

# The Changing Landscape of DES Use Patterns – Finally Stabilizing or Still in Transition?

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**Presenter Disclosure Information for  
Angioplasty Summit 2009**

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***Scientific Advisory Board or Equity:***  
Abbott, Boston Scientific, Cordis,  
and Medtronic



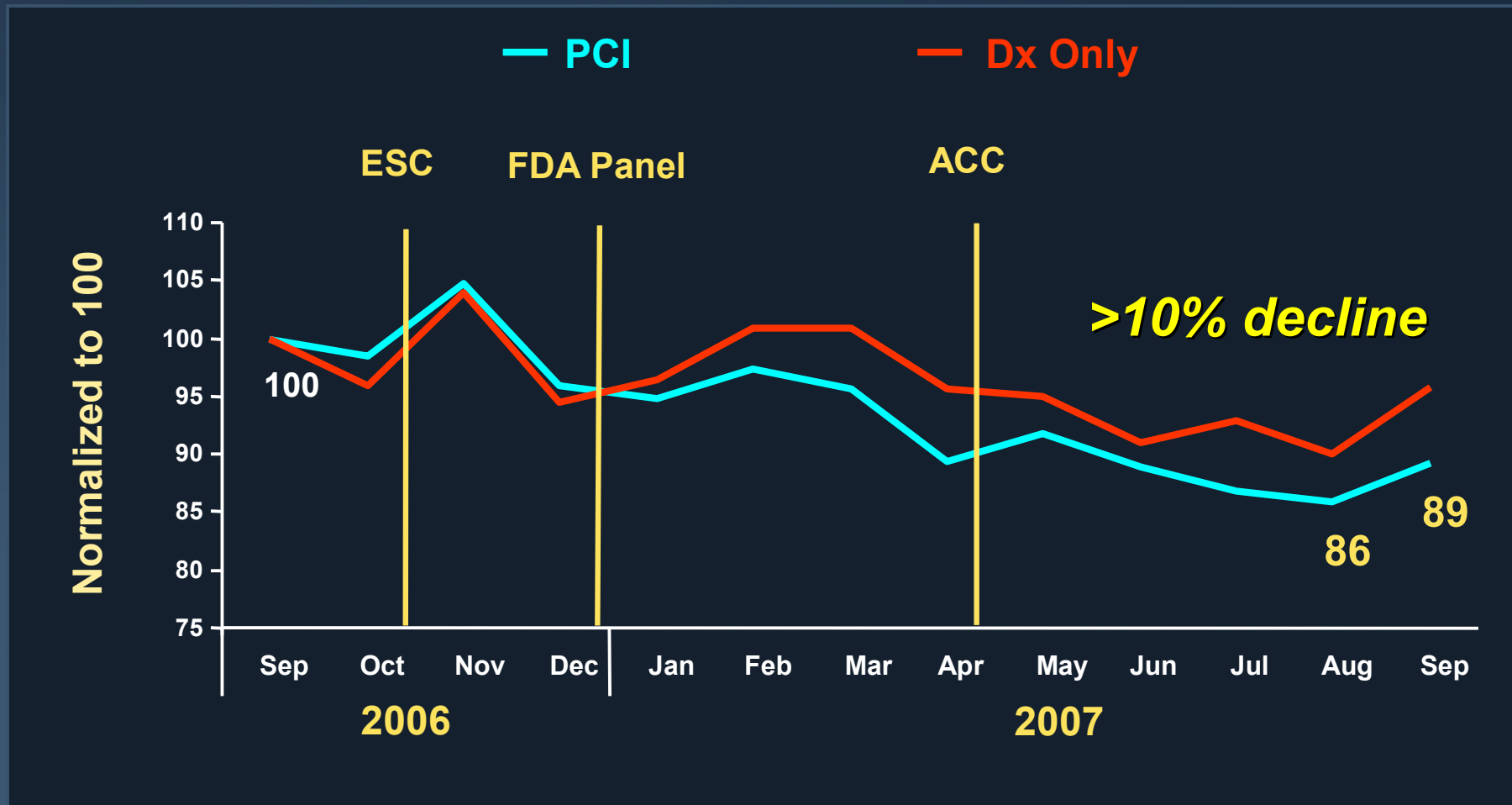
# DES Landscape – 2006-7

## *Clinical Use Patterns*

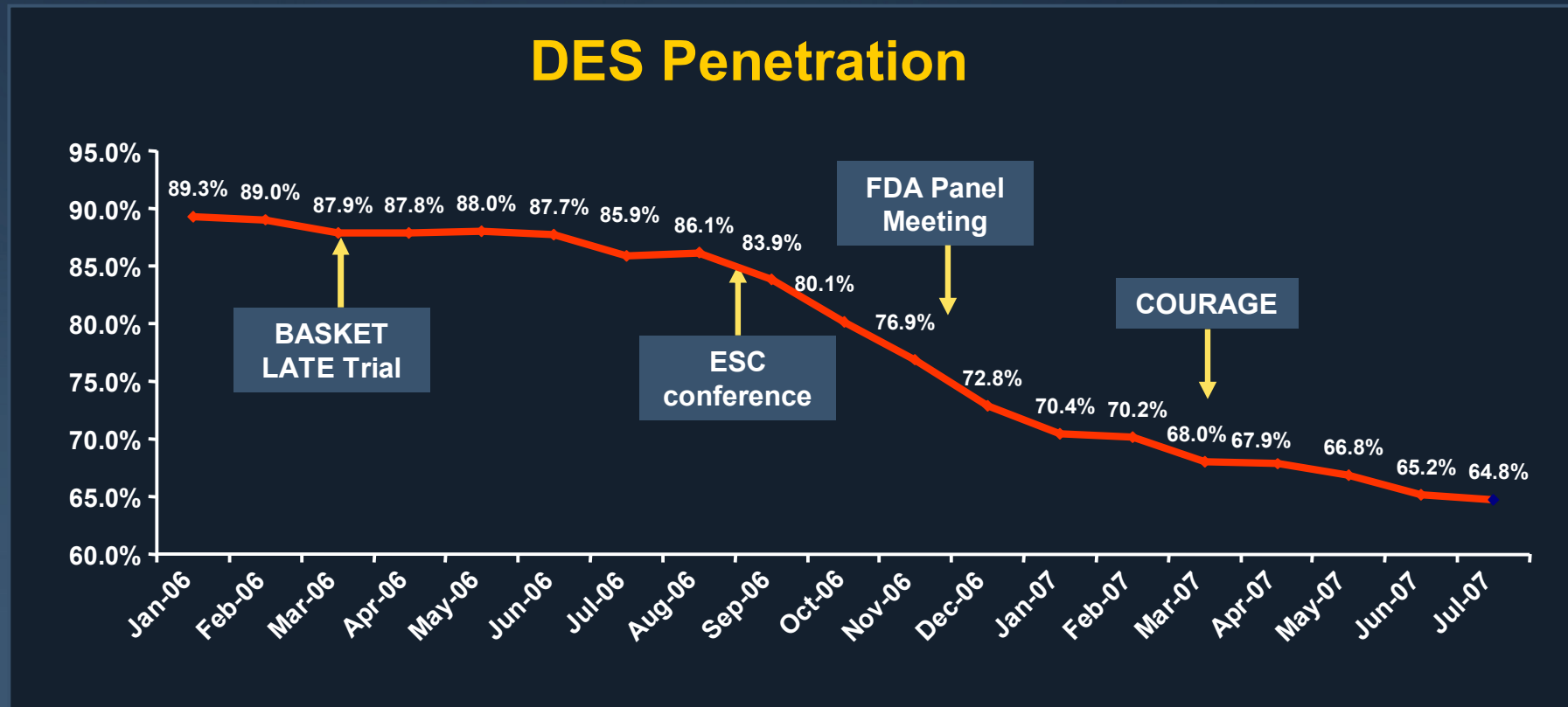
- *There was an unprecedented decline in PCI procedures in 2006-7!*
- The probable cause was the composite of DES safety concerns + increased medical Rx, fueled by the media, which influenced patients and affected the treatment strategies of upstream referring cardiologists.
- There was an even greater decline in DES penetration in 2007, largely felt in the US (marked geographic discordance).



# Coronary Invasive Procedures Sept. 06 – Sept. 07

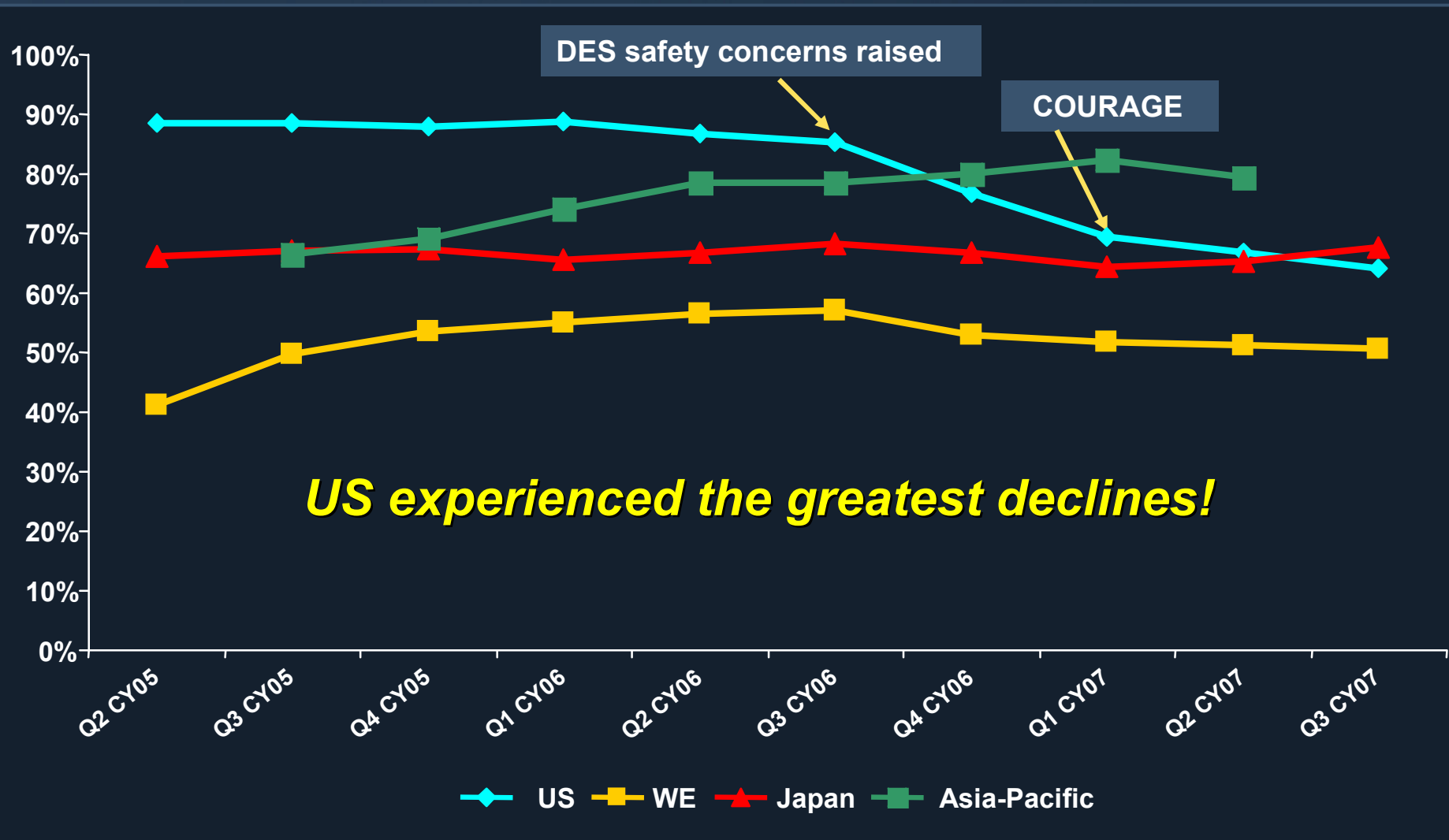


# DES Penetration in the US



***Declines may be leveling in the past few months,  
but Sept. 07 = 62% !***

# DES Penetration by Geography



# DES Landscape – 2006-7

## *Clinical Use Patterns*

- *DES safety concerns, highlighted by the requirement for extended DAPT, was the main reason for declining penetration!*



# The Dark Days of DES

*Fear-based avoidance and distortions  
> the (true) evidence*

## *Definite DES under-use*

~60%  
(<50% EU)  
penetration

← 2006-07

- DES = ↑ thrombosis and ↑ mortality
- COURAGE drives more medical Rx
- *Maybe DES use should be dramatically reduced*





# DES Landscape - 2009

**Have Coronary Procedures Stabilized?**

**Has DES Penetration Rebounded?**

**What is the Impact of the NEW DES?**

**Emerging Influence of Reimbursement?**



# DES Landscape - 2009

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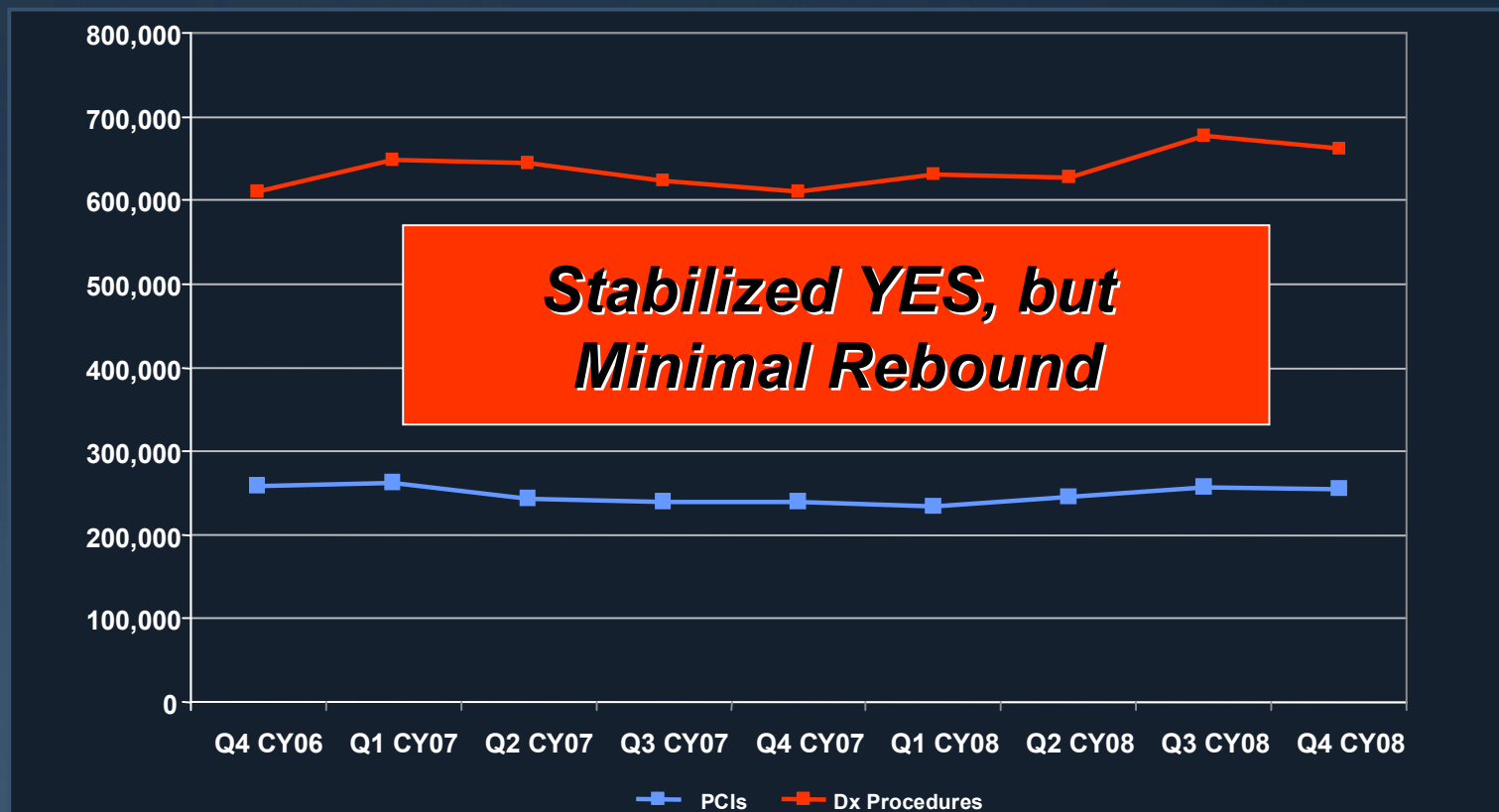
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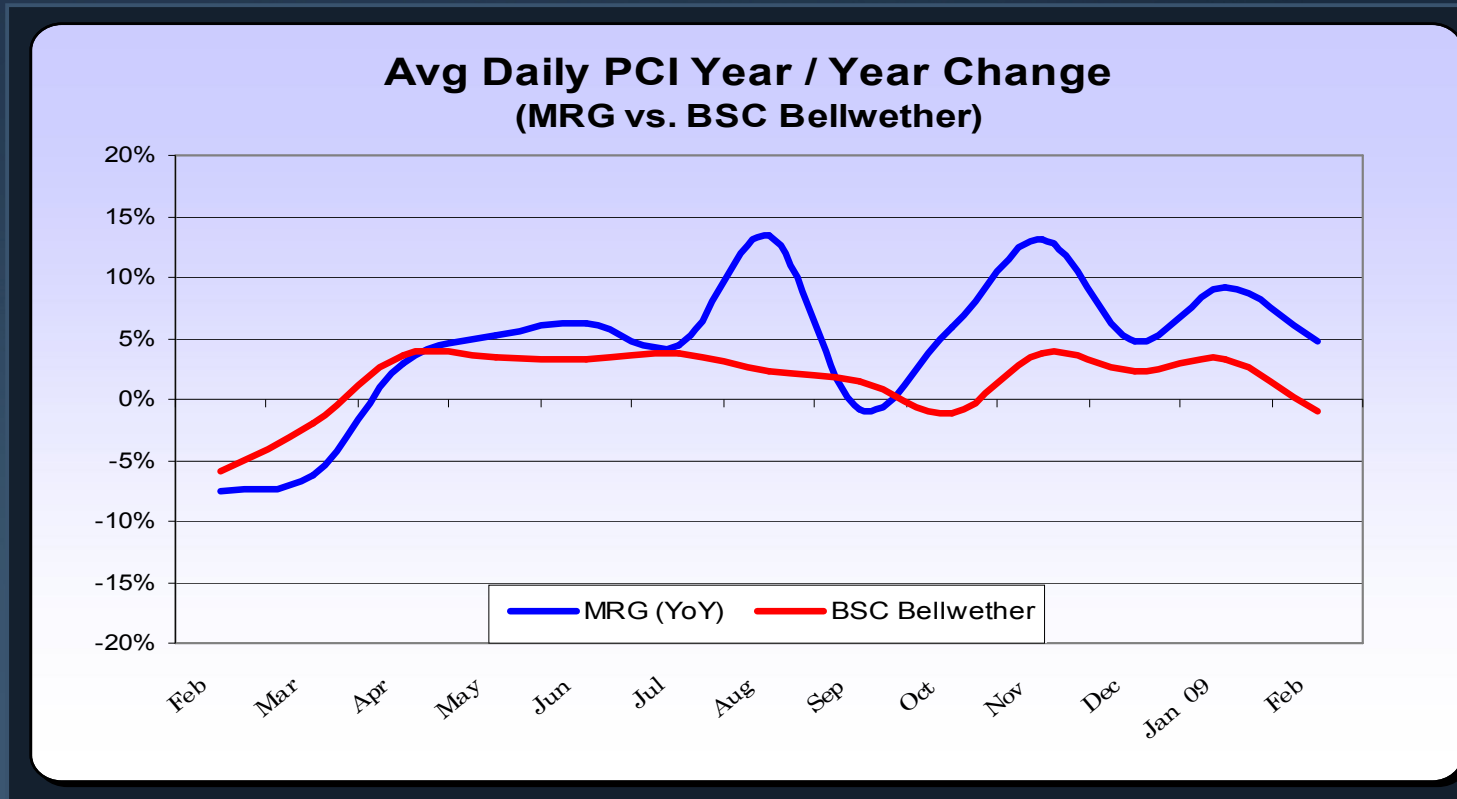
# US PCI and Diagnostic Procedures



% Change – Q4 CY08 vs.	Q4 CY07	Q4 CY06
Dx	+8.6%	+8.5%
PCI	+5.9%	-1.5%



# Average Daily PCI Changes Year Over Year



***Slight increase in PCI procedures YOY,  
during 2008 (2.8%)***

# DES Landscape - 2009

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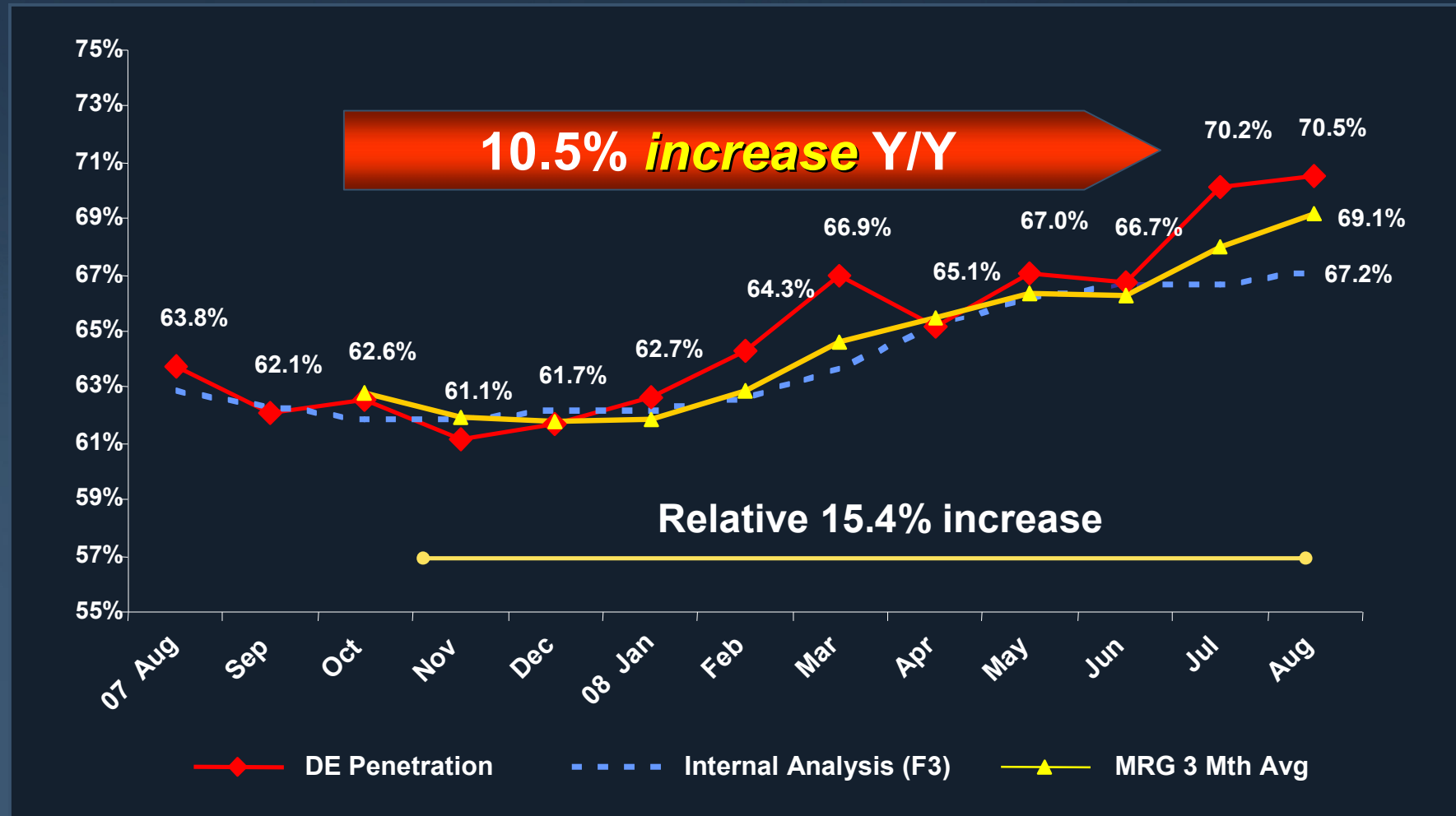
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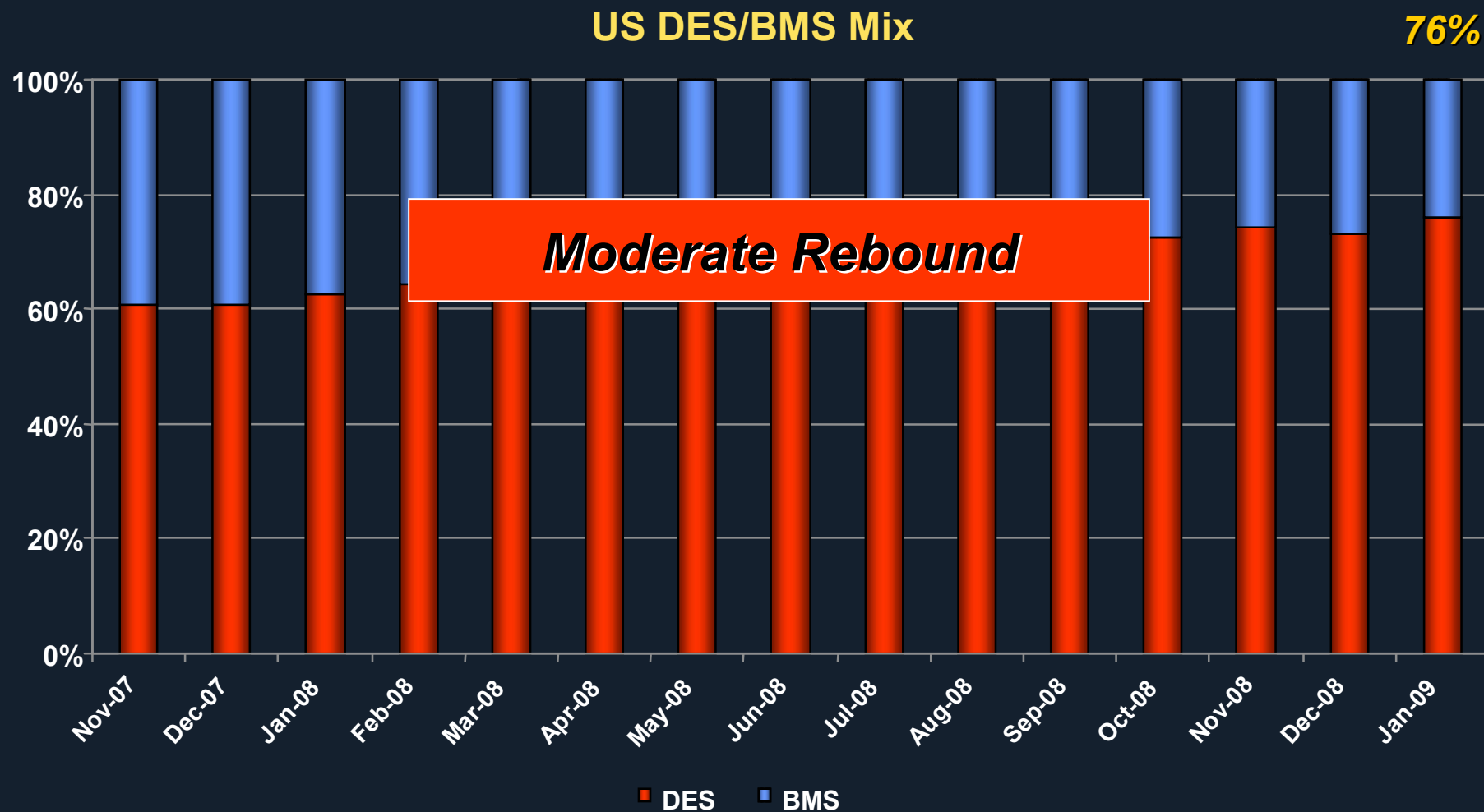
**Emerging Influence of Reimbursement?**



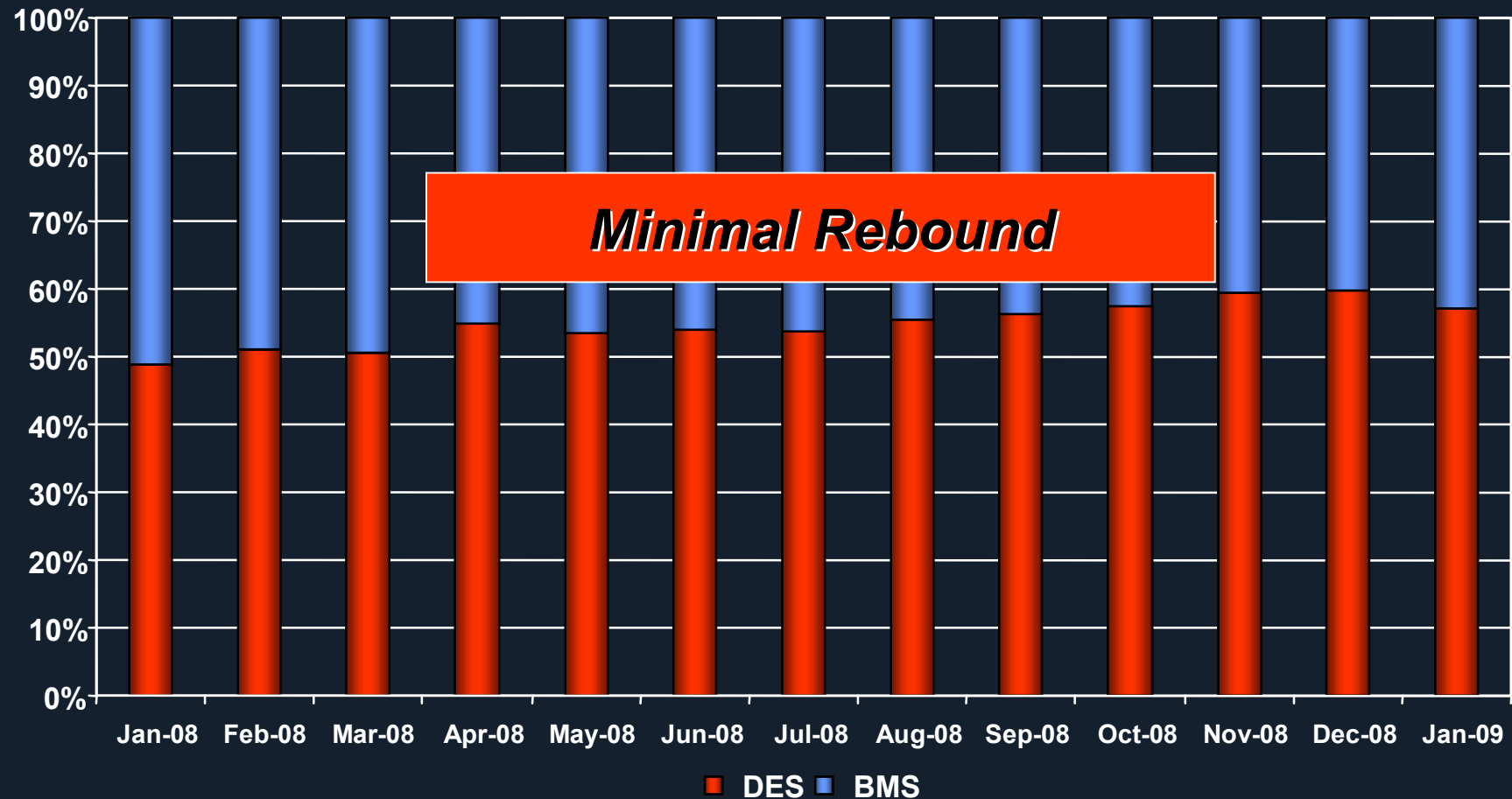
# DES Penetration in the US



# US DES Penetration

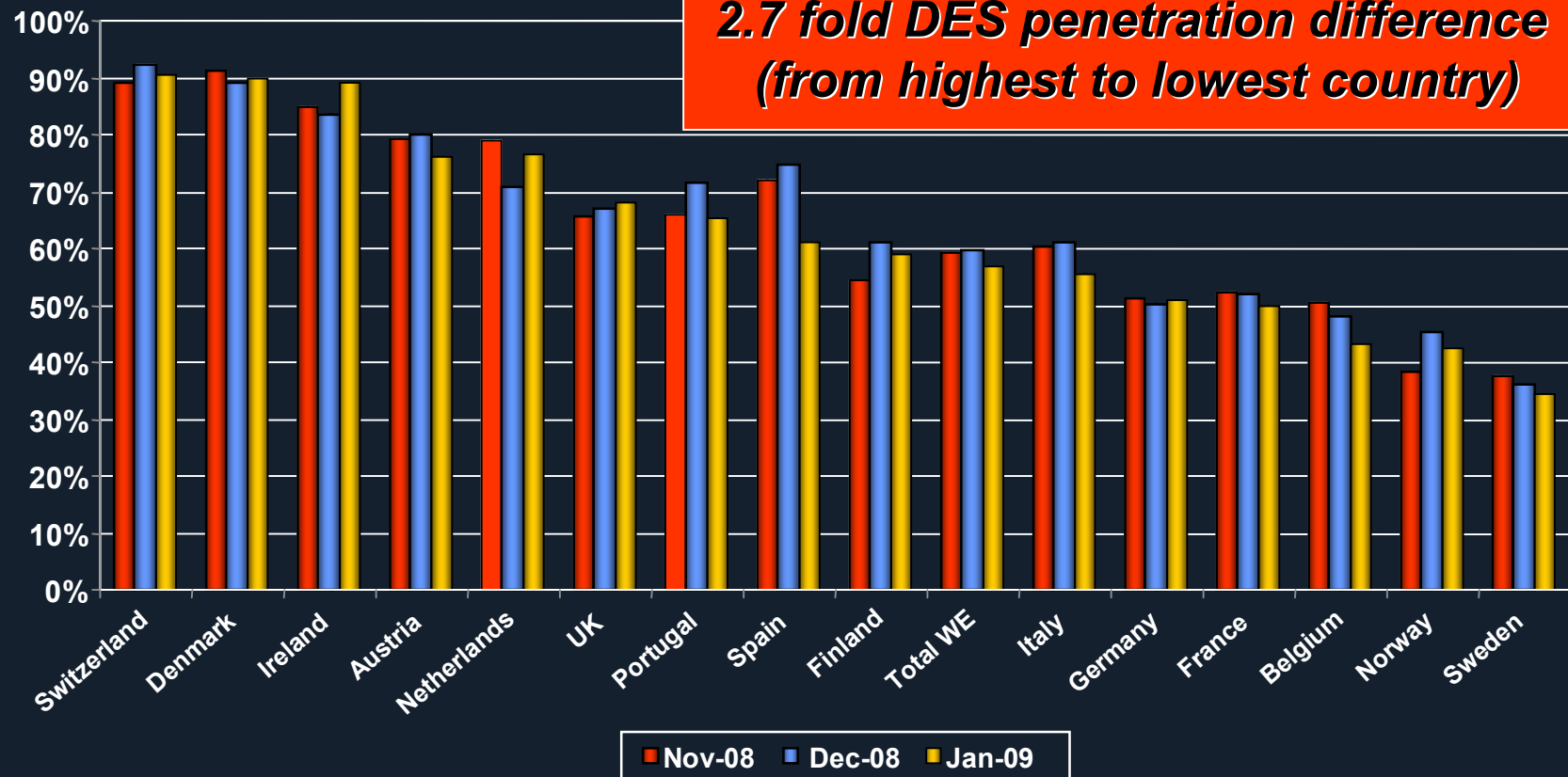


# Western Europe DES Penetration

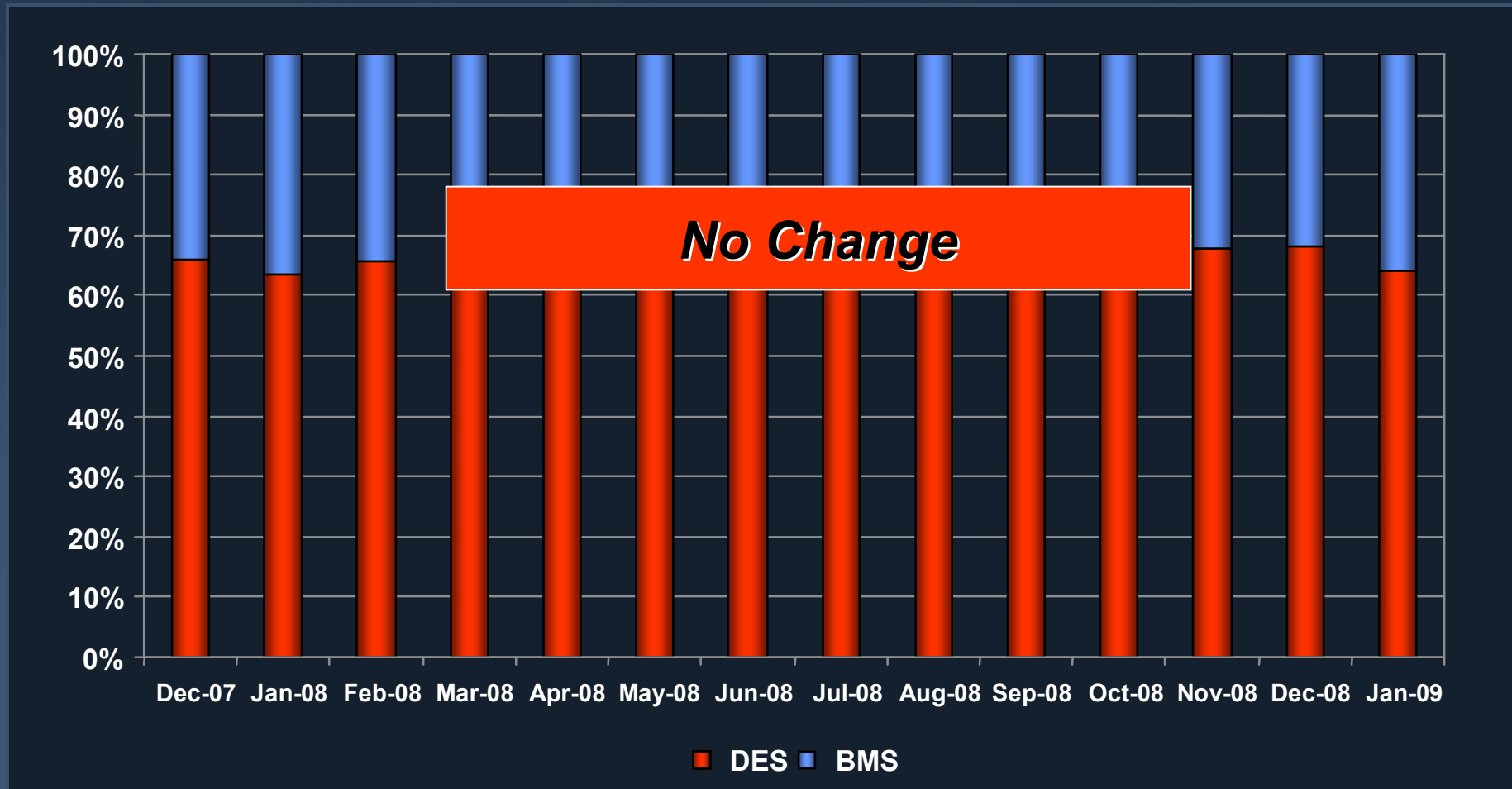




# Western Europe DES Penetration by Country



# Japan DES Penetration



# DES Increase Driven Primarily by Reassurance of Safety

Reason	Average Points Allocated (Change from Q3 '08)
I am more reassured by recent clinical data which shows DES is as safe or safer than BMS	53% (+2%)
DES are becoming more economical	16% (+6%)
More DES are entering the market	15% (-9%)
Referring doctors are more reassured by recent clinical data which shows DES is as safe or safer than BMS	10% (+3%)
Budget constraints are less of a problem	6% (+2%)



# A Slow Return to DES “Normalcy”

## *Reliance on overwhelming evidence*

*Can we regrow the DES forest?*

2007 (late) → now

- PCI better for Sx relief and reducing ischemia
- DES doesn't ↑ mortality or MI (on or off-label use) and reduces TVR ~50% (real world)
- *More confident DES use, but with careful DAPT*

**~75%  
penetration**



# DES Landscape - 2009

**Have Coronary Procedures Rebounded?**

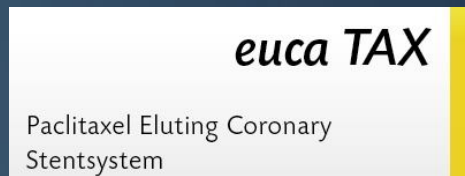
**Has DES Penetration Stabilized?**

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# Today: 22 CE-certified DES

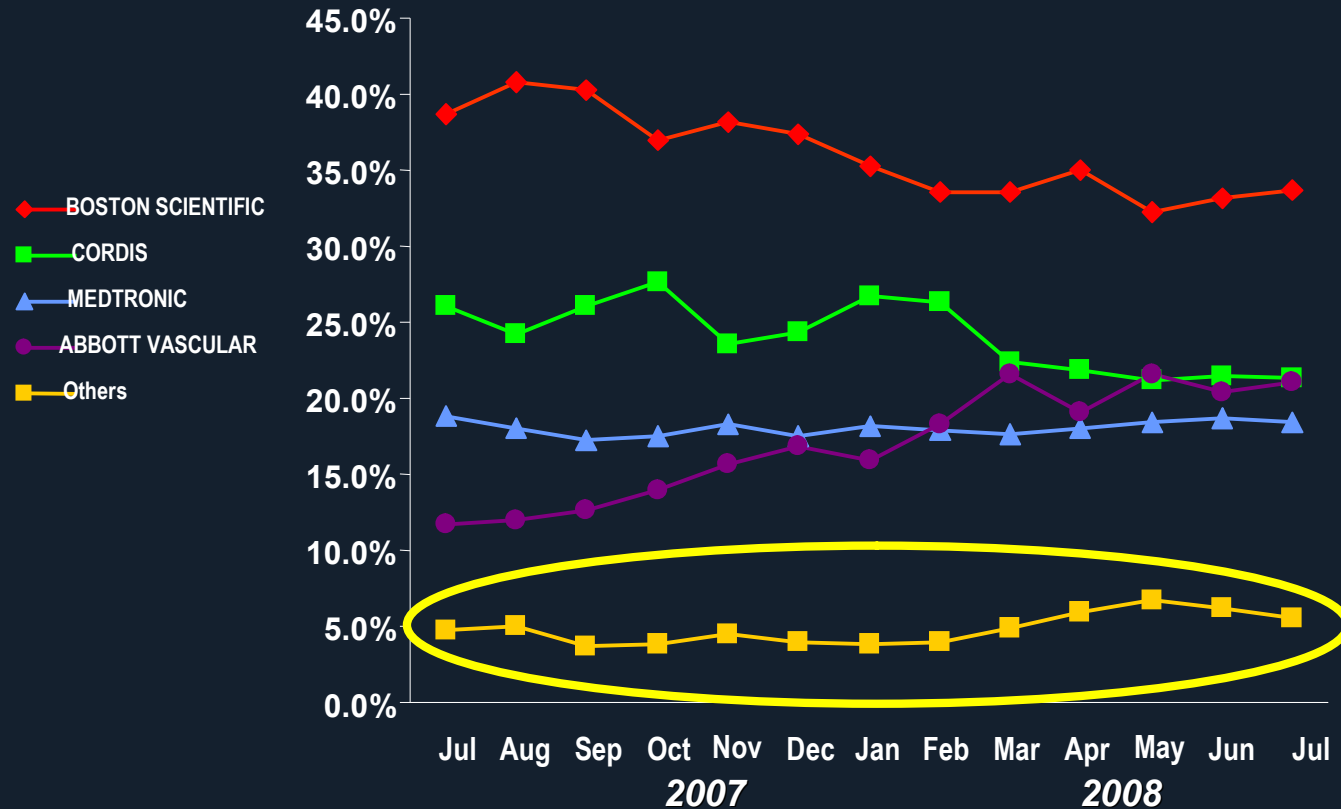


# Market Share by Company (Monthly Usage Raw Data)

EUROPE

MONTHLY

SHIPMENTS

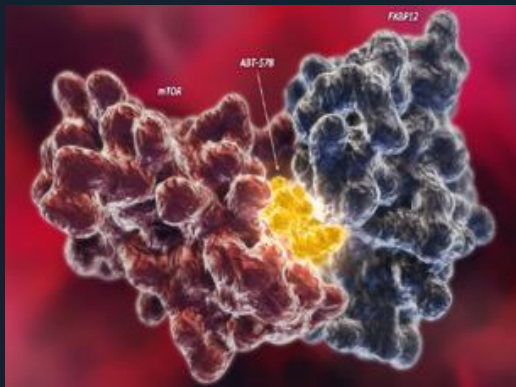


**~ %5 DES share of ALL Other DES in EU**

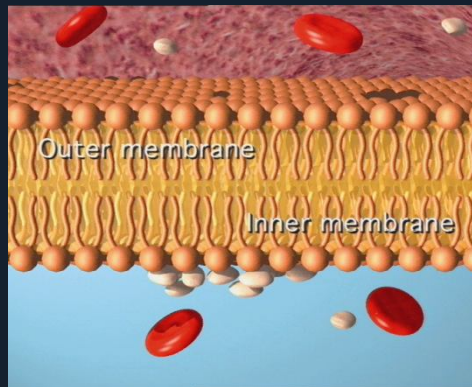


# Drug-eluting Stents 2008

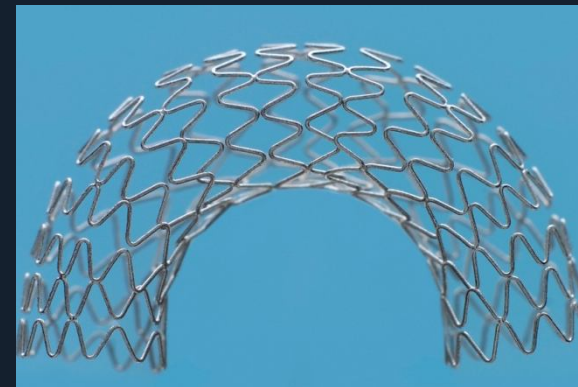
**Endeavor**



**Zotarolimus  
Drug**

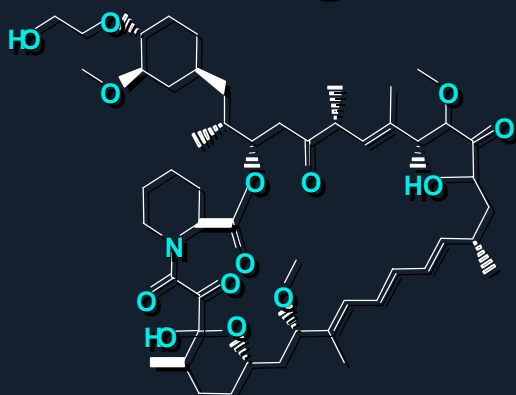


**Phosphorylcholine  
Polymer**

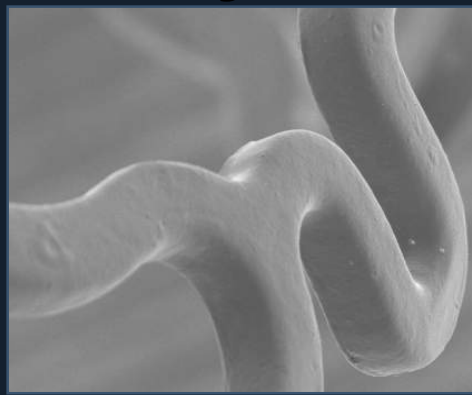


**Driver  
Stent**

**Xience V\***



**Everolimus**



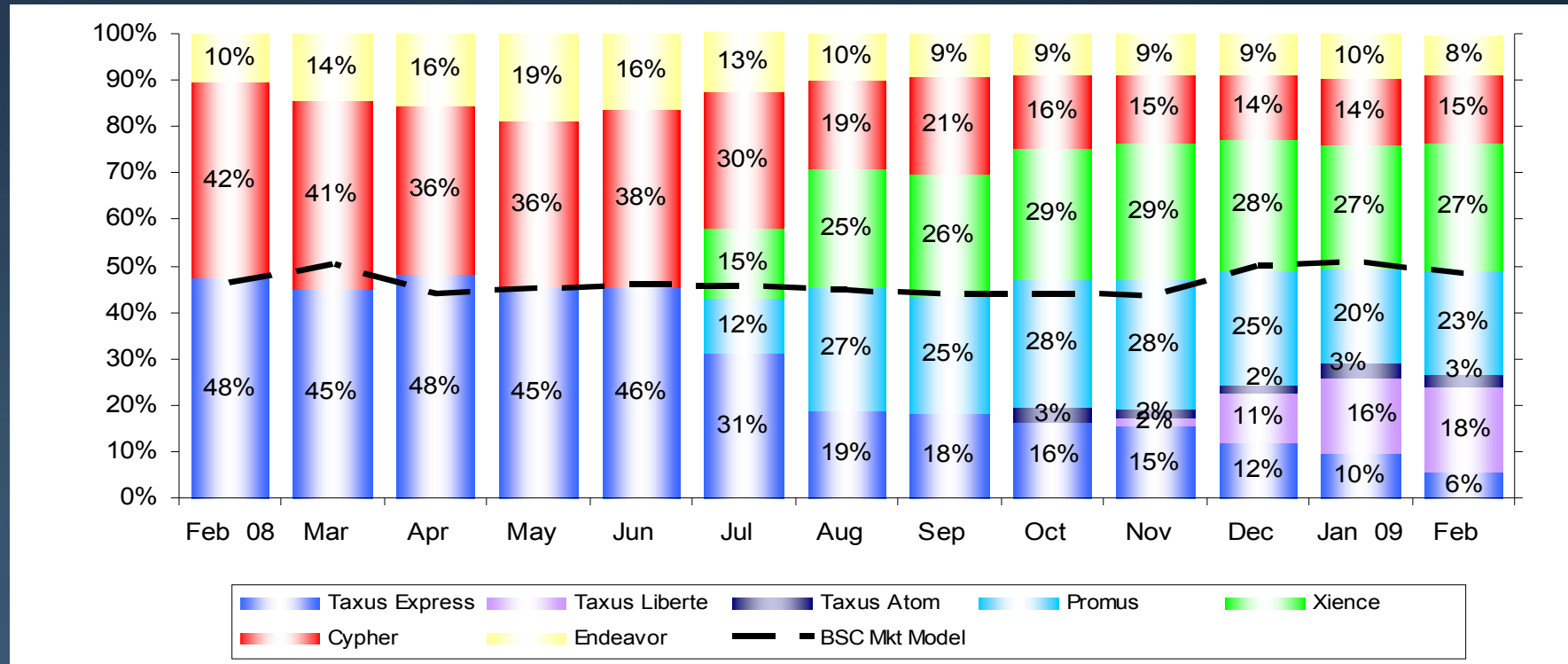
**VDF + HFP copolymer**



**Vision**

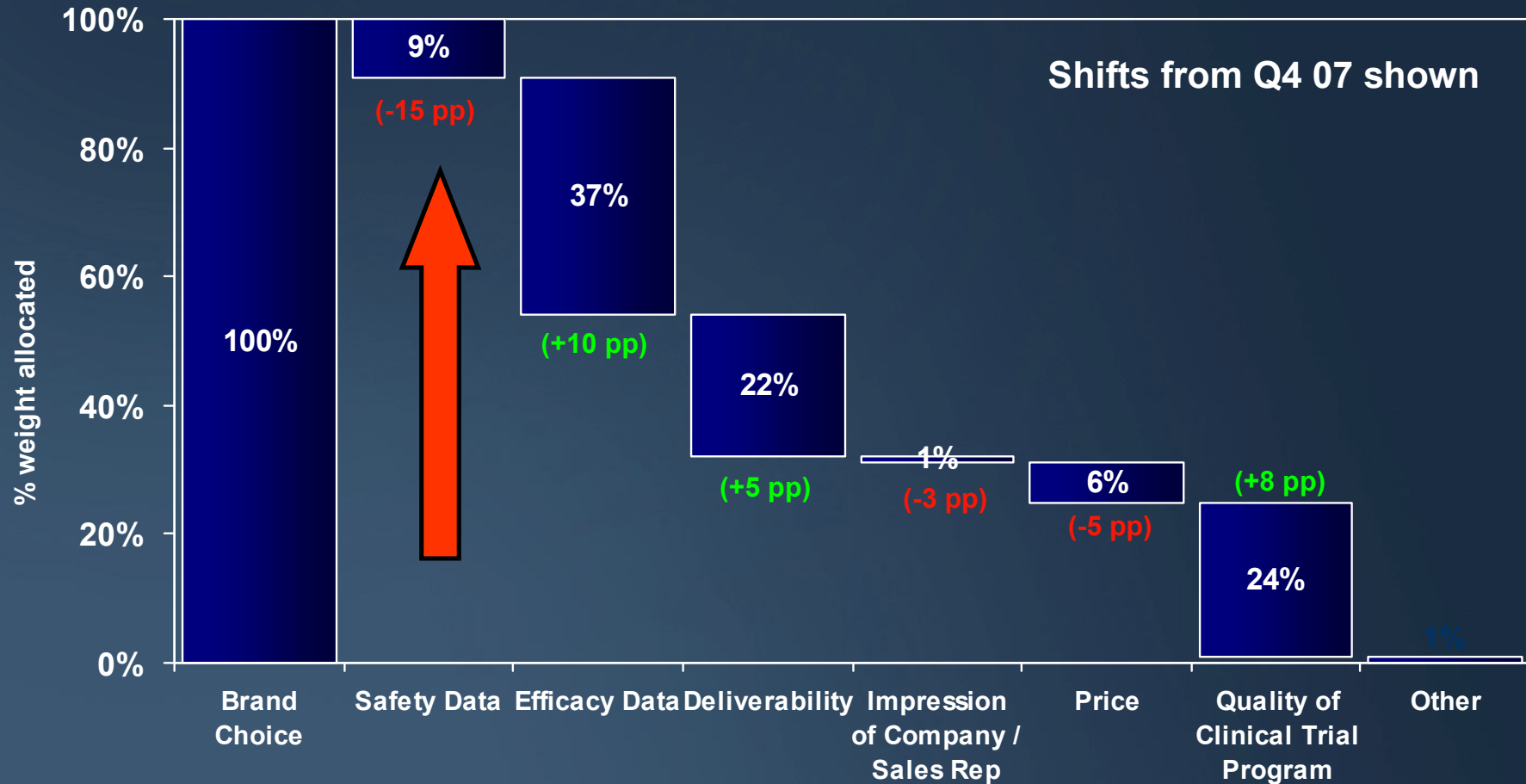


# DES Product Revenue Share: USA



**February, 2009: Everolimus DES (Xience + Promus) = 50%**  
**Paclitaxel DES = 27%**  
**Sirolimus DES = 15%**  
**Zotarolimus DES = 8%**

# DES Brand Preference



# Future DES Decision-Making

**Assess Patient History, Symptoms,  
and Lesion Characteristics**

**Take no chances**

Plavix Resistance  
Emergency PCI (STEMI)  
High risk of bleeding  
Large vessels, SVGs



**BMS  
(Endeavor)**

**Safety first ...**

Elderly patients  
DAPT compliance concerns  
Bifurcations  
2.5-3.5 vessels



**Endeavor  
(Xience/Promus)**

**Efficacy at all costs...**

No risk w/ DAPT  
Very long lesions  
High risk of restenosis  
<2.5 vessels



**Xience/Promus,  
Cypher  
(Taxus, Endeavor)**



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# NICE Final Appraisal of DES

## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

### Final appraisal determination

### Drug-eluting stents for the treatment of coronary artery disease (part review of NICE technology appraisal guidance 71)

NOTE: This guidance replaces sections 1.2-1.4 of NICE technology appraisal guidance 71 (2003).

Sections 1.1 and 1.5 of technology appraisal guidance 71 recommend when to use a stent. This part review recommends under what circumstances a drug-eluting stent should be used.

#### **1 Guidance**

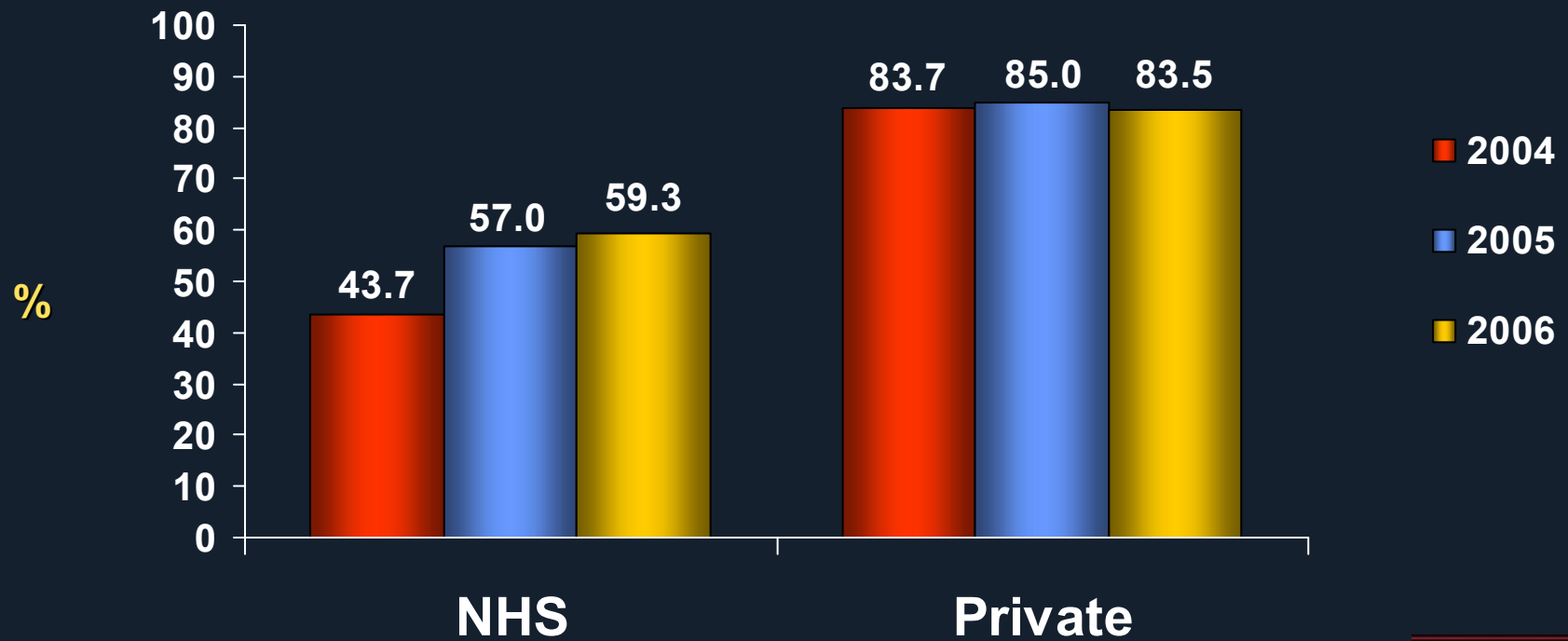
1.1 Drug-eluting stents are recommended for use in percutaneous coronary intervention for the treatment of coronary artery disease, within their instructions for use, only if:

- **target artery < 3mm calibre OR**
- **lesion length is > 15 mm AND**
- **price difference between DES and BMS doesn't exceed £300**



# DES Penetration in the UK

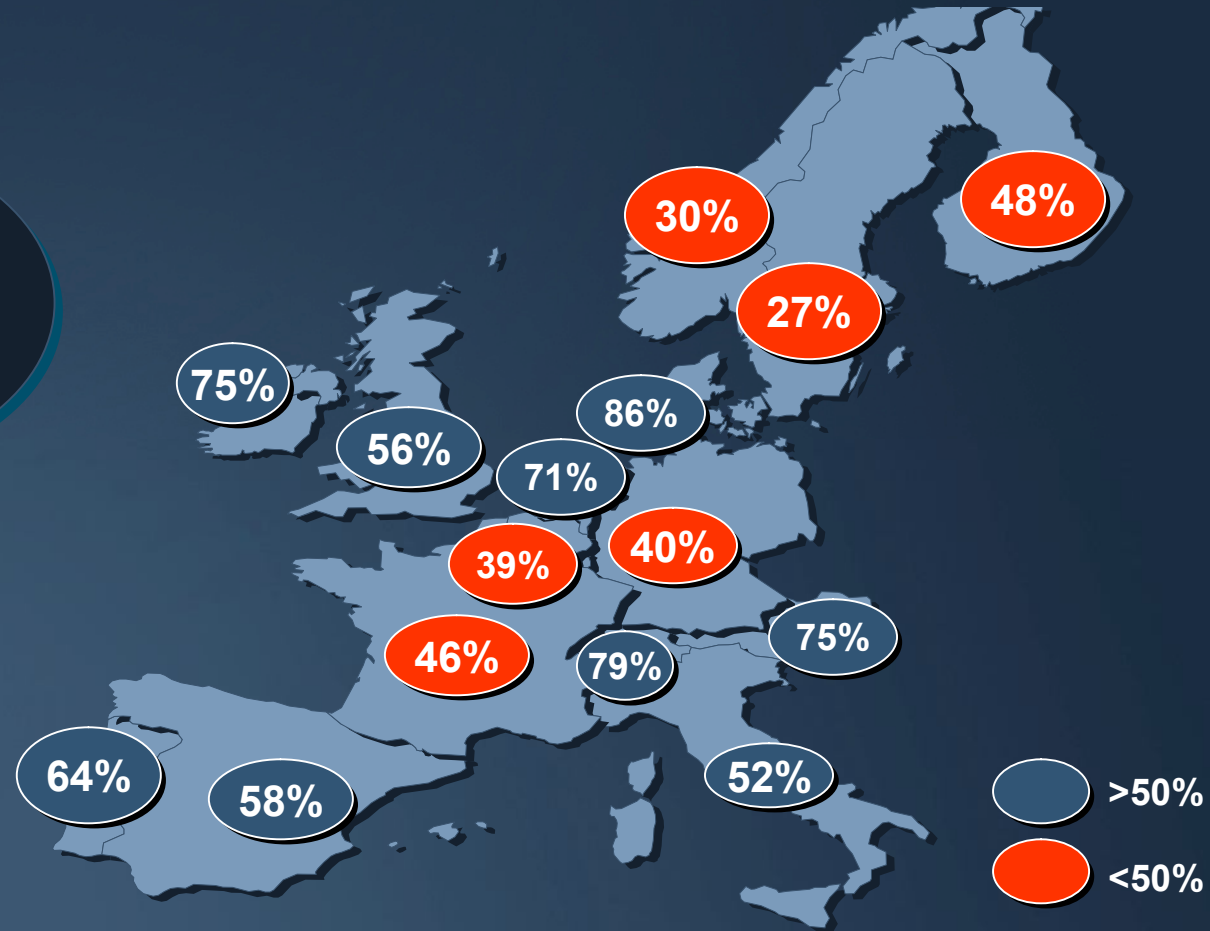
2006 Data from 86 of 91 Centers



# DES Penetration Rates in Western Europe, Q1 2008

## WE Average

50% Overall  
vs.  
65% in U.S.  
65% in Japan



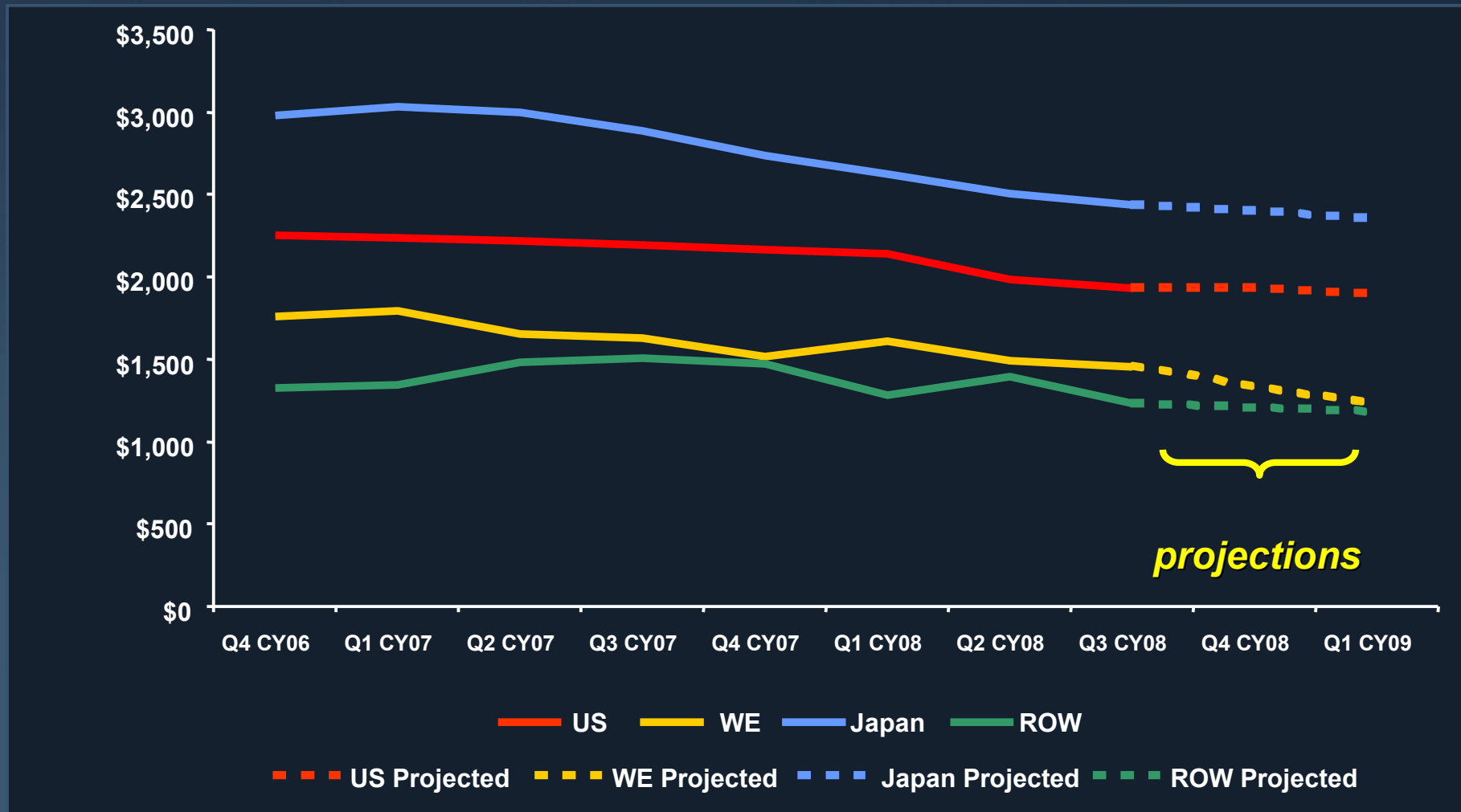
*Significant variability of DES penetration in Western Europe*

# Worldwide DES Reimbursement Varies Significantly by Country

- Hybrid Private / Public healthcare systems
- Self-pay
- National Health Insurance (e.g. UK)
- Individual hospital budgets
- Defined budget for devices (e.g. France)
- Supplemental device payments
- All inclusive Prospective Payment System (e.g. U.S. DRG system)
- Hybrid Prospective Payment System (devices paid separately)



# DES ASPs by Region



# Worldwide DES Reimbursement Examples

- **U.S. – Medicare**
  - Hospital inpatient prospective payment (MS-DRG 246-247 weighted avg.)
    - \$12,068 USD
  - Physician (CPT – 92980)
    - \$ 806 USD (unadjusted)
- **Western Europe – Italy**
  - Hospitals : 21 Regions with 2 possible DRG assignments
    - \$8,000 – \$17,000 USD
    - Additional supplemental payment for DES in select Regions - \$418 - \$1,533 USD
- **Western Europe – Germany**
  - Hospital : 9 possible DRG assignments
    - \$3,385 - \$15,983 USD
    - Additional supplemental payment for DES negotiated by brand
- **Asia – Japan**
  - Hospital paid according to annual budget allocation
    - \$ 4,000 USD per DES

# DES Landscape - 2009

## *Final Thoughts (1)*

- *The 2007 decline in coronary procedures (caths and PCIs) has stabilized with soft signs of a modest recovery*
  - Declining impact of COURAGE philosophy
  - Reassuring PCI safety data
- *DES penetration has shown a slow moderate rebound (esp. in the US), but is unlikely to recapture previous peak levels*
  - Again, reassuring DES safety data (esp. death/MI)
  - ? Impact of “new” DES
  - Still influenced by obligatory long-term DAPT



# DES Landscape - 2009

## *Final Thoughts (2)*

- ***“New” DES in the US (Xience/Promus and Endeavor) have dramatically transformed DES use patterns***
  - Important differences now perceived in safety, efficacy, and deliverability; a multi-DES patient/lesion-specific strategy is pervasive
  - Deliverability is often the dominant determinant of DES selection
  - Despite new DES, surprisingly little price erosion in the US
  - Very little use of “other” DES (non-“BIG 4” CE-approved) in EU, but varies widely in ROW

# DES Landscape - 2009

## *Final Thoughts (3)*

- ***Reimbursement considerations are having a direct and profound impact on DES use penetration worldwide (esp. OUS)***
  - **More onerous restrictions likely forthcoming (creating more OUS DES price reductions)**
  - **Two-tiered DES market clearly established in many geographic environments**
  - **The US is a vulnerable next target (e.g. ongoing CMS discussions about altering reimbursement policies for DES use)!**