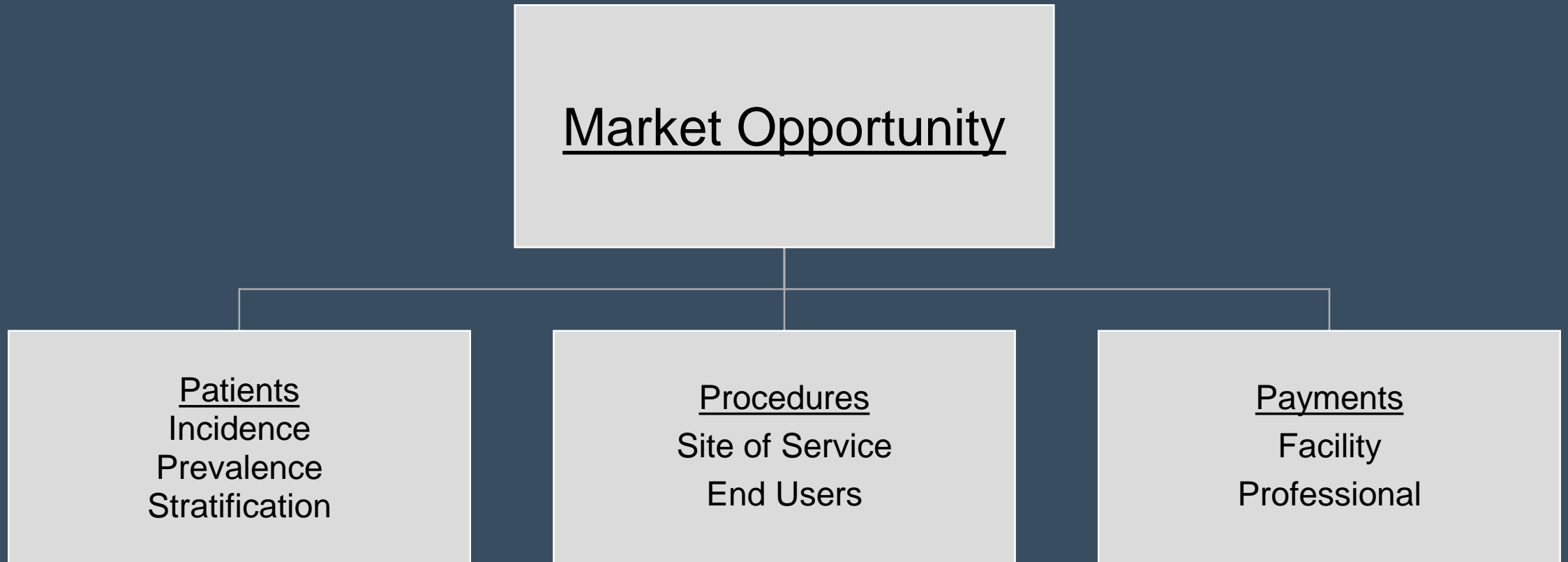
Market Segmentation

Dimensions



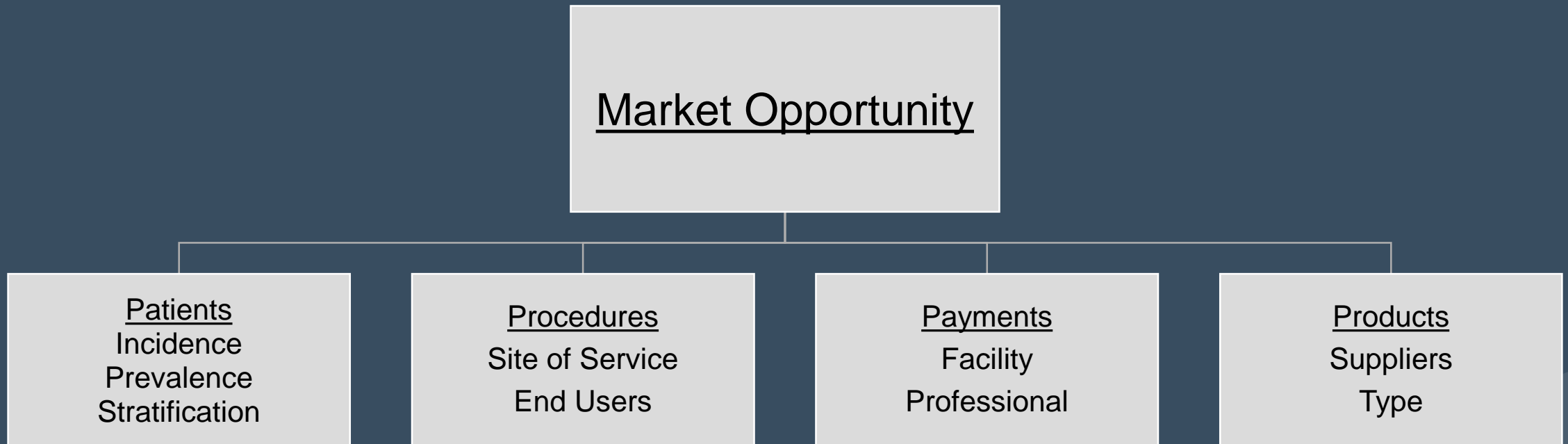
Market Segmentation

Dimensions



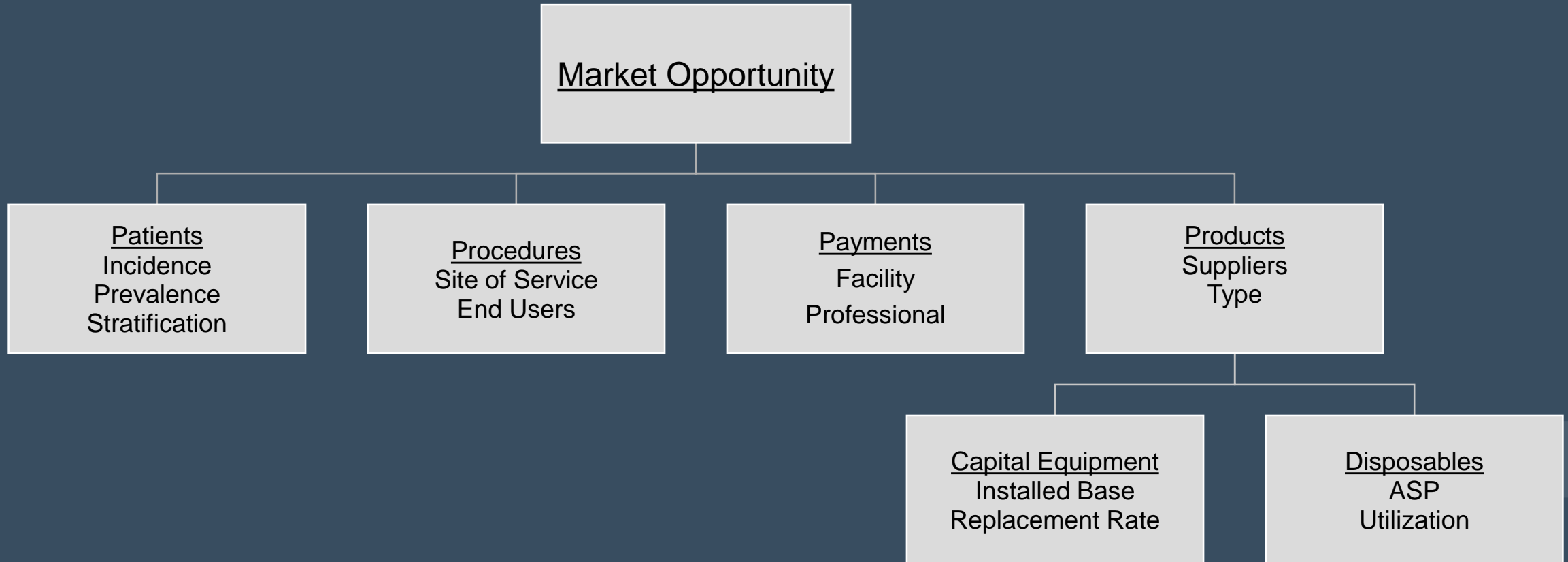
Market Segmentation

Dimensions



Market Segmentation

Dimensions



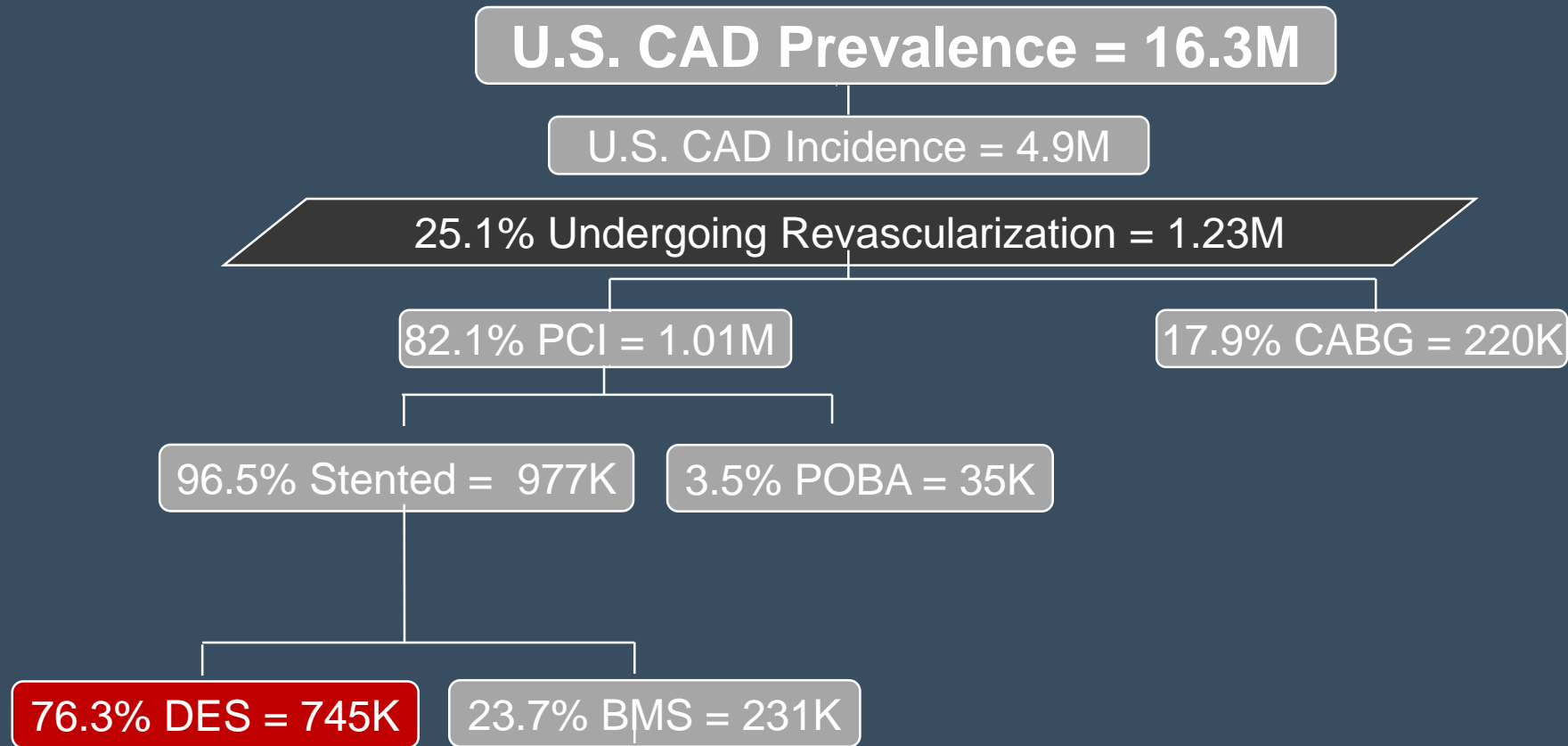
Market Segmentation

Is Bigger Always Better? The Case for Orphan Drugs

- Rare disease patient populations are defined in law as:
 - USA: <200k patients (<6.37 in 10,000 based on US population of 314M)
 - EU: <5 in 10,000 (<250k patients, based on EU population of 506M)
 - Japan: <50k patients (<4 in 10,000 based on Japan population of 128M)
- Financial incentives by law include:
 - Market exclusivity (USA 7 years from approval, EU 10 years)
 - Reduced R&D costs (R&D tax credits, grants, waived fees)
- Significantly higher pricing and costs per patient per year
 - USA mean cost of \$112k (vs. \$23k for non-orphan drugs)
 - USA median cost of \$66k (vs. <\$5k for non-orphan drugs)
- WW orphan drug sales forecast to grow from ~\$100B in 2015 to reach \$178B by 2020
 - 11.7% CAGR, double overall Rx market growth
 - From 6.1% of WW Rx sales in 2000 to 20.2% in 2020
 - Blockbuster potential: by 2020, top 20 orphan drugs are forecast to generate a minimum of \$2.5B in WW annual revenue, reaching as high as \$12.7B

Market Segmentation

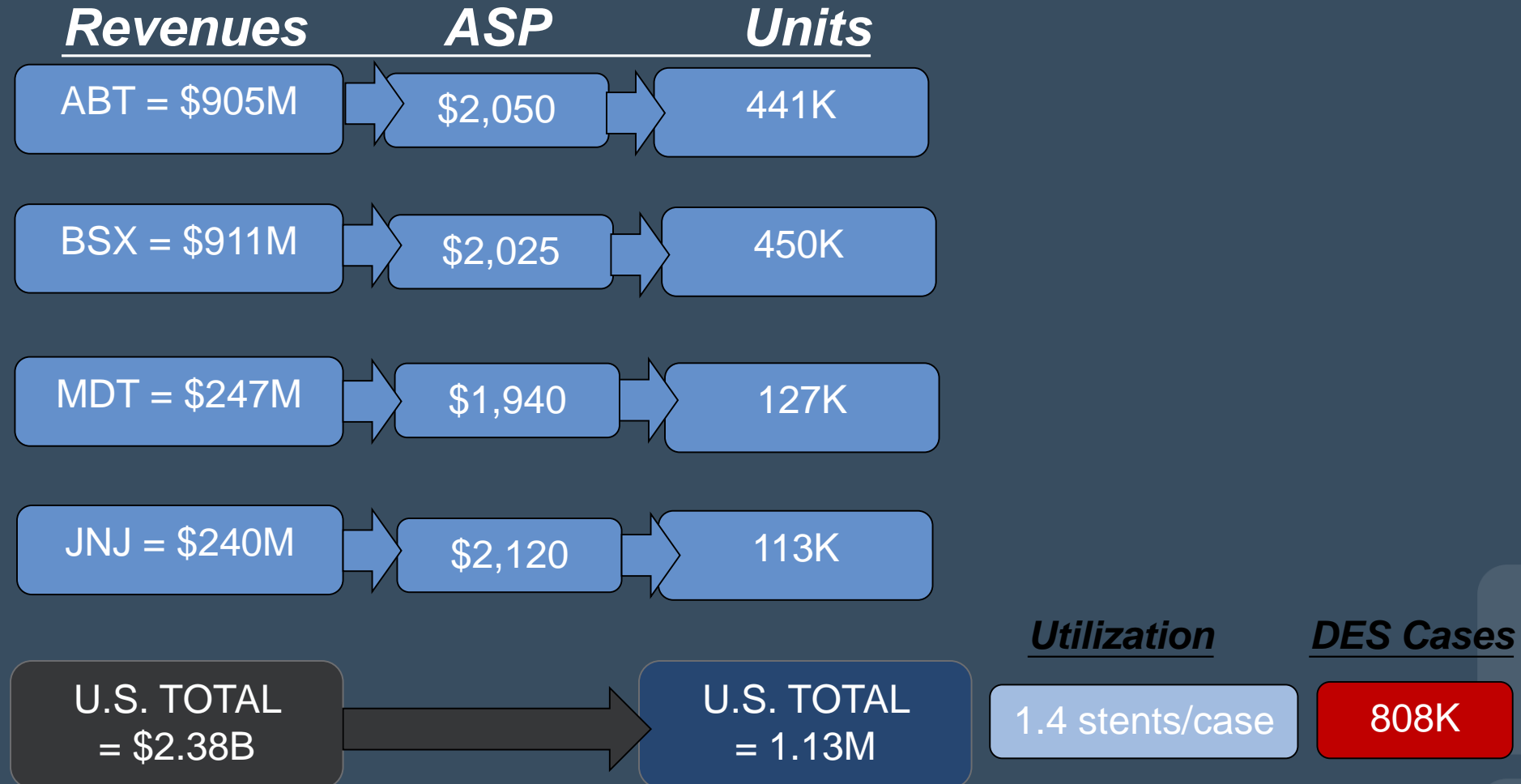
Case Study: Drug Eluting Stents (Top Down)



Note: Actual data is outdated, inaccurate and is shown here for example purposes only. Please do not reproduce or use for market modeling!

Market Segmentation

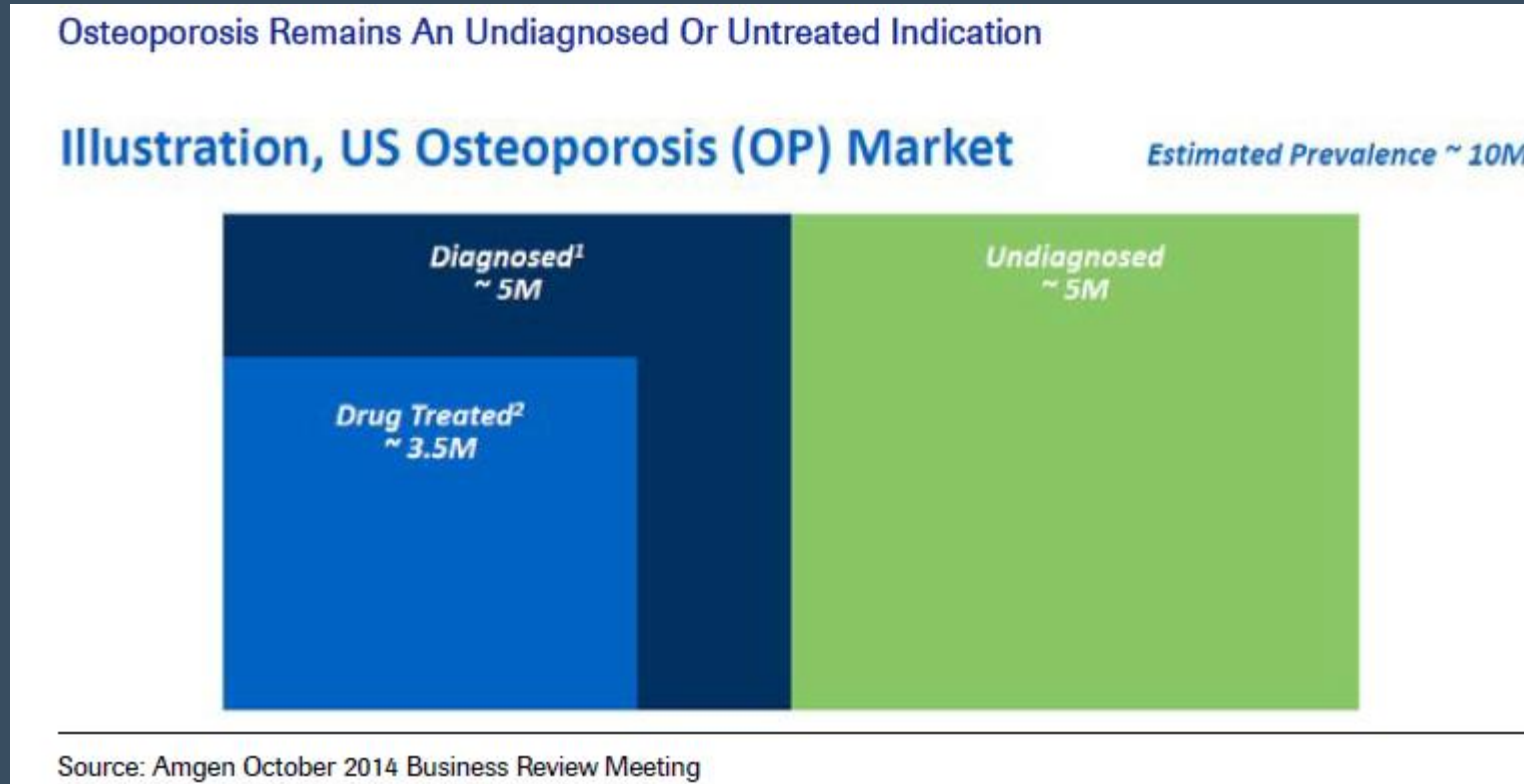
Case Study: Drug Eluting Stents (Bottom Up)



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Market Segmentation

Case Study: Osteoporosis



Source: Cowen and Company

Market Segmentation

Case Study: Osteoporosis

U.S. Denosumab Revenue Model For The Treatment Of PMO

	2015A	2016E	2017E	2018E	2019E	2020E
Osteoporosis						
Number of patients with osteoporosis (M)	12.9	13.1	13.3	13.5	13.7	13.9
<i>% growth in number of patients with osteoporosis</i>	<i>1.5%</i>	<i>1.5%</i>	<i>1.5%</i>	<i>1.5%</i>	<i>1.5%</i>	<i>1.5%</i>
Number of patients diagnosed with osteoporosis (M)	9.4	9.6	9.7	9.9	10.0	10.2
Number of patients actively being treated for osteoporosis (M)	6.4	6.5	6.6	6.7	6.8	6.9
<i>% of patients who stop treatment for osteoporosis (M)</i>	<i>11.0%</i>	<i>11.0%</i>	<i>11.0%</i>	<i>11.0%</i>	<i>11.0%</i>	<i>11.0%</i>
Number of patients who stop treatment for osteoporosis (M)	1.0	1.1	1.1	1.1	1.1	1.1
<i>% of patients candidates for denosumab</i>	<i>50%</i>	<i>50%</i>	<i>50%</i>	<i>50%</i>	<i>50%</i>	<i>50%</i>
Number of patients candidates for denosumab (M)	4.2	4.3	4.4	4.4	4.5	4.6
<i>% of patients administered denosumab</i>	<i>9%</i>	<i>10%</i>	<i>11%</i>	<i>11%</i>	<i>11%</i>	<i>11%</i>
Number of patients administered denosumab (M)	0.4	0.4	0.5	0.5	0.5	0.5
Price of denosumab per patient per year	\$1,750	\$1,800	\$1,850	\$1,900	\$1,950	\$2,000
U.S. denosumab sales in osteoporosis (\$MM)	\$700	\$800	\$857	\$914	\$971	\$1,029
<i>Y/Y growth</i>	<i>12%</i>	<i>14%</i>	<i>7%</i>	<i>7%</i>	<i>6%</i>	<i>6%</i>

Source: Cowen and Company

Market Segmentation

Case Study: Renal Denervation

in millions	2011	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
United States										
Population (millions)	313.3	316.4	319.6	322.8	326.0	329.3	332.5	335.9	339.2	342.6
Adult Population	233.5	236.6	239.8	243.0	246.2	249.5	252.9	256.2	259.6	263.1
% of total	74.5%	74.8%	75.0%	75.3%	75.5%	75.8%	76.0%	76.3%	76.5%	76.8%
Hypertension	60.2	62.1	64.0	65.9	67.9	70.0	72.0	74.1	76.3	78.5
% of total	25.8%	26.2%	26.7%	27.1%	27.6%	28.0%	28.5%	28.9%	29.4%	29.8%
Essential HTN	51.2	52.8	54.4	56.0	57.7	59.5	61.2	63.0	64.9	66.7
% of prevalence	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Secondary HTN	9.0	9.3	9.6	9.9	10.2	10.5	10.8	11.1	11.4	11.8
Diagnosed	43.2	45.1	46.9	48.9	50.8	52.8	54.8	56.8	58.9	61.0
% of prevalence	84.4%	85.4%	86.3%	87.2%	88.0%	88.8%	89.5%	90.2%	90.8%	91.4%
Medically Treated	39.2	41.1	43.0	45.0	47.0	49.1	51.1	53.3	55.4	57.6
% of prevalence	76.6%	77.9%	79.1%	80.3%	81.4%	82.5%	83.5%	84.5%	85.4%	86.3%
Controlled	28.6	30.3	31.9	33.6	35.4	37.2	39.0	40.9	42.8	44.8
% of Rx treated	73.0%	73.7%	74.2%	74.7%	75.3%	75.8%	76.3%	76.8%	77.3%	77.8%
Uncontrolled	10.6	10.8	11.1	11.4	11.6	11.9	12.1	12.4	12.6	12.8
Stage I	9.0	9.2	9.4	9.7	9.9	10.1	10.3	10.5	10.7	10.9
Stage II	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.3	1.3
Stage III	0.5	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Stage II/III	1.6	1.6	1.7	1.7	1.7	1.8	1.8	1.9	1.9	1.9
Anatomical Restrictions	<u>0.5</u>	<u>0.5</u>	<u>0.5</u>	<u>0.5</u>	<u>0.5</u>	<u>0.5</u>	<u>0.5</u>	<u>0.6</u>	<u>0.6</u>	<u>0.6</u>
Target Population	1.1	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3

Source: J.P. Morgan

Market Segmentation

Case Study: Renal Denervation

<u>United States</u>	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Target Population (millions)	1.2	1.2	1.2	1.3	1.3	1.3	1.3
Market Opportunity		\$7,328	\$7,307	\$7,085	\$6,719	\$6,359	\$5,949
Procedure Volume							
Medtronic		12,500	28,500	41,250	54,000	69,750	87,885
Other		<u>0</u>	<u>1,500</u>	<u>13,750</u>	<u>36,000</u>	<u>69,750</u>	<u>107,415</u>
Total		12,500	30,000	55,000	90,000	139,500	195,300
Penetration		1.0%	2.4%	4.3%	6.9%	10.5%	14.5%
Market Shares							
Medtronic		100.0%	95.0%	75.0%	60.0%	50.0%	45.0%
Other			5.0%	25.0%	40.0%	50.0%	55.0%
Pricing							
Average Selling Price		\$6,000	\$5,850	\$5,558	\$5,168	\$4,807	\$4,422
Revenue							
Medtronic		75.0	166.7	229.2	279.1	335.3	388.6
Other		<u>0.0</u>	<u>8.8</u>	<u>76.4</u>	<u>186.1</u>	<u>335.3</u>	<u>475.0</u>
Market Revenue		\$75.0	\$175.5	\$305.7	\$465.2	\$670.5	\$863.6

Source: J.P. Morgan

Market Data

Suggested Resources

Focus	Sources
Patient Data	<ul style="list-style-type: none">• U.S. Census Bureau• Clinical Literature (PubMed)• Professional Societies (e.g. AHA, ACC, ACS, AAOS)
Procedure & Payment Data	<ul style="list-style-type: none">• AHRQ/HCUP (National Inpatient Sample, national ED visits)• NCHS (NHDS, NSAS, NAMCS, etc.)• CMS (Medicare Part B Summary Data, Physician Fee Schedule)• IQVIA (formerly IMS; Rx audits)• Truven Health Analytics (all payer claims data)• Manufacturer reimbursement coding guides
Product Data	<ul style="list-style-type: none">• Public companies (SEC filings, press releases, investor presentations, earnings calls, analyst coverage)• Private companies (D&B/Hoover's, Reference USA, bizjournals.com)• FDA databases (CDER, CDRH)• Syndicated reports from 3rd party market research firms (Informa, BCC Research, Evaluate Pharma, Decision Resources, Frost & Sullivan, GlobalData, GBI Research, iData Research, LifeScience Intelligence)• Equity research reports (individual brokerage firms; Thomson Reuters)
Other Sources	<ul style="list-style-type: none">• American Hospital Association• American Hospital Directory• American Medical Association• Bureau of Labor Statistics• Clinicaltrials.gov

Takeaways

The Importance of Good Market Segmentation

- Viability of an invention requires an understanding of the *addressable* market
- Defining the addressable market requires an understanding of *market segmentation*
 - Patients
 - Procedures
 - Payments
 - Products





Every life deserves world class care.