

EMOCLINIC SYMPOSIUM  
SULLE SPONDE DEL TICINO

“Cardiologia  
ieri, oggi  
e domani”



NOVARA, 7 e 8 Giugno 2018

AUDITORIUM  
BANCA POPOLARE DI NOVARA  
VIA NEGRONI, 11



# Dove sta andando la cardiologia interventistica?



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# *What is (medical) innovation?*

***Novelty that  
creates value***



# Interventional Innovation

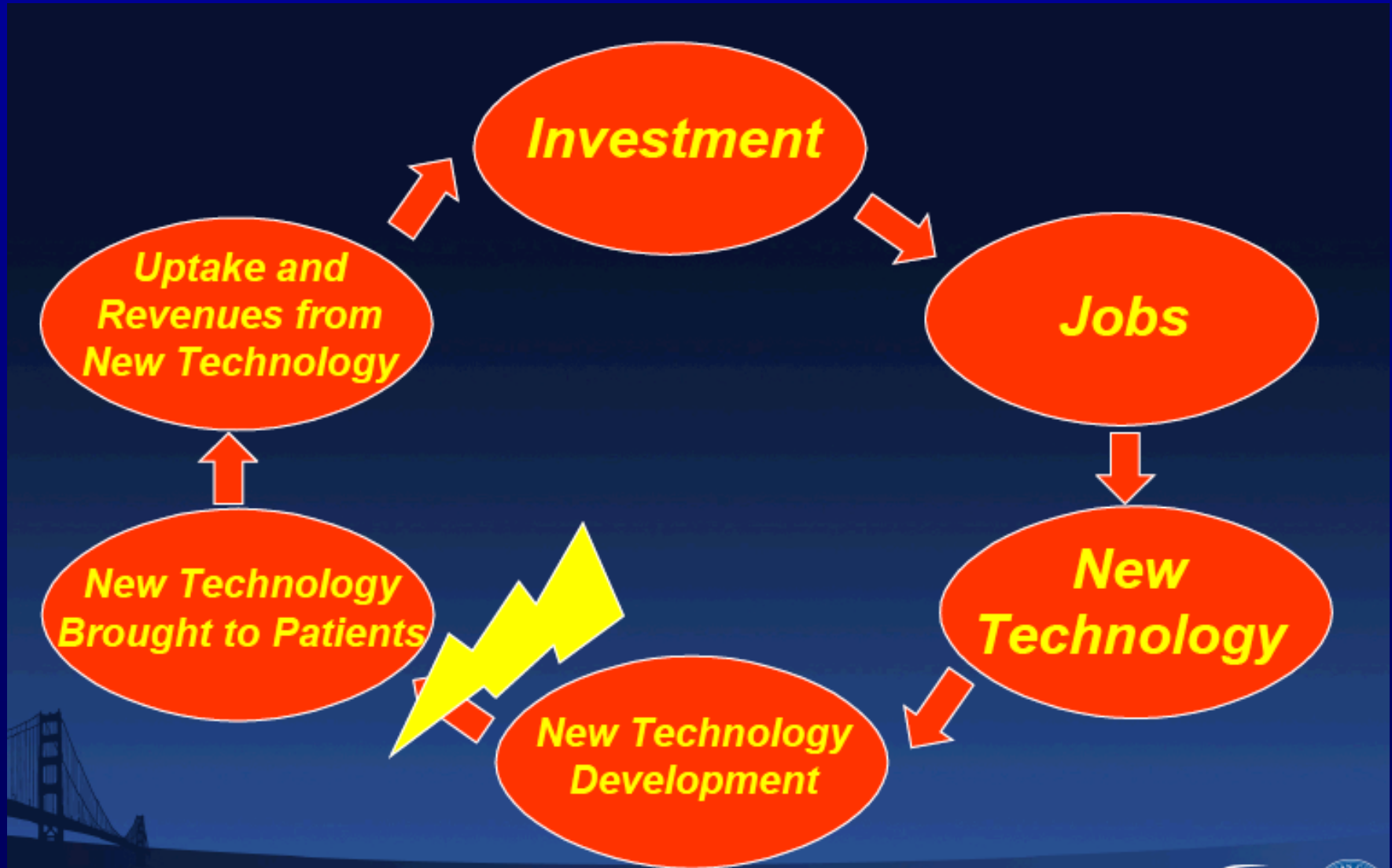
## *Lessons Learned*

- Must address a “clinical need” - a specific and well defined patient care-oriented clinical imperative!
- Can be advanced technology, but must be simple to explain and easy to use
- Evidence-based clinical data “reigns supreme” in 2018 – forget classical marketing concepts
- **Must be cost sensitive and respect problematic economic milieus during a global financial crisis!**



# The Virtuous Cycle of Innovation

*Crisis of Interventional Innovation?*

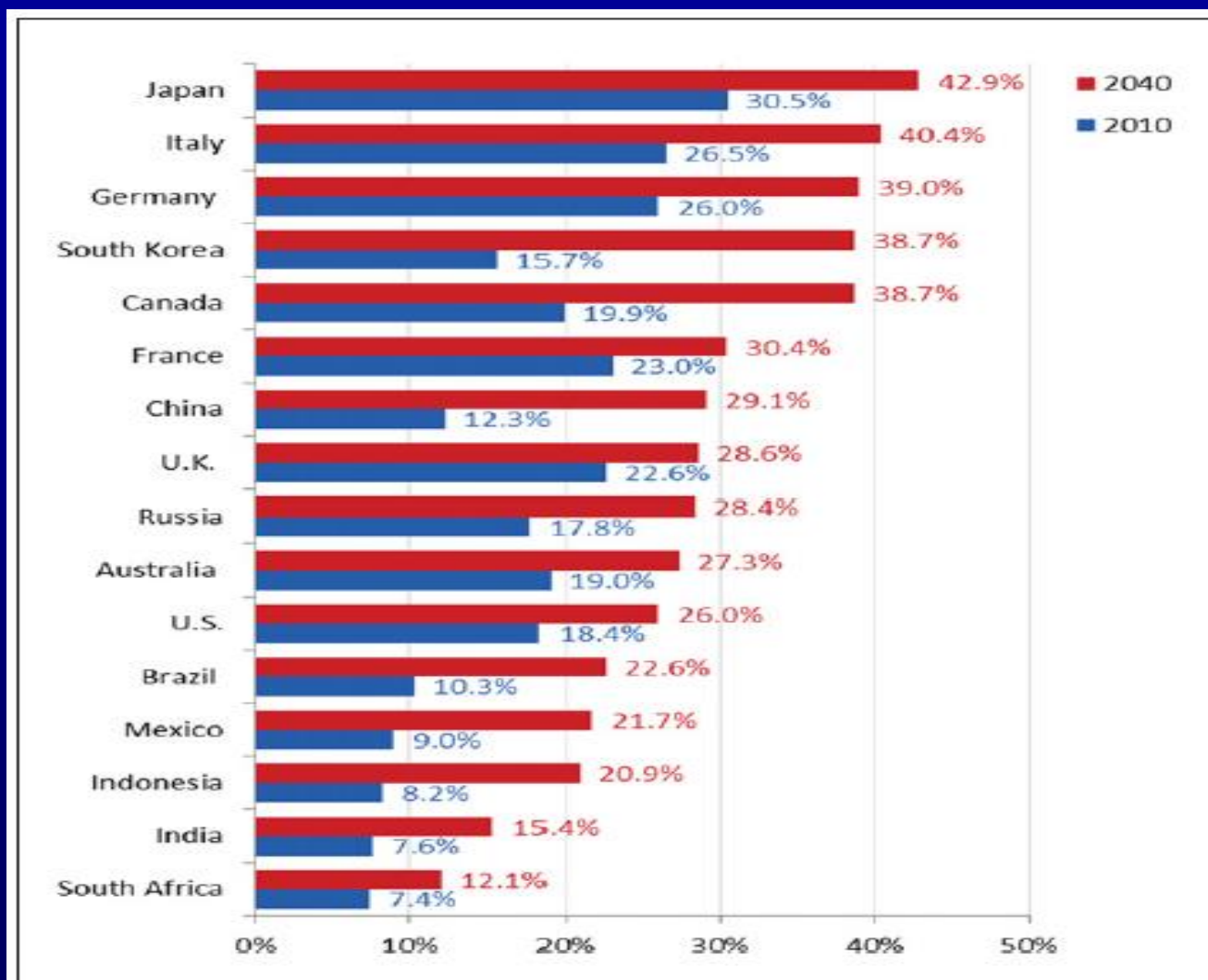


# Forces of Change (1)

***AGING!***

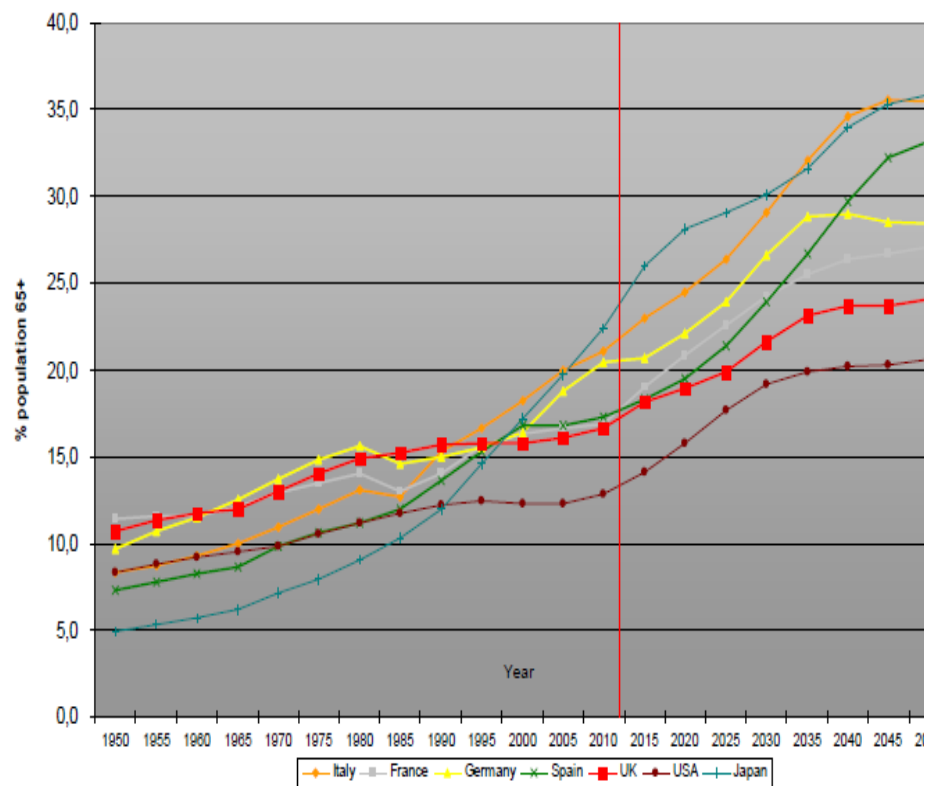


# Elderly (Age 60 Years and Older), as Percent of Population in 2010 and 2040

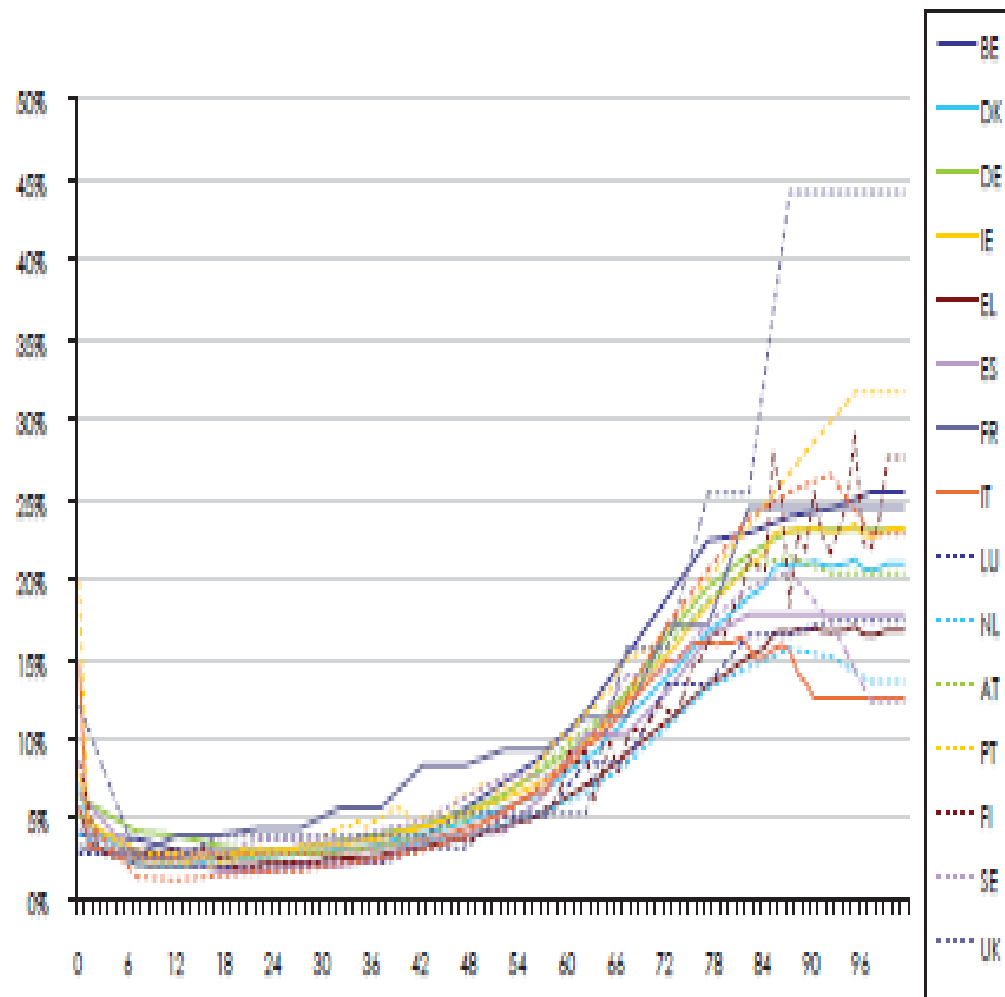


# Aging inflates demand & expenditure

## World population evolution (% of +65)



Source: United Nations' Dept Economic & Social Affairs, 2006



Source: The 2009 Ageing Report: economic and budgetary projections for the EU-27 Member States (2008-2060).

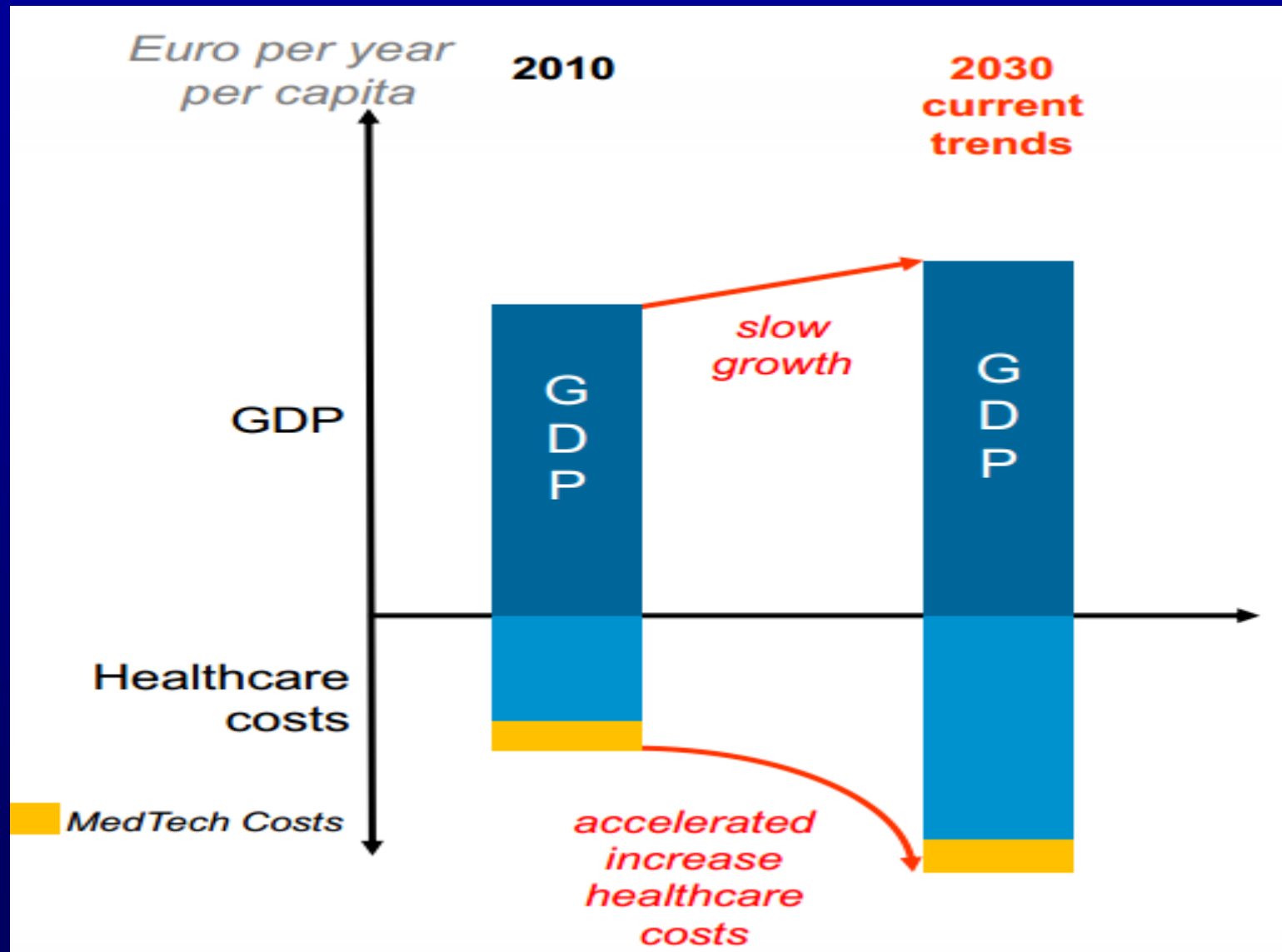
The European Commission (DG ECFIN) and the Economic Policy Committee (AWG) ISBN 978-92-79-11363-9. DOI 10.2765/80301. © European Communities, 2009

# Forces of Change (2)

***Worldwide financial constraints*** -  
affecting physician salaries, hospital  
reimbursement, and industry revenues



# Demand for health care cannot be met



# Per Capita Health Care Spending by Country – 2010

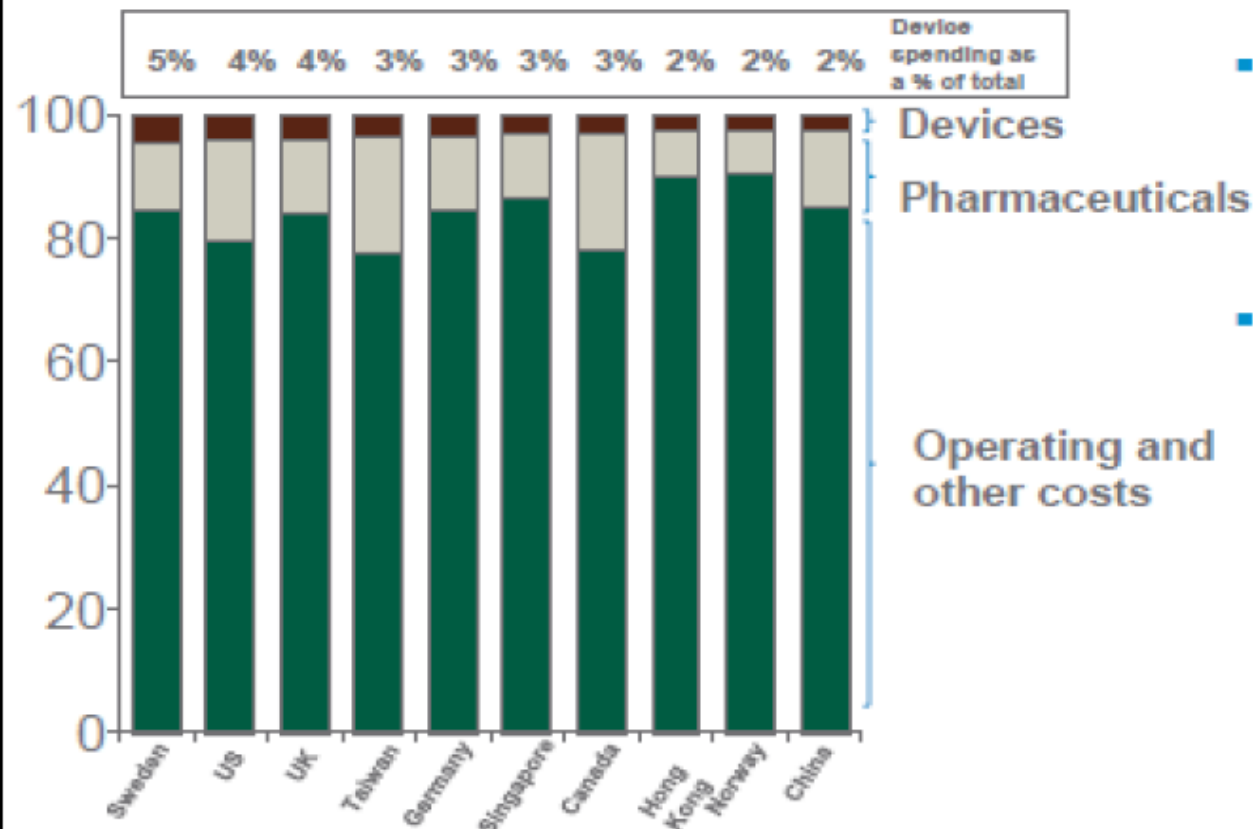


*JAMA, September 26, 2012—Vol 308, No. 12*



# Breakdown of current healthcare spending

(%, 2008)



Source: Espicom; WHO; World Bank, LEK analysis

- Medical device spending accounts for 2-5% of total healthcare spending

- Operational expenses reach ~80-85% of total spending

**Reallocations of spending here have a significant impact!**

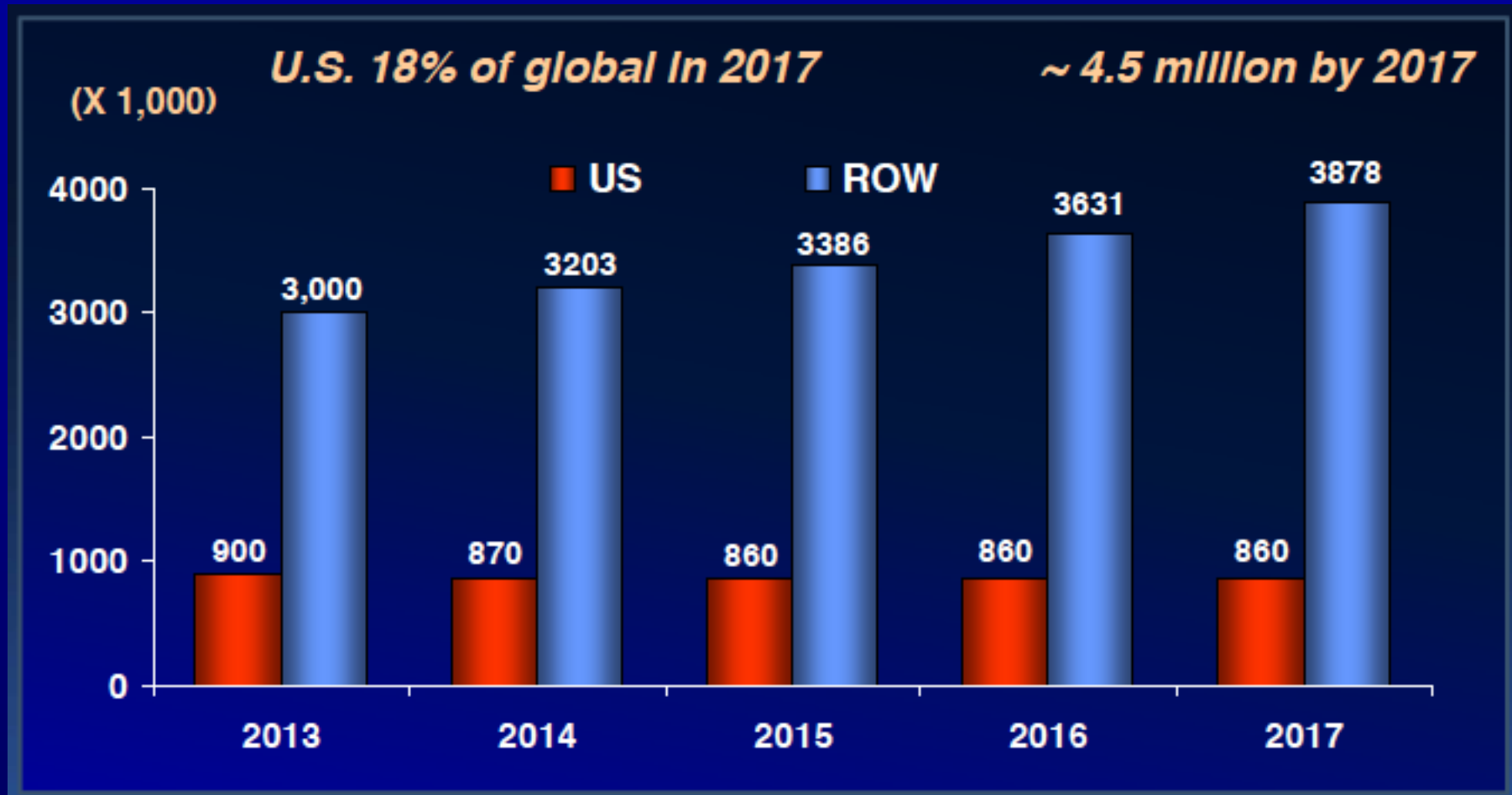


# Forces of Change (3)

*Interventional coronary procedures and revenues are “flat” and won’t demonstrate important growth in the next decade.*

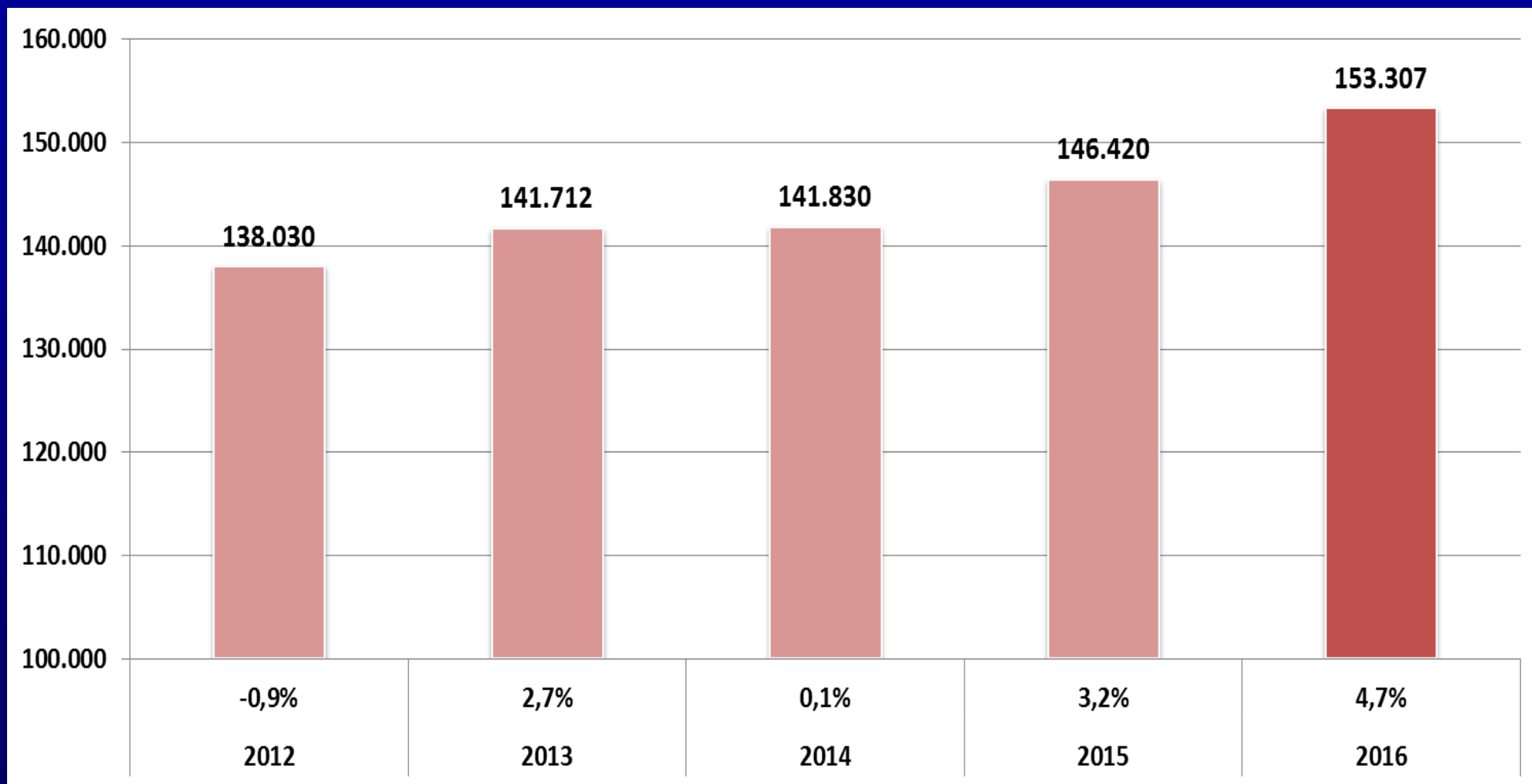


# PCI Procedures Growth from 2013 - 2017

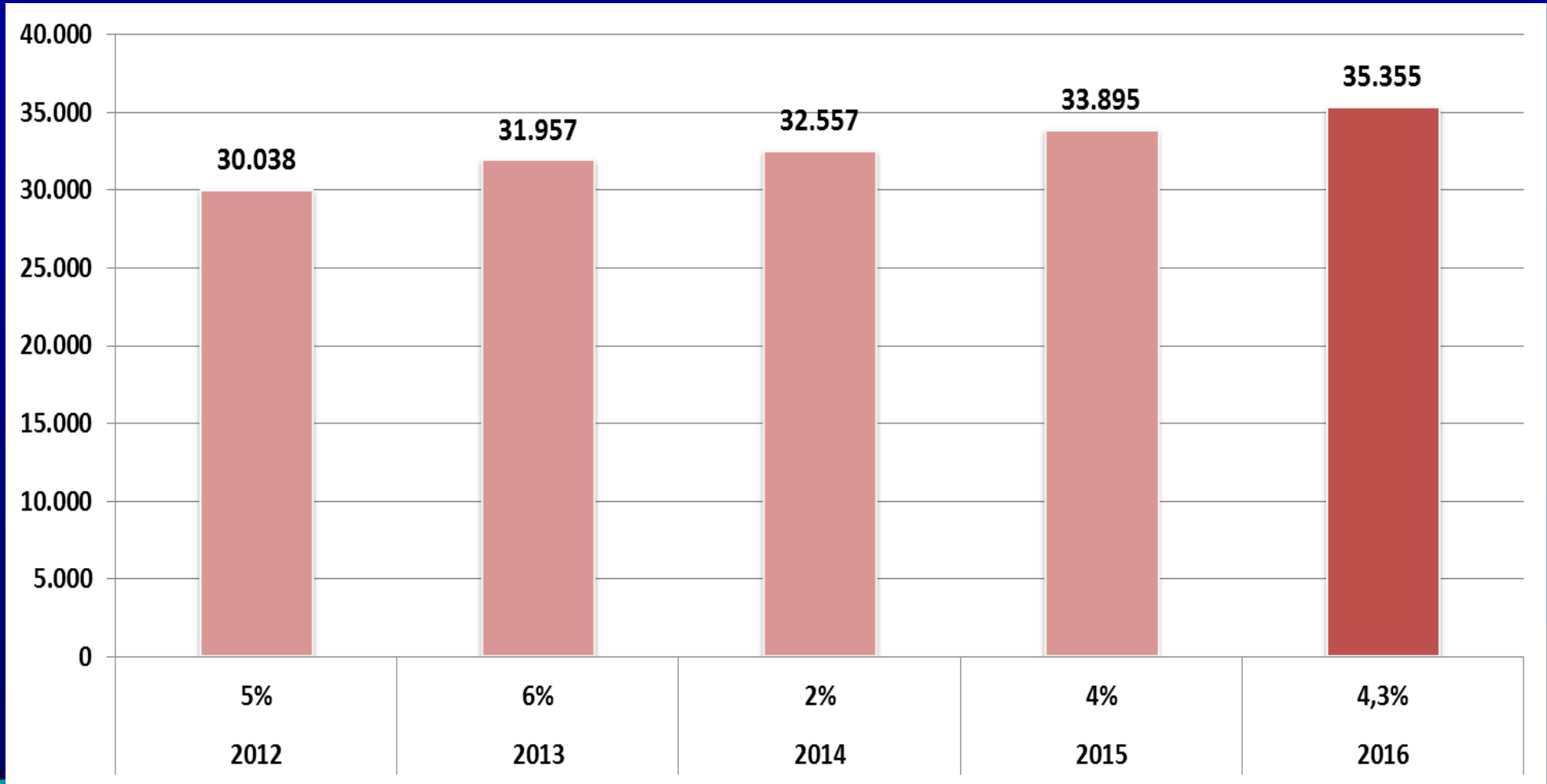


*Multiple Industry Source - 2018*

# Trend Angioplastiche Coronariche in Italia – 2012-2016



# Trend Angioplastiche Primarie in Italia – 2012-2016



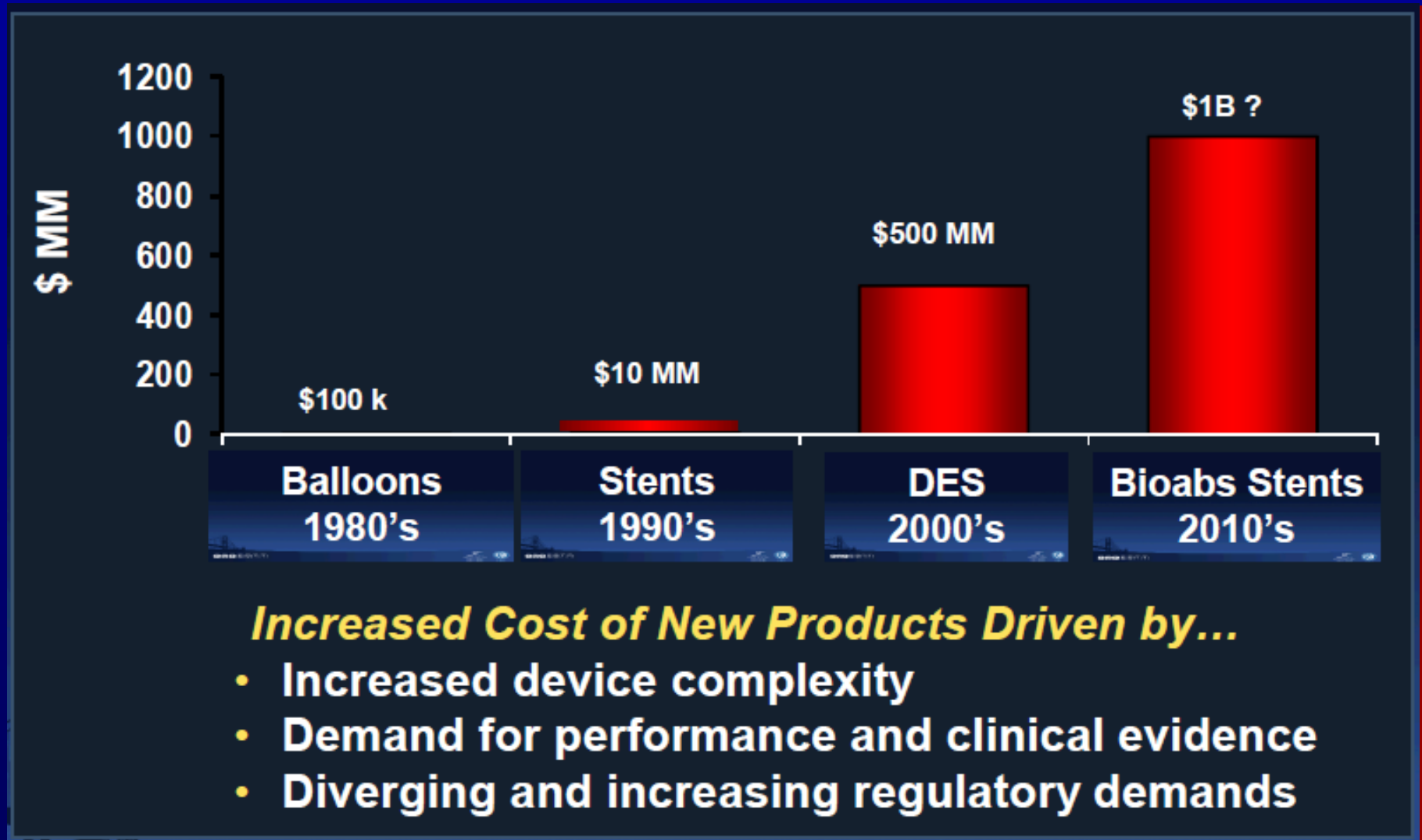
# Forces of Change (4)

*The coronary interventional marketplace is becoming remarkably cost and price sensitive everywhere. The cost burden of investing in iterative “sustaining” medical technologies has skyrocketed.*



# Investment Burden by Era

## *Cost Estimate for Product Introductions*



# Forces of Change (5)

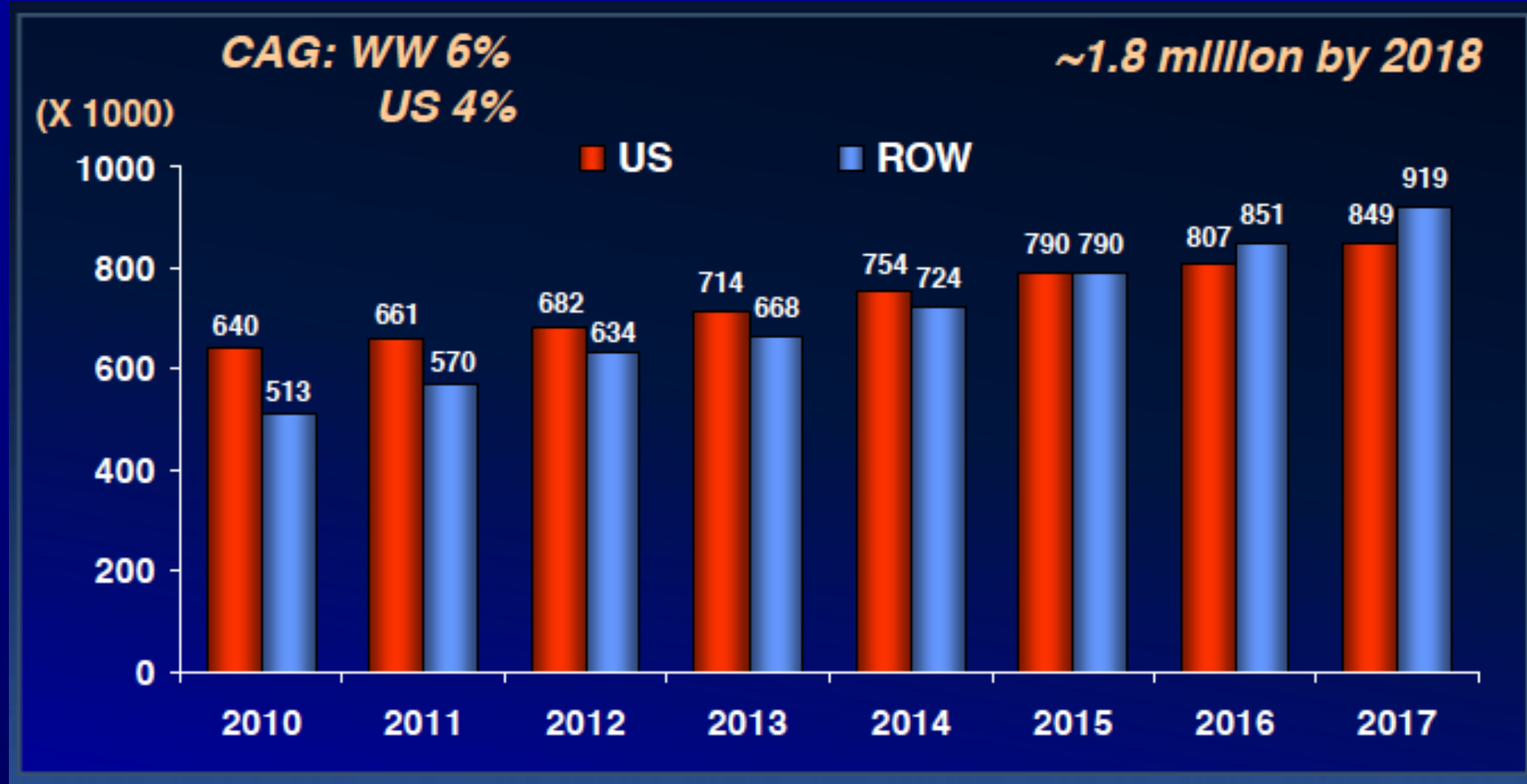
Although “overall” growth in vascular intervention has blunted, there are important areas of opportunity and excitement.

- *Peripheral vascular disease (esp. critical limb ischemia)*
- *Neurovascular disease (esp. acute stroke therapies)*
- *Complex high-risk coronary angioplasty procedures*



# Peripheral Vascular Procedures

## Growth from 2010 - 2017



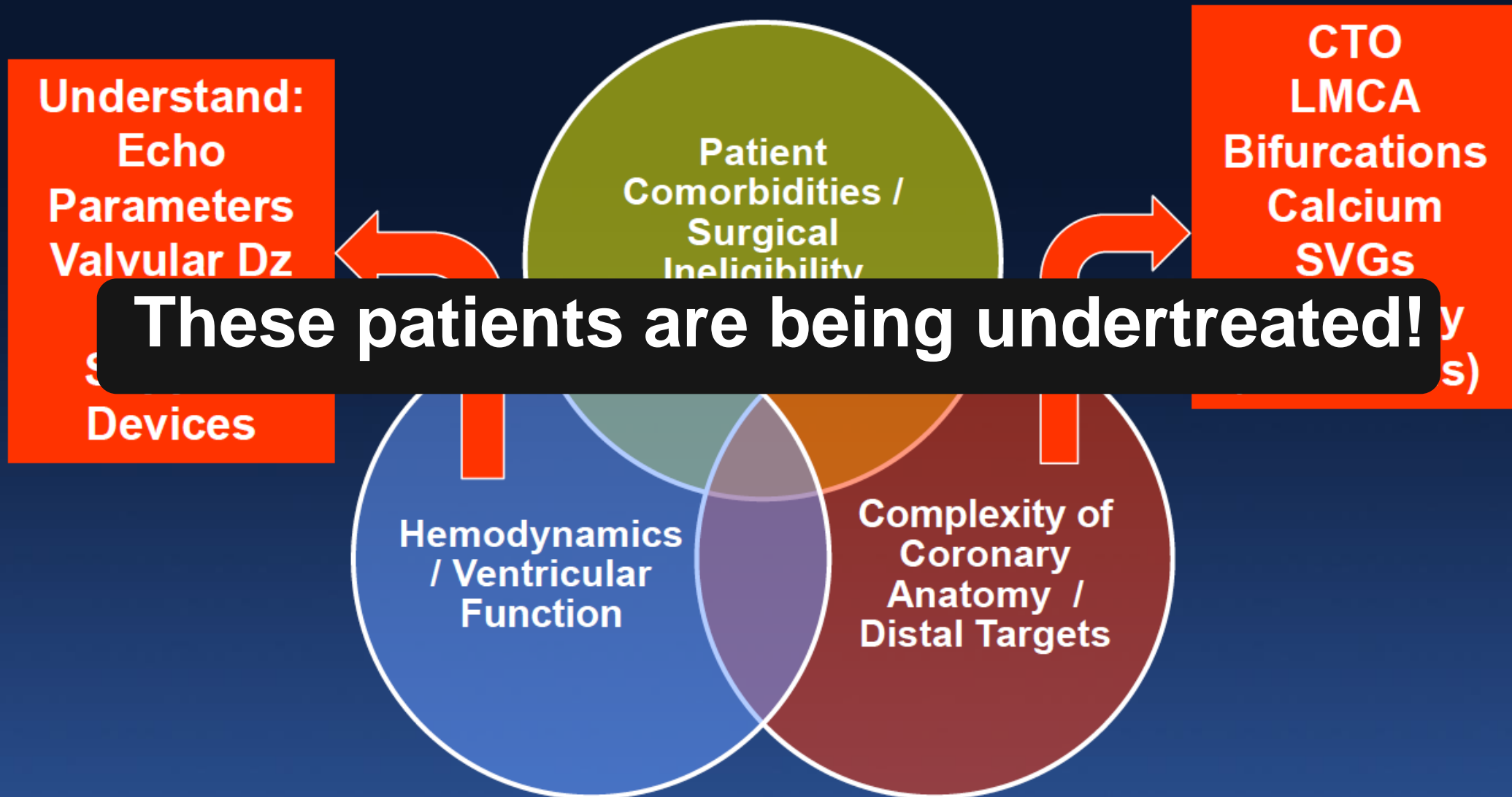
**Multiple Industry Source - 2018**

# Are We Up to the Challenge of Treating Higher-Risk Patients?

***CHIP =  
Complex Higher-Risk  
(and Indicated) Patients***

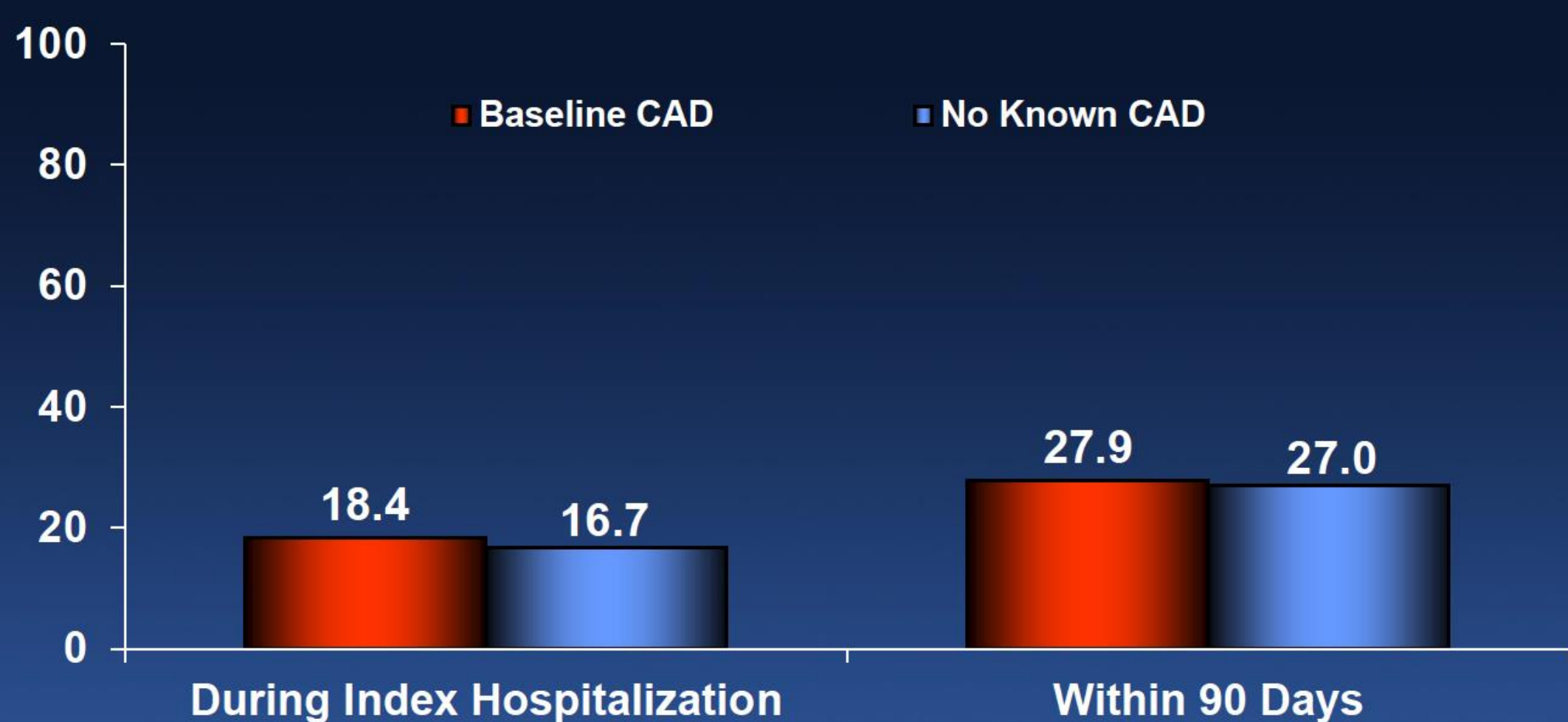


# Definition of the CHIP Population: Complex Higher-Risk (and Indicated) Patients



# Rates of Invasive / Non-invasive Work-up for CAD in 67,640 Patients with New HF as Principal Diagnosis

MarketScan Commercial and Medicare Supplemental Databases  
(1/1/2010-7/31/2014)



# The Basic CHIP Premise

**There is a large underserved patient population that can benefit from revascularization**

- Rather than focusing on low-risk patients who may be “easy to treat”, we need to focus upon higher-risk patients who have the *most to gain*
- These patients will be more commonly seen as our field / the healthcare system evolves
- The development of comprehensive specialists trained with advanced technical and cognitive skills to assess and treat these patients is clearly needed





# ECLIPSE

Evaluation of Treatment Strategies for Severe CaLcific Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Prior to Implantation of Drug Eluting StEnts

**~2000 pts with severely calcified lesions; ~60 US sites**

Randomize

1:1

**Orbital Atherectomy Strategy**

(1.25 mm Crown followed by non-compliant balloon optimization)

2<sup>nd</sup> generation DES implantation and optimization

**Conventional Angioplasty Strategy**

(conventional and/or specialty balloons per operator discretion)

2<sup>nd</sup> generation DES implantation and optimization

**1° endpoints:** 1) Post-PCI in-stent MSA (N~400 in imaging study)  
2) 1-year TVF (all patients)

**2° endpoint:** Procedural Success (stent deployed w/RS<20% & no maj complications)

# Forces of Change (6)

## *THE STRUCTURAL REVOLUTION*

**Non-vascular interventions of all kinds are exploding and providing a meaningful growth stimulus to interventional cardiology**



# Structural Heart Disease

## *Why the excitement?*

- New patient care treatment alternatives for “common” diseases
- Completely “additive” to current cath lab procedural activities
- Crosses sub-specialty territorial boundaries (e.g. imaging, surgery)
- Requires new training and educational initiatives
- *Extra-ordinary economic market potential!!!*



# STRUCTURAL Heart Disease Interventions

- Heart Valves Percutaneous Interventions
- LAA Closure for Stroke Prevention in AF
- Heart Failure Interventional Therapies
  - *Hemodynamic support devices*
  - *Sensors to monitor therapy*
  - *LV remodeling devices*
  - *Contractility modulation*
  - *Micro-VADs (interventional)*
  - *Inter-atrial shunt implants*
  - *Stem cell therapies*



# Transcatheter MV Repair/TMVR: Landscape 2018

## Edge-to-edge

- MitraClip<sup>\*\*\*</sup>
- MitraFlex

## Coronary sinus an

- Cardiac Dimension
- Cerclage annu

## Direct annuloplas

- Mitralign TAM
- Valtech Cardiok
- GDS Accucir
- Millipede IR
- MVRx ART
- Mardil BAC
- Mitraspan
- Valcare Amer
- Micardia enCo

- Cardiac Implants RDS
- QuantumCor (RF)

## MV replacement

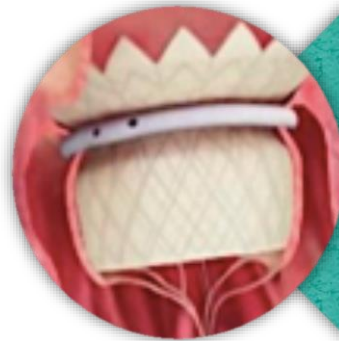
- Edwards CardiAQ<sup>\*</sup>

## MV replacement (cont)

- MitralHeal
- Consultant Saturn
- Atr valve
- Atr Technologies
- resillo
- /enus
- Verso
- ural Systems

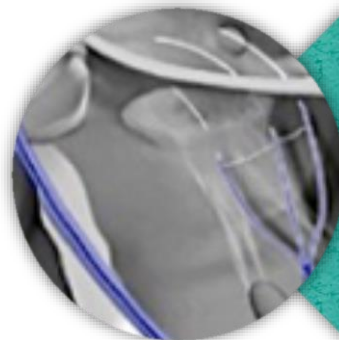
## Approaches

- rd DS 1000<sup>\*\*</sup>
- n neochords<sup>\*</sup>
- c chords<sup>\*</sup>
- Peak Medical<sup>\*</sup>
- eaflet plication<sup>\*</sup>
- ons Mitra-Spacer<sup>\*</sup>
- ech Vchordal
- Mitralix



Trans-catheter  
mitral valve  
**replacement**  
technologies in  
development

32

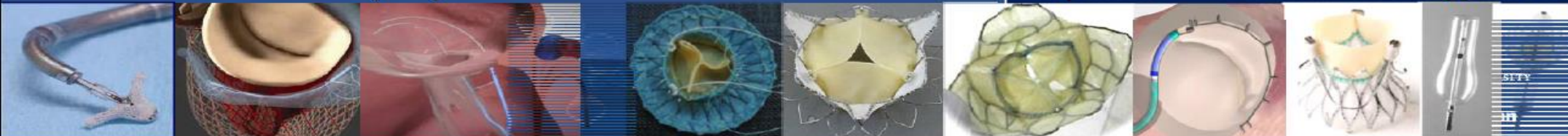


Trans-catheter  
mitral valve  
**repair**  
technologies in  
development

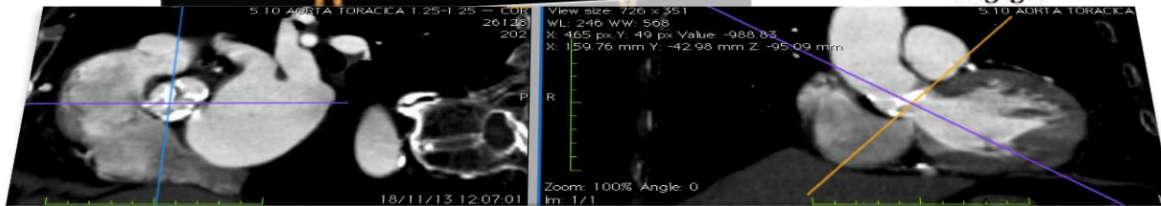
33

- Sinomed Accufit

\*In patients \*CE mark \*FDA approved



# TAVR Landscape 2018



Edwards  
SAPIEN XT  
TF, TA



Edwards  
SAPIEN 3  
TF



Direct Flow  
Medical  
TF



Colibri Heart  
Valve  
TF



Medtronic  
CoreValve  
TF, SC, DAO



Edwards  
Centra  
TF, SC



Boston Scientific  
Sadra Lotus  
TF



Heart Leaflet  
Technology  
TF



St. Jude Medical  
Portico  
TF



Symetis  
Accurate TF  
TF



Medtronic  
Engager



JenaValve  
Technology  
TA



Symetis  
Accurate TA  
TA



St. Jude Medical  
Portico  
TA

# ONGOING ISSUES IN HEART VALVES PI

- Reduce complications
  - vascular, mechanical, bleeding, AKI
- Risk stratification (*Appropriateness!*)
  - Patient-centered approach
- Sustainable health system
  - affordability
  - acceptability to key constituents
  - adaptability



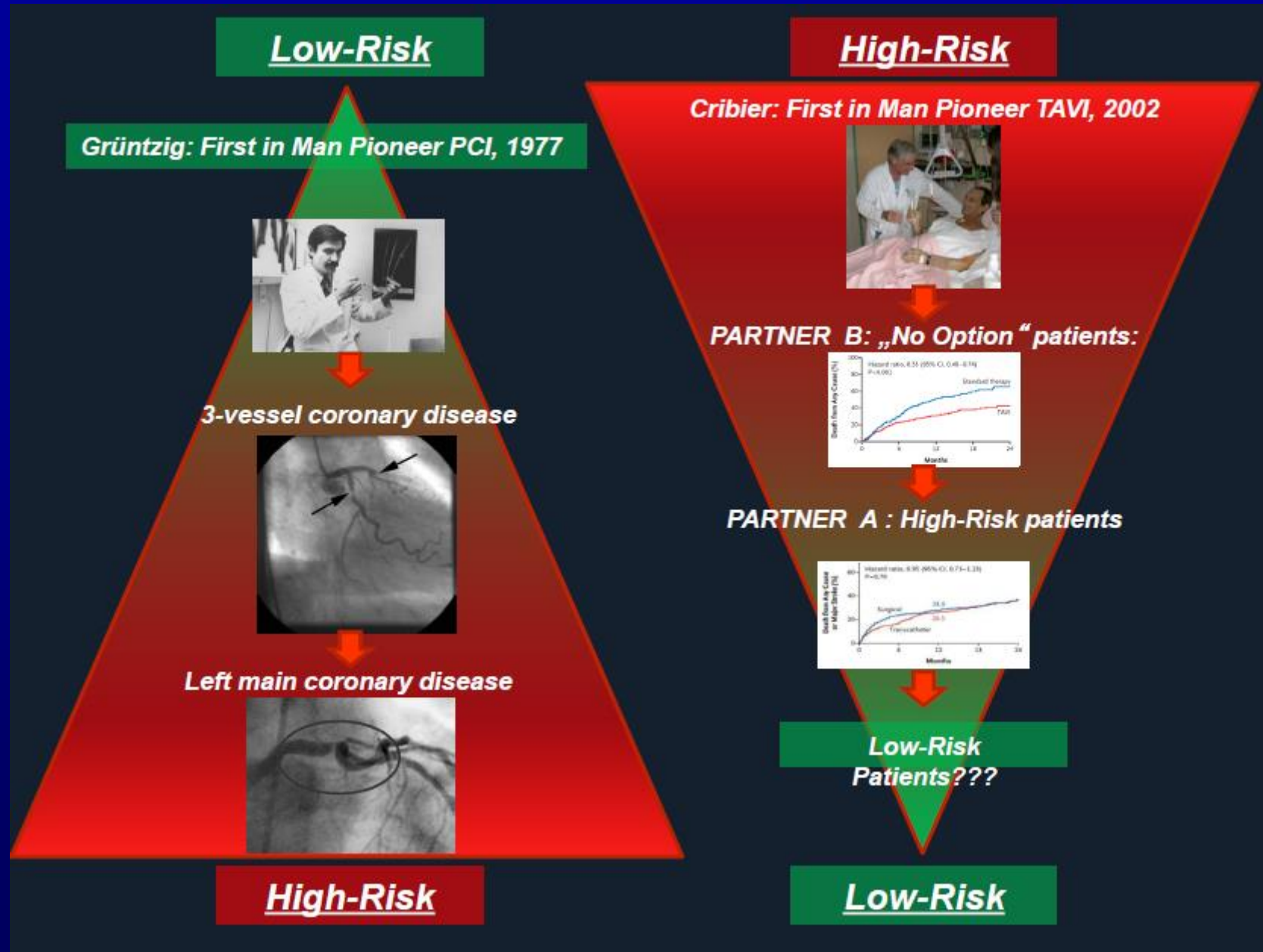
# Forces of Change (7)

**Case mix and complexity trends are different for coronary and structural interventions**



# Coronary

# Structural Diseases

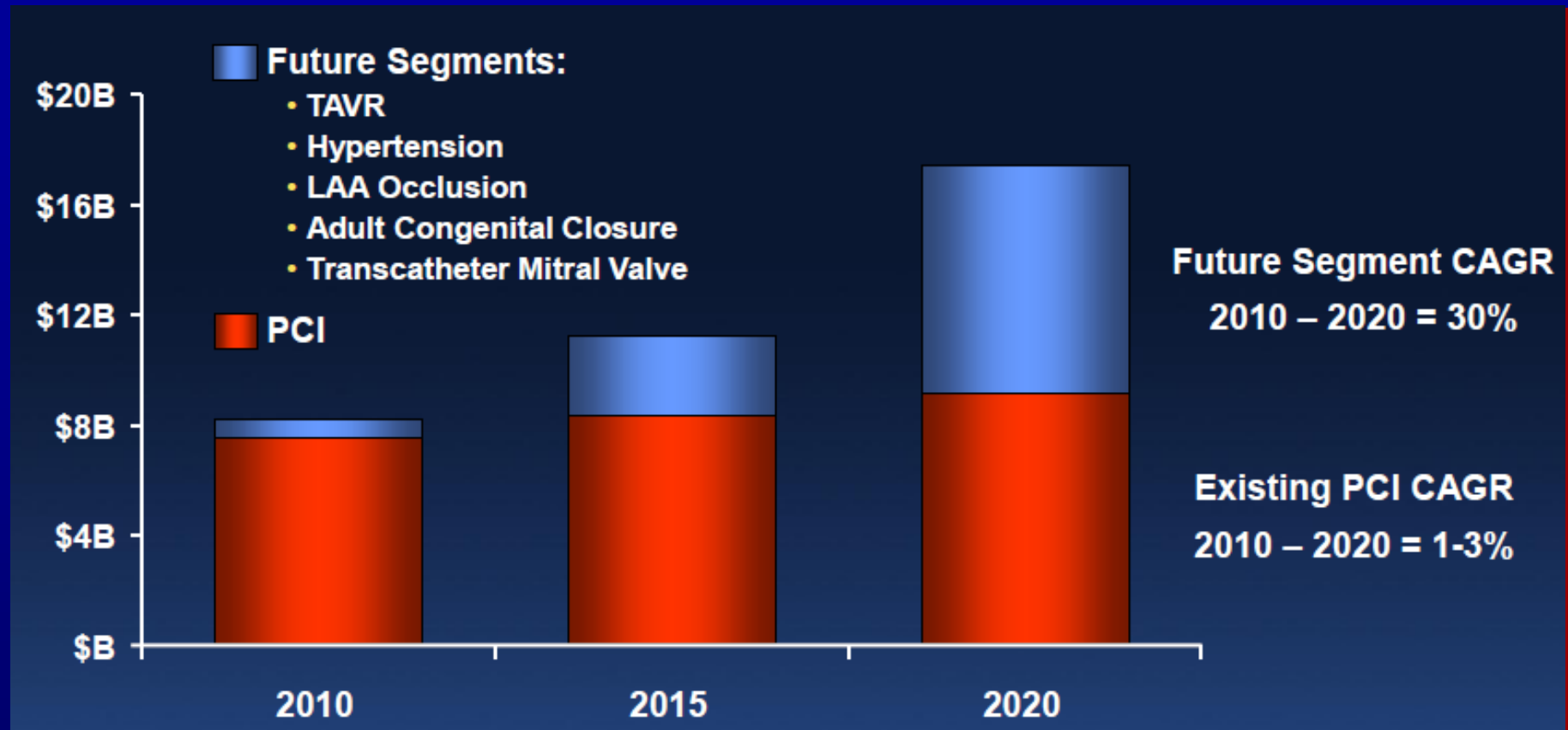


# Forces of Change (8)

*New market segments may  
exceed PCI market size*



# WW Cardiology Market Trends

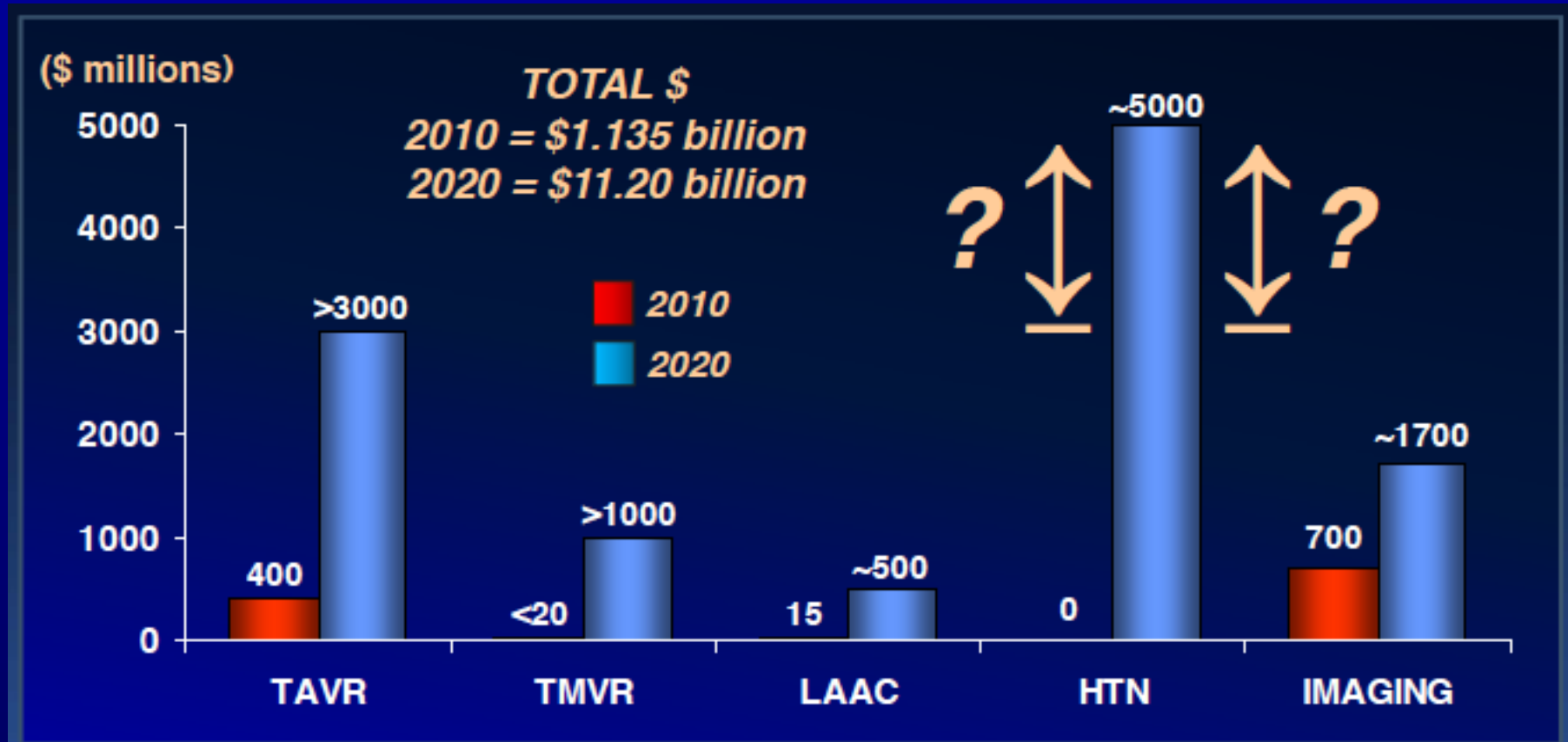


- New market segments may exceed PCI market size by 2020
- Emergence of future segments relies on technology and clinical data
- OUS markets will lead and exceed the size of US markets



# Selected Interventional Growth Markets

## *Projected Revenue Opportunities (2010-2020)*



*Source: Industry Investor Presentations*



# Forces of Change (9)

## *Cultural change and transformation of Interventional Cardiologists*



# IC Perspectives: 1977 - 2018

## *Important Evolution*

**“Early” Days**

***Devices***



***Proceduralists***

**Modern Era**

***Therapies***



***Therapists***

# ***Evolution to Mainstream Therapies - 2018***

***This is the greatest period of transition in the history of interventional CV medicine!***

- **The less-invasive use of catheter-based Rx to remotely treat distant disease targets has transformed medicine.**
- **A major current effort is to redirect intra-vascular interventional therapies to address “mainstream” cardiovascular disease (e.g. AF, Structural, and CHF)**
- **This requires that the interventionalist become an integrated member of a multi-disciplinary team AND learn new cognitive skills; *the transformation from isolated proceduralist to engaged therapist!***



# Interventional Cardiology

## ***The FUTURE!***

*Interventional cardiology enters a new phase of striking diversity and creativity!*

***Adapt  
and  
Evolve!***

